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FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

5 CFR Part 1601

Mutual Fund Window

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Final rule.

SUMMARY: The Federal Retirement Thrift Investment Board (FRTIB) adopts as final, without changes, a proposed rule concerning the Thrift Savings Plan (TSP)'s mutual fund window—which we will make available to TSP participants beginning in June 2022. This final rule establishes a fee designed to guarantee that the availability of the mutual fund window will not indirectly increase the share of TSP administrative expenses borne by participants who choose not to use the mutual fund window. We are also adopting policies to govern fund transfers to and from the mutual fund window, including a restriction on the amount that a participant may invest through the mutual fund window.

DATES: The effective date is June 1, 2022.

FOR FURTHER INFORMATION CONTACT: Kim Weaver, Office of External Affairs, (202) 465–5220 or Laurissa Stokes, Office of General Counsel, (202) 308–7707. For more information about when and how TSP participants can access the mutual fund window, please visit *www.tsp.gov/new-tsp-features/.*

SUPPLEMENTARY INFORMATION: The FRTIB administers the TSP, which was established by the Federal Employees' Retirement System Act of 1986 (FERSA), Public Law 99 335, 100 Stat. 514. The TSP is a tax-deferred retirement savings plan for federal civilian employees and members of the uniformed services. The TSP is similar to cash or deferred arrangements established for private-sector employees under section 401(k) of the Internal Revenue Code (26 U.S.C. 401(k)). The provisions of FERSA that govern the TSP are codified, as amended, largely at 5 U.S.C. 8351 and 8401–79.

FERSA requires the TSP to offer the following individual investment funds to TSP participants: (1) A Government Securities Investment Fund (G Fund); (2) a Fixed Income Investment Fund (F Fund); (3) a Common Stock Index Investment Fund (C Fund); (4) a Small Cap Stock Index Investment Fund (S Fund); and (5) an International Stock Index Investment Fund (I Fund). 5 U.S.C. 8438(b)(1)(A)–(E).

In addition to these five individual funds, the TSP is statutorily required to offer Lifecycle (L) Funds which are target retirement date portfolios comprised of varying proportions of the five individual funds. 5 U.S.C. 8438(c)(2). These statutorily mandated investment options are referred to as the TSP core funds. The FRTIB does not have discretionary authority to increase or change the types of core funds offered to TSP participants.

I. Background

A. What is a Mutual Fund?

A mutual fund is formed when a special type of corporation called a fund company pools money from many individuals and invests the pooled money in other things such as stocks and bonds. Mutual funds offer individuals the ability to invest in hundreds of different holdings without having to make hundreds of separate purchases themselves. A mutual fund's holdings are picked by a professional money manager—called an investment adviser—who is hired by the fund company. Investors buy shares in mutual funds. Investors (or their brokers) purchase mutual fund shares from the fund company itself (or its broker)—as opposed to purchasing them from other investors (or their brokers) on a secondary market such as the New York Stock Exchange. Each share represents an investor's part ownership in the mutual fund and the net aggregate returns of the mutual fund's investment holdings.

B. What is a Mutual Fund Window?

A mutual fund window is a type of brokerage window. A brokerage window is a retirement plan feature that allows participants to open a brokerage account to put some of their retirement savings in investments that are not curated by their retirement plan's fiduciaries.

Some retirement plans call this feature a ''self-directed brokerage option''. ''Brokerage window'' and ''self-directed brokerage option'' are just two different names for the same feature. This feature is often described as ''self-directed'' because it allows participants to forego some of the protections afforded by fiduciary oversight of investments in exchange for access to a much broader choice of investments.

However, investing through a retirement plan feature is never as ''self-directed'' as investing through a brokerage account outside of a retirement plan. For example, retirement plan participants do not pick their own brokerage firm. Usually, one of the retirement plan's service providers (for example, its plan administrator or record keeper) selects a brokerage firm that will provide brokerage accounts and an online trading platform to the retirement plan's participants via a subcontract.

In addition, certain categories of higher-risk trades that can be made in brokerage accounts outside of a retirement plan are often excluded from brokerage windows. These categories include trading on margin and buying put or call options, futures contracts, or cryptocurrency. Subject only to categorical exclusions such as these, the specific investments available through a retirement plan's brokerage window are typically determined by a cluster of agreements negotiated among the plan's service provider, a brokerage firm, and fund companies.

For the TSP's brokerage window, Congress has excluded all categories of investments except for mutual funds.[1] That is why it is called a mutual fund window. It is a type of brokerage window that is limited to mutual funds.

C. Mutual Funds Versus TSP Core Funds: What is the Difference?

Like mutual funds, the TSP core funds offer investors the ability to pool their money with other investors to purchase a share of a portfolio containing hundreds of investment holdings. The difference is that the TSP core funds are designed specifically for TSP participants. Only TSP participants

[1] *See* Thrift Savings Plan Enhancement Act of 2009, Public Law 111–31, Division B, Title I, sec. 104 (codified at 5 U.S.C. 8438(b)(5)(A)).

can invest in them, and their only goal is to maximize participants' retirement savings. Mutual funds, on the other hand, are designed for the general public. As such, many different types of mutual funds exist to satisfy a wide variety of goals.

II. Historical Context

For many years, TSP participants have voiced a desire to have more investment options. In 2009, Congress passed legislation that authorized, but did not require, the FRTIB to offer a mutual fund window to TSP participants. *Thrift Savings Plan Enhancement Act of 2009,* Public Law 111–31, Division B, Title I, sec. 104 (codified at 5 U.S.C. 8438(b)(5)(A)).

In the same year that Congress authorized the FRTIB to offer a mutual fund window, the FRTIB's Executive Director initiated discussions with the FRTIB Board members and the Employee Thrift Advisory Council (ETAC) [2] about adding a mutual fund window to the TSP. In the April 2009 FRTIB Board meeting, the four Board members in attendance deadlocked on the decision to adopt a resolution in support of the mutual fund window by a vote of two-to-two.[3]

To inform future discussions, the FRTIB assembled a cross-functional team of subject matter experts from its operations, legal, investment, finance, communications, research, and technology offices who spent the next several years studying industry practices, participant preferences, costs, and operational considerations associated with adding a mutual fund window to the TSP. Their research was presented to the FRTIB Board members and ETAC during public meetings in May 2014, November 2014, and July 2015.[4]

In July 2015, the FRTIB Board members voted unanimously in support of adding a mutual fund window to the TSP. The FRTIB Executive Director committed to including a mutual fund window in the scope of services sought the next time the FRTIB recompeted its major service provider contract(s). In August 2019, the FRTIB announced the release of a request for proposals for various recordkeeping and plan administration services, including a mutual fund window. The contract was awarded in November 2020. The FRTIB is currently undergoing a transition to its new service provider(s).

III. Proposed Rule

On January 26, 2022, the FRTIB published a proposed rule with request for public comments in the **Federal Register** (87 FR 3940, January 26, 2022). We proposed to collect an administrative fee of $55 annually from mutual fund window users to guarantee that the availability of the mutual fund window does not indirectly increase the share of TSP administrative expenses borne by participants who choose not to use the mutual fund window. The preamble of the proposed rule informed the public that TSP mutual fund users will also incur other costs such as: (1) An annual maintenance fee of $95, (2) a per trade fee of $28.75, and (3) fees and expenses imposed by the specific mutual fund(s) in which they invest. We explained that these other costs are outside the scope of the proposed rule.

We also proposed several terms and conditions that would govern fund transfers to and from the mutual fund window. For example, the proposed rule would require a minimum initial transfer of $10,000 and limit investments through the window to no more than 25% of the participant's TSP account value. In addition, the proposed rule would count transfers to and from the mutual fund window against an existing limitation on the number of interfund transfers participants are allowed to make per month.

We received feedback from 100 commenters. Their comments fell into ten broad areas of concern, and our response to each concern is provided below.

IV. Response to Public Comments

A. Account Maintenance Fee and Trading Fee

We received 44 comments from participants who believe the $95 annual maintenance fee and a $28.75 per trade fee are not competitive with prices negotiated by other retirement plans. Before addressing these comments, we want to note that the annual maintenance fee and per trade fee were negotiated using the procedures of Federal Acquisition Regulation (FAR) part 15 and were evaluated for reasonableness in accordance with FAR 15.404–1. We also note that this final rule governs only the fees determined by the Executive Director in his role of setting policy to implement specific Congressional directives. Fees negotiated through acquisition procedures are beyond the scope of this final rule.

Nevertheless, we think it is important to address the concerns raised by these commenters. The comments indicate that many TSP participants are under the impression that other retirement plans negotiate free brokerage services. We looked into what have been described as ''free'', ''no-transaction-fee'', and ''zero cost'' mutual fund trades offered to participants in other retirement plans. We found that those prices are often caveated with fine print disclaimers, such as this:

No-Transaction-Fee (NTF) mutual funds are no-load mutual funds for which [brokerage firm] does not charge a transaction fee. NTFs, as well as other funds, have other continuing fees and expenses described in the fund's prospectus. [Brokerage firm] receives remuneration from fund companies for record keeping, shareholder and other administrative services. The amount of remuneration is based in part on the amount of investments in such funds by [brokerage firm] clients.

The remuneration (*i.e.,* fees) that brokerage firms receive from fund companies are treated by the fund companies as fund expenses, which are ultimately passed on to the people who have already invested in the fund. This type of arrangement between a brokerage firm and a fund company is called revenue sharing.

Revenue sharing is not inherently pernicious. In many industries, revenue sharing is like a referral fee that a business owner might pay to compensate a person for bringing a new customer to their business. For most businesses, revenue sharing is a marketing cost borne by the business.

Fund companies are, of course, businesses also. But fund companies are structurally different from other corporations. They typically have no employees, no physical assets, and no tangible products. They are just a collection of contracts relating to pools of money (*i.e.,* funds), and they charge their costs of doing business to the people who have invested in the funds, regardless of how well the funds perform. Their unique corporate structure has led both Congress and the U.S. Supreme Court to conclude that ''the forces of arm's-length bargaining

[2] ETAC is comprised of representatives from Federal and Postal unions and management associations, as well as a representative from the Department of Defense on behalf of uniformed service members. ETAC provides advice on matters relating to TSP investment policies and plan administration.

[3] *See* April 2009 FRTIB Board Meeting Minutes, *available at https://www.frtib.gov/MeetingMinutes/2009/2009Apr.pdf.* Links to attachments accompanying the minutes are embedded in the PDF of the minutes.

[4] *See* May 2014 FRTIB Board Meeting Minutes, *available at https://www.frtib.gov/MeetingMinutes/2014/2014May.pdf;* November 2014 FRTIB Board Meeting Minutes, *available at https://www.frtib.gov/MeetingMinutes/2014/2014Nov.pdf;* July 2015 FRTIB Board Meeting Minutes, *available at https://www.frtib.gov/MeetingMinutes/2015/2015Jul.pdf.* Links to attachments accompanying the minutes are embedded in the PDFs of the minutes.

do not work in the mutual fund industry in the same manner as they do in other sectors of the American economy.'' *Jones* v. *Harris Assocs. L.P.,* 559 U.S. 335, 338 (2010), quoting S. Rep. No. 91–184, at 5 (1969). This does not mean that there is something sinister about the mutual fund industry. It means only that the nature of the product makes the usual distinctions between price, cost, revenue, profit, and quality less clear than they are in other industries.

Fund companies are not required to provide individualized statements to investors, detailing the exact dollar amount of the fund's fees that each investor has indirectly paid. Consequently, revenue sharing between retirement plans, record keepers, brokerage firms, and fund companies can lead to confusing, opaque fee disclosures. Revenue sharing converts explicit fees (*e.g.,* account maintenance fees and transaction fees) into less transparent fees (*e.g.,* fees embedded in the fund's expense ratio). By including the fees in the fund's expense ratio, the return on an investment in that fund is reduced. Most participants in private sector plans have no idea that revenue sharing exists, much less how much it decreases the return of their investments.[5]

The FRTIB values transparency. We believe TSP participants need, and deserve, to see the dollar amount of the fees they pay for their mutual funds. Toward that end, TSP participants will pay account maintenance fees and certain transaction fees directly rather than paying them indirectly through revenue sharing. Furthermore, FRTIB has contractually required the TSP record keeper, their trading platform provider, their broker-dealer(s), and any of their other affiliates or subcontractors to rebate all revenue sharing payments, or any other type of indirect compensation, they receive in connection with participants' mutual fund window investments. The rebates will be credited to participants' mutual fund window accounts. This ensures that the dollar amounts of all fees and expenses borne by TSP participants for services provided in connection with their mutual fund window investments are explicitly disclosed.

B. Concern That Participants Might Be Confused by New Fees

One commenter expressed concern that participants might inadvertently incur fees which can, over time, cause serious damage to their retirement savings. We share this concern. Even small differences in fees can translate into large differences in returns over time. That is why we have chosen to make the fees paid to our service providers explicit at the risk of appearing less competitive than plans that compensate their service providers through revenue sharing arrangements. We intend to provide ongoing communication and education to TSP participants about the impact of fees on their retirement goals. We will also ensure that participants have convenient access to mutual fund prospectuses prior to making investment decisions.[6] In addition, participants will have access to a tool that allows them to sort mutual funds by expense ratio, starting with the lowest expense ratios first.

C. Minimum Core Balance

We received 29 comments opposed to restricting the amount that a participant may invest through the mutual fund window. Under the proposed rule, transfers to a mutual fund window account cannot cause a participant's mutual fund window account balance to exceed 25% of their total TSP balance. In effect, the proposed rule would require participants to maintain 75% of their balance in the TSP core funds.

Some commenters described the minimum core balance as ''punitive'' and suggested that it casts doubt on the FRTIB's sincerity in touting the mutual fund window as a benefit to TSP participants. Others are concerned that this restriction will impede their ability to achieve diversification among the funds in their mutual fund window account. We believe these commenters misunderstand the intended role of the mutual fund window. The mutual fund window enhances the TSP as a supplement to, rather than an alternative to, the core fund options.

Other commenters described the minimum core balance as ''paternalistic'' and asked the FRTIB to respect their autonomy when it comes to making financial decisions. We are sympathetic to these requests for more freedom of choice and autonomy. But retirement savings is a context in which autonomy is already constrained. Retirement plans (whether private or government-sponsored) are tax-incentivized programs. People who choose to participate in retirement plans benefit personally from a large tax subsidy. The law mandates some constraints on autonomy to ensure those tax subsidies are effective for their intended purpose. Some constraints arise from the fact that fiduciaries of retirement plans can be sued by participants for exposing participants' retirement savings to too much risk. Consequently, we are compelled to balance requests for more freedom of choice against the risk of damaging the trust placed in us by the vast majority participants who do not have the time it takes to research thousands of complex investment choices.

Several commenters believe that a 40% or 50% minimum core balance would be more reasonable. We understand that many private sector retirement plans offer brokerage windows with lower minimum core balance requirements, and that 50% is very common. However, it is not uncommon among the largest of private sector retirement plans to require participants to maintain 80% of their total balance in core funds.[7] Given the TSP's size, and the extraordinary amount of trust placed in us by more than 6.5 million participants, we believe it is appropriate for the FRTIB's minimum core balance to be near the higher end of the range of minimum core balances that are common in the private sector.

One commenter suggested tying the minimum core balance amount to each individual participant's years of service and gradually decreasing it in increments of 5% per year as the participant's years of service increase. For example, a participant with two years or less of service would be required to maintain a minimum core balance of 75%, a participant with 3 years of service would be required to maintain a minimum core balance of 70%, a participant with 4 years of service would be required to maintain a minimum core balance of 65%, and so on. We believe the enormous

[5] *See* ''401(k) Plans: Increased Educational Outreach and Broader Oversight May Help Reduce Plan Fees'', GAO–12–325 (April 24, 2012), *available at https://www.gao.gov/products/gao-12-325;* ''GAO: How Revenue Sharing Can Work, and Its Potential Impact on Participants' Account Balances'', YouTube, U.S. Government Accountability Office, 24 April 2012, *https://www.youtube.com/watch?v=PIRGduLn59A;* ''401(k) Retirement Plans: Many Participants Do Not Understand Fee Information, but DOL Could Take Additional Steps to Help Them'', GAO–21–357 (July 27, 2021), *available at https://www.gao.gov/products/gao-21-357.*

[6] Mutual funds use a document called a prospectus to disclose information about the fund to investors. The U.S. Securities Exchange Commission requires mutual funds to include certain information about the fund's fees and expenses in the prospectus.

[7] ''Understanding Brokerage Windows in Self-Directed Retirement Plans'', Report to Honorable Martin Walsh, Secretary of the Department of Labor, Advisory Council on Employee Welfare and Pension Benefit Plans (2021), at 24, *available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2021-understanding-brokerage-windows-in-self-directed-retirement-plans.pdf.*

administrative complexity of this approach would outweigh any conceivable advantage it could offer.

One commenter suggested the use of messaging and warning banners instead of a minimum core balance requirement to mitigate the potential for participants to invest heavily in undiversified funds. In our experience, messaging campaigns work best when the message is a rule of thumb—simple, universal, and clear. We are concerned that any message simple enough to be effective (such as, ''Don't put all your eggs in one basket'') would be insufficiently nuanced to be accurate in the context of the mutual fund window. Since almost all mutual funds can claim to be ''diversified'' in the sense that they have many different holdings, a simple message about the importance of diversification could be misleading without a host of additional specifications—such as the difference between diversifying within an asset class and diversifying across asset classes.

One commenter asked whether a mutual fund window account balance that, due to earnings, exceeds the 25% restriction will be adjusted (*i.e.,* liquidated) to bring the account to 25% of the participant's total TSP balance. Investment earnings that cause a mutual fund window account balance to exceed 25% of a participant's total TSP balance will be permitted to remain in the mutual fund window account. However, a participant will not be permitted to transfer funds from the core funds to the mutual fund window if the participant's mutual fund window account balance (including earnings) already exceeds the 25% restriction or if the transfer would cause the participant's mutual fund window account balance (including earnings) to exceed the 25% restriction.

D. Fiduciary Oversight

One commenter suggested that mutual funds offered through the window should be ''vetted'' by fiduciaries to ensure that they are prudent investments. Another commenter suggested that the FRTIB should offer a large variety of funds to ensure that there is no appearance of ''favoritism'' toward any mutual funds or fund companies.

TSP participants will have access to approximately 300 mutual fund families. A mutual fund family includes all the separate funds offered by a single fund company. Since each family consists of multiple funds, the total number of funds available to TSP participants will be in the thousands.

We have taken measures toward ensuring that our record keeper and brokerage firm are not motivated by conflicts of interest or other misaligned incentives that could influence which funds or fund families they make available to TSP participants. Many retirement plan record keepers also own subsidiaries that are fund companies or that provide investment management services to fund companies. It is common for these record keepers to design investment menus and exercise influence on retirement plan participants in a manner that benefits their subsidiaries. We have mitigated such conflicts of interests by hiring a record keeper that is not in the business of selling mutual funds.

We intend to monitor for practices that might intentionally or unintentionally nudge participants to choose more expensive funds (or share classes) over less expensive funds (or share classes) with similar risk/return attributes. Toward that end, we have contractually guaranteed ourselves a say in the choice architecture of the digital interface through which participants choose mutual funds (*e.g.,* the order in which choices are displayed and the language used to frame the choices). We will also ensure that if a mutual fund has a share class that gives preferential treatment to institutional investors (*e.g.,* money managers, insurance companies, investment banks, commercial trusts, endowment funds, and hedge funds), those institutional share classes will be made available to TSP participants.

We will not, however, evaluate or monitor any of the mutual funds to ensure that they are prudent investments. This mirrors the practice of private sector retirement plans.[8] Fiduciary oversight of thousands of funds would place unreasonable cost and resource burdens on the FRTIB. Those cost increases could disadvantage TSP participants relative to participants of private sector retirement plans—whose fiduciaries do not evaluate or monitor investments offered through brokerage windows except in extraordinary circumstances. We are also concerned that the potential for appearing to favor some fund companies over others could raise novel issues under government ethics and contracting laws; and could run counter to the spirit of a myriad of provisions in the Federal Employees' Retirement System Act that are designed to insulate the TSP from political involvement.

We considered the less costly, less complicated alternative of implementing a screen whereby the FRTIB would adopt criteria (*e.g.,* expense ratio of 1.00% or below) and restrict the window to those mutual funds that meet the FRTIB's criteria. But we have decided against any screening criteria because we are concerned it would blur the distinction between funds that are fully endorsed by fiduciaries (*i.e,* the TSP's core funds) and funds that only meet certain minimum thresholds established by fiduciaries. Participants who only want simple choices that are fully endorsed by the FRTIB may feel overwhelmed or misled if we make it hard to distinguish between the level of fiduciary involvement in TSP core funds and the level of fiduciary involvement in the funds offered through the mutual fund window. In view of this concern, we believe that the vast majority of TSP participants will be better served by a clear, frequent, prominent, and unequivocal warning that the FRTIB does not provide fiduciary oversight of the mutual funds offered through the window.

Participants who prefer funds that are overseen by FRTIB fiduciaries should invest in the TSP core funds.

E. Other Investment Options

Several commenters suggested that, instead of mutual funds, the FRTIB should offer individual stocks, individual bonds, or exchange-traded funds through the brokerage window. By law, mutual funds are the only type of investment the FRTIB is permitted to offer through the brokerage window.[9] Mutual funds offer certain advantages over purchasing individual stocks and bonds, such as built-in professional management; and they are the most common type of investment in private sector 401(k) retirement plans. Although exchange-traded funds offer similar advantages, they are not—technically speaking—mutual funds.[10]

[8] ''Understanding Brokerage Windows in Self-Directed Retirement Plans'', Report to Honorable Martin Walsh, Secretary of the Department of Labor, Advisory Council on Employee Welfare and Pension Benefit Plans (2021), at 47, *available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2021-understanding-brokerage-windows-in-self-directed-retirement-plans.pdf* (''Investments accessible through a brokerage window are not routinely monitored by plan fiduciaries, and most experts conclude that, except perhaps in extraordinary circumstances, plan fiduciaries are not obligated to monitor brokerage window investments nor do their fiduciary duties apply with respect to those investments.'').

[9] *See* Thrift Savings Plan Enhancement Act of 2009, Public Law 111–31, Division B, Title I, sec. 104 (codified at 5 U.S.C. 8438(b)(5)(A)).

[10] *See* ''Mutual Funds and Exchange-Traded Funds (ETFs)—A Guide for Investors, U.S. Securities Exchange Commission'', *available at https://www.sec.gov/reportspubs/investor-publications/investorpubsinwsmfhtm.html.*

F. Objections to Offering a Mutual Fund Window

Several commenters objected to the fact that the FRTIB is offering a mutual fund window at all. Others believe that the mutual fund window should be a lower priority than other possible improvements to the TSP. The decision to offer a mutual fund window was made by a vote of the FRTIB Board members in July 2015 and, therefore, is not the subject of this regulation.

Nevertheless, we wish to assure these commenters that the FRTIB is also adding a host of other new features which are consistent with many of the priorities these commenters have articulated. We do not believe that satisfying the diverse preferences of the TSP's 6.5 million participants must be a zero-sum game. We are confident we can offer a mutual fund window for participants who want it at no cost to participants who don't, while also offering many other new features that participants with other priorities will appreciate. For information about other new features, we invite TSP participants to view *https://www.tsp.gov/new-tsp-features/.*

Some commenters suggested that, instead of offering a mutual fund window, the FRTIB should expand the number of its core funds or should select indexes that allow for more diversification within its individual core funds. The FRTIB does not have the statutory authority to expand its core fund options. Only Congress can do that, and Congress authorized a mutual fund window instead of adding more funds to the TSP's core fund menu. Congress has historically found that offering a small core menu of low-cost, passively-managed funds is most conducive to promoting the integrity of the Thrift Savings Fund.[11]

The FRTIB periodically hires professional investment consultants to evaluate the diversification of the TSP's core fund menu compared to the menus of other retirement plans and to perform benchmark studies of the TSP's individual core funds. We invite TSP participants to view these studies at *https://www.frtib.gov/ReadingRoom/.*

G. Administrative Fee

We received 6 comments relating to the $55 administrative fee. Four commenters supported the fee and two commenters objected to it.

One commenter suggested that a $25-$30 fee would be more reasonable. This commenter did not offer a rationale for why $25-$30 would be more reasonable or suggest an alternative means of deriving an appropriate fee amount. Another commenter suggested that all TSP participants should share in the cost of the mutual fund window. We believe this suggestion would conflict with an explicit Congressional directive to ''ensure that any expenses charged for use of the mutual fund window are borne solely by participants that use such window.'' 5 U.S.C. 8438 (b)(5)(B). We are, therefore, adopting the proposed rule as final without substantive change.

H. Number of Interfund Transfers

We received 22 comments objecting to an existing rule that allows only two interfund transfers per month. We proposed that the transfer from a participant's TSP account to their mutual fund window account, or vice versa, will count toward the existing monthly limit on interfund transfers. Trading within the mutual fund window will be restricted only by fees and rules that may be imposed by the mutual funds in which participants choose to invest.

None of the commenters addressed the application of the FRTIB's existing rule to transfers to and from the mutual fund window. Instead, the commenters objected, more generally, to the existing rule as it currently applies to the TSP's core funds.

We sought public comments on the existing rule long ago. We published it as a final rule in April 2008.[12] Every comment about interfund transfers provided in response to our mutual fund window proposed rule was thoroughly addressed in the preamble of the 2008 final rule. We are not revisiting the existing rule. We, therefore, believe these comments are outside the scope of the final rule that we are publishing today.

The purpose of the existing rule is to prevent a small number of TSP participants who pursue ''market timing'' active investment strategies from diluting the earnings of other TSP participants and adversely affecting the ability of TSP investment managers to replicate the performance of selected indexes as required by law. The rationales for the existing rule are equally applicable to transfers to and from the mutual fund window. We are, therefore, are adopting the proposal as final without change.

I. Minimum Initial Transfer

We received 3 comments objecting to our proposal to require a $10,000 minimum initial fund transfer to the mutual fund window. As explained in our proposed rule, the combination of the $10,000 initial fund transfer requirement and the 75% minimum core balance requirement means that an account must have at least $40,000 to be eligible to take advantage of the mutual fund window. The purpose of this requirement is to ensure that participants have some investment experience before they confront additional risks and expenses that may be associated with using the mutual fund window.

Two commenters expressed concern that the minimum initial transfer requirement would prohibit new employees from accessing the mutual fund window. One commenter pointed out that, with today's highly mobile workforce, many new TSP participants may have gained sufficient investment experience from retirement assets they have invested elsewhere. We note that new employees can roll over money into the TSP from other retirement plans to meet the $10,000 minimum initial fund transfer requirement. We believe the ability to roll other retirement investments into the TSP is sufficient to address the concern that experienced investors who are new Federal employees will not be able to access the mutual fund window.

Two commenters stated that the minimum initial fund transfer amount is higher than the industry norm. Brokerage firms often impose minimum initial fund transfer requirements for the purpose of ensuring that the cost of servicing a large number of small investments does not exceed the revenue the brokerage firm requires to offer its services. The FRTIB's minimum initial fund transfer requirement serves a very different purpose, which makes a comparison to industry norms inapposite. We are, therefore, adopting the proposed rule as final without change.

J. Miscellaneous

One commenter suggested that the proposed rule relies on outdated survey results concerning the preferences of TSP participants. We believe this commenter misunderstood the purpose for which we cited 2008 survey results in the proposed rule. We cited 2008 survey results merely to provide

[11] Federal Employees' Retirement System Act of 1986, Public Law 99–335, H.R. CONF. REP. 99–606, 1986 U.S.C.C.A.N. 1508 (''Most importantly, the three funds authorized in the legislation are passively managed funds, not subject to political manipulation. A great deal of concern was raised about the possibility of political manipulation of large pools of thrift plan money. This legislation was designed to preclude that possibility.'').

[12] *Participants' Choices of TSP Funds,* 73 FR 22049 (April 24, 2008), *available at https://www.federalregister.gov/documents/2008/04/24/E8-8957/participants-choices-of-tsp-funds.*

chronological historical context for the evolution of the legislation that authorized the FRTIB to offer a mutual fund window and the FRTIB's subsequent decision to exercise that authority. For a thorough account of all the research and deliberation behind the FRTIB's 2015 decision to offer a mutual fund window, we invite TSP participants to view the May 2014, November 2014, and July 2015 Board meeting materials at *https://www.frtib.gov/MeetingMinutes/.*

One commenter asked if a participant must set up two mutual fund window accounts if a participant wants to invest both traditional and Roth contributions. Nothing in the proposed rule or this final rule requires a participant set up two mutual fund window accounts for this purpose. A participant can transfer both traditional and Roth contributions into the same mutual fund window account.

One commenter asked, with respect to the mutual fund window, how the FRTIB would address future legislation that might restrict investing in certain foreign countries and how the FRTIB would implement such legislation. The FRTIB will comply with legislation enacted by Congress that applies to the TSP. The manner in which we would implement such legislation depends on the specific legislation.

One commenter considered the process of investing through the mutual fund window too cumbersome and suggested we make a money market sweep fund available within the TSP so participants would not have to invest in a core fund prior to transferring money to the mutual fund window. To make the TSP's recordkeeping more efficient and keep costs low for all participants, the record keeper, through a brokerage firm, will handle all operations of the mutual fund window, including the sweep fund that will receive transfers from the core funds. Having the TSP operate the sweep fund would negate the efficiency gains that come from outsourcing the operation of the mutual fund window to the record keeper and brokerage firm.

One commenter asked why participants cannot invest their employee contributions directly into the mutual fund window. Allowing direct contributions to the mutual fund window would require creating linkages between hundreds of government payroll offices and the mutual fund window, which again, would undermine the efficiency gains that come from outsourcing the operation of the mutual fund window.

Many commenters objected to the 12 p.m. eastern time cutoff for transferring amounts to and from the mutual fund window. The 12 p.m. eastern time cutoff for all TSP transactions is set forth in 5 CFR 1601.32 and was not a subject of the proposed mutual fund window regulation. Therefore, the comments are beyond the scope of this regulation. Nevertheless, we will address the concerns.

Since the TSP went to a daily valuation in 2003, we have required that transactions must be requested before 12 p.m. eastern time to post on the same day. For transactions requested at or after 12 p.m. eastern time, the transaction will post the next business day. The 12 p.m. eastern cutoff is necessary to allow the TSP to begin the investment transaction cycle which, given the size of the TSP and number of transactions it processes each day, is a multipart and complex process. Because the transfer into and out of the mutual fund window will involve the sale or purchase of TSP funds, such transfers are also subject to the 12 p.m. eastern time cutoff. Transactions within the mutual fund window (*i.e.,* purchase and sale of mutual funds) are generally subject to a 4 p.m. eastern time cutoff. Some mutual funds may have earlier purchase cutoff times prior to the 4 p.m. eastern time cutoff, which would be disclosed by fund.

V. Final Rule

For reasons explained above, the FRTIB is adopting the proposed rule as final, without any substantive changes. Although the comments received did not cause us to make changes to the proposed rule, we did carefully consider all comments received. We have appreciated the opportunity to review and respond to comments from participants who take an active interest in the TSP and wish to offer suggestions. The comment process allowed us to address any misunderstandings about the mutual fund window, to learn if there are unanticipated legal or policy impediments to the proposal, and to hear suggestions about how better to implement the mutual fund window.

Regulatory Flexibility Act

This regulation will not have a significant economic impact on a substantial number of small entities. This regulation will primarily affect Federal employees, members of the uniformed services who participate in the TSP, and beneficiary participants.

Paperwork Reduction Act

This regulation does not require additional reporting under the criteria of the Paperwork Reduction Act.

Unfunded Mandates Reform Act of 1995

Pursuant to the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 602, 632, 653, and 1501–1571, the effects of this regulation on state, local, and tribal governments and the private sector have been assessed. This regulation will not compel the expenditure in any one year of $100 million or more by state, local, and tribal governments, in the aggregate, or by the private sector. Therefore, a statement under 2 U.S.C. 1532 is not required.

Submission to Congress and the General Accounting Office

Pursuant to 5 U.S.C. 810(a)(1)(A), the FRTIB submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States before publication of this rule in the **Federal Register**. This rule is not a major rule as defined at 5 U.S.C. 804(2).

List of Subjects in 5 CFR Part 1601

Government employees, Pensions, Retirement.

Ravindra Deo,

Executive Director, Federal Retirement Thrift Investment Board.

For the reasons stated in the preamble, the FRTIB amends 5 CFR chapter VI as follows:

PART 1601—PARTICIPANTS' CHOICE OF TSP FUNDS

■ 1. The authority citation for part 1601 continues to read as follows:

Authority: 5 U.S.C. 8351, 8432d, 8438, 8474(b)(5) and (c)(1).

■ 2. Add subpart F to read as follows:

Subpart F—Mutual Fund Window

Sec.

1601.51 Applicability.
1601.52 Fund transfers.
1601.53 Fees.

§ 1601.51 Applicability.

This subpart applies only to the transfer of amounts between the TSP core funds and the mutual fund window; it does not apply to the investment of future deposits, which is covered in subpart B of this part, or fund reallocations or fund transfers among the TSP core funds, which is covered in subpart C of this part.

§ 1601.52 Fund transfers.

(a) *Fund transfers into mutual fund window.* A participant may elect to make one or more fund transfers to the mutual fund window from the portion

of his or her TSP balance invested in the TSP core funds, subject to the following rules:

(1) The participant must establish a mutual fund window account that is separate from his or her TSP account. A participant with more than one TSP account may establish a separate mutual fund window account for each TSP account, and the limitations and fees described in subpart will apply separately to each account;

(2) If the participant does not have an acknowledgment of risk on file as of the date of his or her initial fund transfer request to the mutual fund window, the participant must complete an acknowledgment of risk for the fund transfer to be processed;

(3) Fund transfers must be made in whole dollar increments (percentages are not permitted);

(4) The following limitations must be satisfied:

(i) A participant's initial fund transfer into his or her mutual fund window account must be at least $10,000 and may not exceed 25 percent of the participant's TSP account balance, as of the date of such transfer; and

(ii) Subsequent fund transfers into a participant's mutual fund window account may not cause the balance in the participant's mutual fund window account to exceed 25 percent of the participant's total TSP balance, as of the date of any such transfer;

(5) Each fund transfer into the mutual fund window counts toward the monthly limit set forth in § 1601.32(b);

(6) Amounts transferred to a participant's mutual fund window account will initially be invested in a sweep money market fund. Subsequently, the participant may direct the investment of the transferred amounts into any mutual fund(s) that are available through the mutual fund window;

(7) Fund transfers are subject to the fees set forth in § 1601.53; and

(8) A participant may not withdraw funds directly from his or her mutual fund window account. To make a withdrawal, the participant must elect a fund transfer back to the TSP core funds as described in paragraph (b) of this section. Upon completion of such fund transfer, the participant may make a withdrawal in accordance with 5 CFR part 1650.

(b) *Fund transfers back to TSP core funds.* A participant may elect to make a fund transfer to the TSP core funds from amounts invested in his or her mutual fund window account, subject to the following rules:

(1) Fund transfers must be made in whole dollar increments (percentages are not permitted);

(2) Amounts to be transferred from a participant's mutual fund window account to the TSP core funds must first be transferred to the sweep money market fund. Subsequently, the participant may direct the investment of the transferred amounts into the TSP core funds;

(3) Each fund transfer back to the TSP core funds from the mutual fund window account counts toward the monthly limit set forth in § 1601.32(b); except, however, that a participant may always elect a fund transfer from the mutual fund window account to the G Fund; and

(4) Fund transfers are subject to the fees set forth in § 1601.53.

(c) *Forced transfers.* The TSP record keeper will force a transfer from the participant's mutual fund window account to the TSP core funds in the following situations, and subject to the following rules:

(1) A forced transfer may occur if the balance invested in the TSP core funds is insufficient to cover:

(i) Amounts necessary to comply with a court order, legal process, or levy described in 5 CFR part 1653;

(ii) A beneficiary asset transfer;

(iii) A required minimum distribution;

(iv) An automatic cash out distribution; or

(v) Any other payment or transfer that the Board is required by law to make from the participant's TSP account balance;

(2) The amount of the forced transfer shall be equal to the amount of the insufficiency described in paragraph (c)(1) of this section, plus $1,000; except, however, that if the participant's mutual fund window account balance is less than $25,000, the entire mutual fund window account balance shall be transferred to the TSP core funds;

(3) Forced transfers shall be liquidated from the participant's mutual fund window account first from amounts held in the sweep money market fund; and then from amounts invested in mutual funds, beginning with the position with the highest balance;

(4) Forced transfers from a participant's mutual fund window account to the TSP core funds shall be invested according to the participant's existing contribution allocation; and

(5) The participant shall be responsible for any fees incurred as a result of the forced transfer.

§ 1601.53 Fees.

(a) The Board will allocate a portion of the TSP's administrative expenses to mutual fund users by charging an administrative fee of $55.00 annually. The amount of this fee will be redetermined once every three years by multiplying the average mutual fund window account balance by the TSP administrative expense ratio, as of the date of redetermination.

(b) The fee described in paragraph (a) of this section is in addition to any mutual fund window account maintenance fees, trading fees, and fees and expenses associated with the specific mutual fund(s) in which the participant chooses to invest.

[FR Doc. 2022–09972 Filed 5–9–22; 8:45 am]

BILLING CODE 6760–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0084; Project Identifier MCAI–2020–01312–A; Amendment 39–22012; AD 2022–08–09]

RIN 2120–AA64

Airworthiness Directives; Pilatus Aircraft Ltd. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Pilatus Aircraft Ltd. (Pilatus) Model PC–24 airplanes. This AD was prompted by a failure of the dual ethernet communication channel on a dual-channel data concentration and processing unit, which triggered the opening of electronic circuit breakers that caused several unintended system activations. This AD requires installing a software (SW) upgrade to the utility management system (UMS), as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 14, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 14, 2022.

ADDRESSES: For EASA material incorporated by reference in this final rule, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *www.easa.europa.eu.* You may find the EASA material on the EASA website at *https://ad.easa.europa.eu.* For service information identified in this final rule, contact Pilatus Aircraft Ltd., CH–6371, Stans, Switzerland; phone: +41848247365; email: *techsupport.ch@pilatus-aircraft.com;* website: *http://www.pilatus-aircraft.com/.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110. Service information that is approved for IBR is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0084.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0084; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the EASA AD, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4059; email: *doug.rudolph@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2020–0200, dated September 21, 2020 (EASA AD 2020–0200), to correct an unsafe condition on Pilatus Model PC–24 airplanes, all serial numbers. EASA AD 2020–0200 was prompted by a report that, during climb, a Model PC–24 airplane experienced a dual ethernet communication channel failure on a dual-channel data concentration and processing unit. The failure triggered the opening of electronic circuit breakers, which led to degradation of environmental control system functionalities, the deployment of all passenger oxygen masks, and the autopilot entering into emergency descent mode. According to EASA, various crew alerting system messages were displayed and the functionality of other systems (such as flaps, fuel indication, and the ice protection system) was significantly degraded.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Pilatus Model PC–24 airplanes. The NPRM published in the **Federal Register** on February 3, 2022 (87 FR 6087). The NPRM was prompted by the failure of the dual ethernet communication channel on a dual-channel data concentration and processing unit identified in EASA AD 2020–0200. The NPRM proposed to require installing a SW upgrade to the UMS, as specified in EASA AD 2020–0200.

The FAA is issuing this AD to prevent failure of the dual ethernet communication channel on a dual-channel data concentration and processing unit. The unsafe condition, if not addressed, could result in increased pilot workload and reduced control of the airplane.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the costs.

Conclusion

These airplanes have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA notified the FAA about the unsafe condition described in the EASA AD. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. This AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed EASA AD 2020–0200, which specifies upgrading the UMS SW and prohibits installing an earlier version of the SW. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Related Service Information

The FAA reviewed Pilatus PC–24 Service Bulletin No. 42–010, dated January 21, 2020. This service information contains procedures for upgrading the UMS SW to Build 7.3.

Differences Between This AD and the EASA AD

Where EASA AD 2020–0200 requires compliance after its effective date, this AD requires using the effective date of this AD. Where EASA AD 2020–0200 prohibits the installation of an affected part ''from the effective date'' of EASA AD 2020–0200, this AD requires using ''as of the effective date of this AD.'' Although the service information referenced in EASA AD 2020–0200 specifies reporting information to the manufacturer, this AD does not include that requirement.

Costs of Compliance

The FAA estimates that this AD affects 42 airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor Cost	Parts cost	Cost per airplane	Cost on U.S. operators
Install SW upgrade to UMS	8 work-hours × $85 per hour = $680	$5,000	$5,680	$238,560

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue

rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2022–08–09 Pilatus Aircraft Ltd.: Amendment 39–22012; Docket No. FAA–2022–0084; Project Identifier MCAI–2020–01312–A.

(a) Effective Date

This airworthiness directive (AD) is effective June 14, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pilatus Aircraft Ltd. Model PC–24 airplanes, all serial numbers, certificated in any category.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 2200, Auto Flight System; 2400, Electrical Power System; 3140, Central Computers (EICAS); 3500, Oxygen System; and 4500, Central Maint, Computer.

(e) Unsafe Condition

This AD was prompted by a failure of the dual ethernet communication channel on a dual-channel data concentration and processing unit, which triggered the opening of electronic circuit breakers that caused several unintended system activations. The FAA is issuing this AD to prevent failure of the dual ethernet communication channel on a dual-channel data concentration and processing unit. The unsafe condition, if not addressed, could result in increased pilot workload and reduced control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

(1) For Group 1 airplanes as defined under the ''Definitions'' section in European Union Aviation Safety Agency AD 2020–0200, dated September 21, 2020 (EASA AD 2020–0200): Install the build 7.3 standard software upgrade to the utility management system software in accordance with paragraph 1 and the ''Ref. Publications'' section of EASA AD 2020–0200, except you are required to comply within 30 days after the effective date of this AD. After updating the software, do not install on that airplane utility management system software that is earlier than version 7.3.

(2) For Group 2 airplanes as defined under the ''Definitions'' section in EASA AD 2020–0200: As of the effective date of this AD, do not install utility management system software that is earlier than version 7.3 on any airplane.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (i) of this AD and email to: *9-AVS-AIR-730-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(i) Related Information

For more information about this AD, contact Doug Rudolph, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4059; email: *doug.rudolph@faa.gov.*

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2020–0200, dated September 21, 2020.

(ii) [Reserved]

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *www.easa.europa.eu.* You may find the EASA material on the EASA website at *https://ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0084.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on May 3, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–09815 Filed 5–9–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0043; Airspace Docket No. 21–ASW–25]

RIN 2120–AA66

Amendment of Class E Airspace; Weatherford, OK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Weatherford, OK. This action as the result of an airspace review caused by the decommissioning of the Weatherford non-directional beacon (NDB). The geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Rebecca Shelby, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5857.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E airspace extending upward from 700 feet above the surface at Thomas P. Stafford Airport, Weatherford, OK, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 8992; February 17, 2022) for Docket No. FAA–2022–0043 to amend the Class E airspace at Weatherford, OK. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received. Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 amends the Class E airspace extending upward from 700 feet above the surface to within a 6.5-mile (reduced from a 7.1-mile) radius at Thomas P. Stafford Airport, Weatherford, OK, by removing the Weatherford NDB and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database, removing the city associated with the airport in the header of the airspace legal description to comply with changes to FAA Order JO 7400.2N, Procedures for Handling Airspace Matters. This action is necessary due to an airspace review caused by the decommissioning of the Weatherford NDB which provided navigation information for the instrument procedures this airport.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW OK E5 Weatherford, OK [Amended]

Thomas P. Stafford Airport, OK
(Lat. 35°32′45″ N, long. 98°40′07″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Thomas P. Stafford Airport.

Issued in Fort Worth, Texas, on May 2, 2022.

Martin A. Skinner,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–09754 Filed 5–9–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0123; Airspace Docket No. 22–ANE–01]

RIN 2120–AA66

Establishment of Class E Airspace; Jaffrey, NH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace extending upward from 700 feet above the surface for Jaffrey/Silver Ranch Airport, Jaffrey, NH, to accommodate area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures (SIAPs) serving this airport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783.

FOR FURTHER INFORMATION, CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E airspace for Jaffrey/Silver Ranch Airport, Jaffrey, NH, to support IFR operations in the area.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 12408, March 4, 2022) for Docket No. FAA–2022–0123 to establish Class E airspace extending upward from 700 feet above the surface for Jaffrey/Silver Ranch Airport, Jaffrey, NH.

Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in Paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic routes, and reporting points.

The Rule

The FAA is amending 14 CFR part 71 by establishing Class E airspace extending upward from 700 feet above the surface within a 7.1-mile radius of Jaffrey/Silver Ranch Airport, Jaffrey, NH, providing the controlled airspace required to support RNAV (GPS) standard instrument approach procedures for IFR operations at this airport.

Class E airspace designations are published in Paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is minimal. Since this is a routine matter that only affects air traffic procedures an air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air)

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANE MA E5 Jaffrey, NH [Established]

Jaffrey/Silver Ranch Airport, NH
(Lat. 42°48′18″ W ″N, long. 72°00′11″ W)

That airspace extending upward from 700 feet above the surface within a 7.1-mile radius of Jaffrey/Silver Ranch Airport.

Issued in College Park, Georgia, on May 2, 2022.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2022–09720 Filed 5–9–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 91

[Docket No. FAA–2022–0619]

Statement of Policy on Performance Requirements for Operators of Aircraft That Are Equipped With Automatic Dependent Surveillance-Broadcast (ADS–B) Out

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Policy statement.

SUMMARY: This action announces revisions to the FAA's policy on performance requirements for aircraft with Automatic Dependent Surveillance-Broadcast (ADS–B) Out equipment using the Selective Availability (SA)-Aware receivers in ADS–B rule airspace. The FAA will no longer expect aircraft with this equipment to perform a preflight availability prediction before operating in ADS–B rule airspace.

DATES: The policy described herein is effective May 10, 2022.

FOR FURTHER INFORMATION CONTACT: For technical information concerning this action, contact James Marks, Flight Technologies and Procedures Division, Aviation Safety, at (202) 267–8790.

SUPPLEMENTARY INFORMATION:

Authority for This Action

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code (49 U.S.C.). Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

The ADS–B Out equipage and performance requirements in §§ 91.225 (Automatic Dependent Surveillance-Broadcast (ADS–B) Out equipment and use) and 91.227 (Automatic Dependent Surveillance-Broadcast (ADS–B) Out equipment performance requirements) of title 14 of the Code of Federal Regulations (14 CFR) were promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103 (Sovereignty and Use of Airspace) and in Subpart III, Section 44701 (General Requirements). Under Section 40103, the FAA is charged with prescribing regulations on the flight of aircraft (including regulations on safe altitudes) for navigating, protecting, and identifying aircraft and the efficient use of the navigable airspace. Under section 44701, the FAA is charged with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce.

In § 91.227, the FAA set forth the ADS–B Out equipment performance requirements including accuracy and integrity performance standards. This policy statement is within the scope of the FAA's authority and informs operators equipped with Selective Availability (SA)-Aware receivers about a change to the FAA policy requiring they perform preflight availability predictions to ensure their avionics broadcast elements required by § 91.227 as part of their § 91.103 (Preflight Action) obligations.

I. Background

In 2010, the FAA issued a final rule prescribing equipage requirements and performance standards for ADS–B Out avionics on aircraft operating in certain airspace after January 1, 2020.[1] ADS–B Out is an advanced surveillance technology that combines an aircraft's position source, other aircraft avionics, and a ground receiver infrastructure to create an accurate and shared surveillance picture between aircraft and air traffic control (ATC). ADS–B Out provides air traffic controllers with real-time position information that is, in most cases, more accurate than the information available with current radar-based systems. With more accurate information, ATC will be able to position and separate aircraft with improved precision and timing so that efficiency and capacity will increase beyond current levels to meet the predicted demand for ATC services while maintaining or improving safety.

[1] Final Rule, Automatic Dependent Surveillance-Broadcast (ADS–B) Out Performance Requirements to Support Air Traffic Control (ATC), 75 FR 30160 (May 28, 2010).

ADS–B Position Sources

Aircraft with ADS–B Out equipment continually broadcast information, such as identification, position, altitude, and velocity, through an onboard transmitter, which can be received by ADS–B ground stations (or satellite receivers) and by other aircraft appropriately equipped to receive this information. The ADS–B Out rule specifies the aircraft's ADS–B Out equipment performance requirements for each flight in rule airspace rather than requiring any particular type of position source. All currently approved position sources rely on a Global Positioning System (GPS) receiver.[2] The quality of each type of receiver can be described by its ''rule performance'' availability, which means the GPS receiver's ability to achieve the performance requirements of § 91.227(c)(1)(i) and (iii) for navigation accuracy category for position (NACp) and navigation integrity category (NIC). Technical Standard Order (TSO)-C166b and TSO–C154c contain the avionics standards for outputting NACp and NIC.

FAA ADS–B Service Availability Prediction Tool (SAPT)

The ADS–B Service Availability Prediction Tool (SAPT) is a preflight resource developed by the FAA, that predicts the ability of standard GPS receivers to meet the requirements of § 91.227(c)(1)(i) and (iii) along a given route of flight. This prediction is based on the ability of the aircraft's position source (*e.g.,* GPS receiver) to meet ADS–B performance requirements based on the type of GPS receiver (FAA TSOs C129, C129a, C145c/C146c, and C196) and the predicted status of the GPS constellation. The SAPT also evaluates if backup surveillance is available where position source performance is predicted to fall below requirements.[3] The ADS–B SAPT is primarily intended for pilots, dispatchers, and commercial operators to verify their predicted position source performance before flight and ensure compliance with the ADS–B Out rule.[4]

Exemption No. 12555

In April 2015, Airlines for America (A4A) petitioned the FAA, on behalf of

[2] GPS is a specific type of Global Navigation Satellite System (GNSS).

[3] FAA plans to begin divesture of some radar infrastructure as part of the transition to a satellite-based navigation and surveillance system. During the period from 2020 to 2025, FAA's planned radar divestures will focus primarily on eliminating redundant/overlapping radars.

[4] For more information on the SAPT, the FAA has developed the ADS–B SAPT/Receiver Autonomous Integrity Monitoring (RAIM) User Guide, which is available at: *https://sapt.faa.gov/adsb-start.php.*

A4A member airlines, for an exemption from the Navigation Accuracy Category for Position (NACp) and Navigation Integrity Category (NIC) requirements of the rule. A key premise of the exemption was an understanding that certain position sources were more likely than others to not perform at the required level established by the ADS–B Out rule. In August 2015, the Administrator issued Exemption No. 12555,[5] a time-limited grant of exemption from § 91.227(c)(1)(i) and (iii) for the period from January 1, 2020, through December 31, 2024. Exemption 12555 permits operation of aircraft equipped with TSO–C129 (SA-On) and TSO–C196 (SA-Aware) in ADS–B Out rule airspace during periods when the GPS position provided to the installed ADS–B Out equipment does not achieve the required accuracy or integrity performance, provided certain conditions and limitations are met. Additionally, Exemption 12555 does not require aircraft equipped with SA-Aware GPS receivers to use a preflight availability prediction tool.

2019 Policy Statement

On July 3, 2019, the FAA published a **Federal Register** document with its policy on performance requirements for operators equipped with ADS–B Out, including those equipped with a SA-Aware position source.[6] The FAA found that Wide Area Augmentation System (WAAS)[7] was the only GPS position source that consistently provided the equivalent availability to radar at 99.9 percent availability.[8] The FAA also believed that SA-Aware receivers could meet a similar 99.9 percent availability as long as there was no significant reduction in the GPS satellite constellation. Given since the data at the time of publication of the 2019 policy was limited, the FAA determined that aircraft equipped with GPS position sources such as Selective Ability-On (SA-On or SA-Aware were more likely to experience performance outages that limited their access to the airspace defined in the ADS–B rule.

The 2019 policy statement reiterated § 91.103's requirement that pilots become familiar with all available information concerning a flight. The FAA explained that given the previously identified limitations of SA-On and SA-Aware receivers, the use of a preflight prediction tool is a reliable way of satisfying due diligence requirements under § 91.103. Therefore, these operators were required to confirm that a planned route of flight would comply with the ADS–B performance requirements in § 91.227(c)(1)(i) and (iii). Operators could use any reliable preflight prediction tool, with the SAPT providing a comprehensive and reliable preflight prediction for operators. The policy statement explained that for operators who had been notified by the FAA of consistent and repeated ADS–B Out performance issues, conducting an operation in accordance with the policy without first redressing the identified non-performance issue would be considered a continuation of the non-compliance with the performance requirements. Also, if an operator failed to conduct a preflight availability prediction for the operator's intended operation and subsequently encountered degradation of GPS performance that resulted in the aircraft falling below the performance requirements of § 91.227(c)(1)(i) and (iii), that operator would be deemed to have violated the ADS–B rule—even if the operator's flight were to be rerouted due to unforeseen circumstances.

Performance Based Operations Aviation Rulemaking Committee (PARC) Exemption 12555 Action Team

In August 2020, the FAA tasked the PARC to form an action team comprised of industry stakeholders and FAA subject matter experts to report on the following:

1. Identify barriers and appropriate mitigations to air carrier Exemption 12555 equipage plans that lead to full compliance with § 91.227; and
2. Describe status of applicable equipment availability relative to achievement of operator equipage plans toward end state of Exemption 12555 on December 31, 2024.

The PARC provided a forum for the U.S. aviation community to discuss, prioritize, and resolve issues, provide direction for U.S. flight operations criteria and produce U.S. consensus positions for global harmonization on performance-based airspace operations. The PARC action team requested that the FAA provide a report on ADS–B Out equipped aircraft with approved position sources and their ability to meet the equivalent operational availability of radar (99.9% or greater availability requirement). In addition to the 4 years of data used to support the 2019 policy document, an additional 3 years of position source performance data was given to the PARC action team to analyze.

FAA analysis and prior modeling in support of the ADS–B Aviation Rulemaking Committee indicated that the critical ADS–B quality parameter was the NIC parameter defined in § 91.227(c)(1)(iii). FAA data indicated a historical operational availability with regard to required NIC rule performance for the following ADS–B position source types:

—SA-On GPS receivers achieved between 98–99% operational availability;
—SA-Aware GPS receivers achieved 99.9%, or greater, operational availability; and
—Satellite-Based-Augmentation System (SBAS) receivers achieved 99.9%, or greater, operational availability

In consideration of these findings, the PARC Exemption 12555 action team recommended removing the requirement for aircraft equipped with SA-Aware GPS receivers to use a preflight availability prediction tool (*e.g.,* the Service Availability Prediction Tool (SAPT)).

The FAA agrees that the demonstrated performance of SA-Aware GPS receivers has been equivalent to, or better than, a single radar since the FAA began monitoring ADS–B performance in 2015. Years of additional data and assurances that the GPS constellation will remain at current levels have given the FAA confidence that SA-Aware GPS receivers will consistently provide the availability required by the ADS–B regulation. The FAA accepts any residual risk associated with SA-Aware GPS receiver performance falling below the regulatory requirement. As such, the FAA is adopting the subject PARC Exemption 12555 action team recommendation and is revising preflight policy issued in 2019 for aircraft equipped with SA-Aware GPS receivers in this document.

II. Discussion of the Policy

Preflight Availability Prediction Policy

Given the demonstrated performance of SA-Aware (TSO–C196) GPS receivers over a seven-year monitoring period and the expectation that the GPS constellation will provide coverage at current levels for the foreseeable future, the FAA now finds that such GPS receivers consistently provide an equivalent availability to that of a single radar at 99.9 percent operational availability. Aircraft equipped with SA-Aware GPS receivers during periods of GPS constellation degradation that negatively impact the ability of ADS–B

[5] Regulatory Docket Number FAA–2015–0971 (FAA Exemption No. 12555) at *https://www.regulations.gov/docket/FAA-2015-0971.*

[6] Statement of Policy on Performance Requirements for Operators of Aircraft That are Equipped with ADS–B Out, 84 FR 31713 (July 3, 2019).

[7] WAAS is a regional a space-based augmentation system (SBAS) operated by the FAA.

[8] FAA also determined that certain GPS tightly integrated with inertial navigation systems would also provide 99.9 percent availability.

Out equipment to meet performance requirements associated with the rule will be deemed compliant with the ADS–B Out rule requirements. Therefore, the operators of aircraft equipped with position sources that meet the performance requirements of TSO–C196 (SA-Aware) is not required to perform a preflight availability prediction to fulfill their § 91.103 due diligence obligation. For aircraft equipped with GPS receivers that do not meet the performance requirements of TSO–196 or TSO–C145/146, the operator must run a preflight prediction.

Due to the reduced performance of SA-On receivers relative to ADS–B rule requirements, operators of aircraft with these receivers are expected to use a preflight availability prediction tool to predict the ability of an aircraft position source to meet the performance requirements of § 91.227(c)(1)(i) and (iii) along a given route of flight. For non-exemption holders with SA-On receivers and exemption holders after expiration of Exemption 12555, a preflight availability prediction tool should be used to comply with § 91.103 due diligence requirements for a planned route of flight in ADS–B rule airspace. If the predicted SA-On receiver performance does not support compliance with § 91.227 for the proposed flight, the FAA expects operators to adjust the flight plan (*e.g.,* departure time, route) as needed to avoid any areas or time periods predicted with degraded GPS performance. Holders of Exemption 12555 are expected to follow the conditions of that exemption until it expires on December 31, 2024.

After an operator receives a satisfactory preflight availability prediction for an intended operation, there may be certain conditions that warrant a subsequent prediction. For example, a change in departure time or a change in the satellite constellation as indicated by a Notice to Air Missions (NOTAM) may have an effect on the predicted GPS performance for the intended operation. If an operator becomes aware of a change that could result in degraded GPS performance prior to receiving an initial ATC clearance for the intended route of flight, the operator should—consistent with preflight action required by § 91.103—conduct a subsequent preflight availability prediction for the planned flight to ensure that GPS performance is still predicted to comply with the performance requirements of § 91.227(c)(1)(i) and (iii).

The duty under § 91.103 to conduct a subsequent preflight availability prediction for an intended route of flight will cease once an operator receives an ATC route clearance for the intended operation. More specifically, if an operator receives a satisfactory preflight availability prediction and an ATC route clearance for the intended operation, the FAA will consider the operator as having exercised its due diligence in ensuring the intended operation complies with the performance requirements in § 91.227. Therefore, upon receiving a satisfactory preflight availability prediction and an ATC clearance for an intended route of flight, the operator will be deemed to have complied with the preflight availability prediction requirement and the performance requirements of § 91.227(c)(1)(i) and (iii).

The FAA recognizes that there are circumstances outside the operator's control that may result in unanticipated changes to an operator's planned route of flight, which may cause temporary degraded GPS performance and technical noncompliance with § 91.227(c)(1)(i) and (iii). For example, ATC will continue to exercise its responsibility for the safe and efficient movement of air traffic, including changes to the routing of traffic to achieve those objectives. In addition, a planned route of flight may be changed due to environmental conditions, such as a thunderstorm, or an operator may experience unexpected GPS degradations during flight. After an ATC route clearance is obtained for the flight, the FAA does not expect an operator to conduct a subsequent preflight availability prediction to accommodate rerouting caused by ATC or environmental conditions.

The FAA notes that the policy described above applies only to those operators who have exercised due diligence required in § 91.103 by performing a preflight availability prediction. For example, if an operator fails to conduct a required preflight availability prediction for the operator's intended operation and subsequently encounters technical non-compliance with the performance requirements of § 91.227(c)(1)(i) and (iii), that operator will be deemed to have violated the ADS–B rule even if the operator's flight were rerouted due to unforeseen circumstances.

When an operator performs a preflight availability prediction using the FAA's SAPT tool, the SAPT retains a record of each transaction enabling the FAA to confirm that an operator took preflight action. The FAA recommends that operators using an alternate tool retain documentation that verifies the completion of the satisfactory preflight availability prediction for each intended route of flight. The FAA recommends that the prediction should be done not more than 24 hours prior to the planned departure. Predictions using SAPT to determine the availability of backup surveillance per Exemption 12555 should be done within the 3 hours prior to a planned departure.

GPS Interference

There may be times when the GPS position source cannot meet the required technical performance due to planned GPS interference. In the event of a scheduled interference outage of GPS, the FAA will issue a NOTAM that identifies the airspace and time periods that may be affected by the interference. The affected area will frequently encompass a large radius of ADS–B Out rule airspace. The FAA finds that requiring operators to avoid the affected area would cause significant disruption to air traffic in that vicinity. Furthermore, there is no guarantee that these operators would experience actual interference and a degradation in GPS performance in the area. For these reasons, the FAA has determined that it would be impractical and not in the public interest to require operators to avoid the affected area based on the chance that an otherwise compliant flight could experience GPS interference.

Accordingly, operators should proceed with their intended operation if the only anticipated ADS–B noncompliance would be due to the planned GPS interference. Under this policy, an operator who is required to perform a preflight availability prediction for the intended route of flight is still required to obtain a satisfactory preflight availability prediction. When a NOTAM identifies the airspace and time periods that may be affected by GPS interference, an operator will not be required to alter his or her route of flight to avoid the area based solely on that NOTAM. As explained in the preamble to the final rule, if an aircraft's avionics meet the performance requirements but unexpected GPS degradations during flight inhibit the position source from providing adequate accuracy and integrity, ATC will be alerted via the aircraft's broadcasted data and services will be provided to that aircraft using the backup strategy. If an operator encounters actual GPS interference during their flight that results in a degradation of ADS–B Out performance, the policy described above will apply provided the operator has taken the appropriate preflight actions.

SAPT Outages

As noted, certain operators are required to use a preflight availability prediction tool prior to a planned flight. Some operators will use the FAA SAPT for this purpose. The FAA intends that SAPT will be continuously available to operators. However, because unexpected circumstances could lead to a SAPT outage, the inability to access the tool could have an adverse impact on operators with SA-On receivers. As previously noted in Advisory Circular (AC) 90–114, *ADS–B Operations,* ATC will issue a NOTAM announcing when the SAPT is not available.

The FAA understands that a SAPT outage prevents those operators who hold relief under Exemption No. 12555 from confirming the availability of back-up surveillance as required under the exemption's conditions and limitations.[9] It also reduces the ability of non-exemption holders without their own preflight availability prediction tool to determine that a particular operation will meet the performance requirements prior to conducting an operation. The unavailability of the SAPT for brief periods would result in operators having to choose between conducting flights that might result in non-compliance or not conducting an operation that might have complied with ADS–B Out rule performance. The FAA does not intend to inhibit operators from conducting otherwise permissible operations when the SAPT is unavailable. As such, when there is a SAPT outage, the policy described above will apply to operators who rely on the SAPT if their operation falls below the performance requirements.

III. Summary

Unless otherwise authorized by ATC, all aircraft operating in the airspace identified in § 91.225 must comply with the ADS–B Out performance requirements in § 91.227. Under the FAA's revised policy, aircraft equipped with SA-Aware GPS receivers described in this document are not required to perform a preflight service availability prediction, including those aircraft not covered by Exemption 12555. Aircraft equipped with SA-On receivers should continue performing preflight availability predictions and can use the guidance contained in AC 90–114, *ADS–B Operations,* when conducting preflight actions for operations planned within airspace described in § 91.225. Holders of Exemption 12555 must continue to meet the conditions and limitations associated with the exemption. Holders of Exemption 12555 should revise applicable equipage plans to reflect any changes affected by policy contained in this document and submit revised plans to the FAA per conditions specified by the exemption.

As described in this document, there are circumstances outside of an operator's control that may result in a temporary degradation of GPS performance and an apparent violation of § 91.227. An operator may exercise due diligence in performing a preflight availability prediction for its intended route of flight but experience rerouting by ATC after obtaining an initial ATC route clearance, which may cause an unanticipated degradation of performance. Additionally, an operator may encounter actual GPS interference on its intended path of flight, which would affect the ability of an aircraft to meet the performance requirements of § 91.227. Lastly, an operator may not be able to complete a preflight availability prediction for its intended route of flight due to the FAA's SAPT being out of service. As previously explained, the FAA recognizes that these situations are outside of the operator's control. Therefore, the FAA will not take legal enforcement action for apparent noncompliance with § 91.227 due to the circumstances discussed in this document to the extent such an application would impose a standard of conduct wholly outside the operator's control.

IV. Effective Date

Policy in this document is effective immediately and supersedes policy contained in FRN Docket No. FAA–2019–0539. Additional information on the policy described in this document will be contained in the next revision of AC 90–114, *ADS–B Operations.*

Issued in Washington, DC, on May 4, 2022.

Gregory E. Schwab,

Acting Chief of Staff, Air Traffic Organization.

[FR Doc. 2022–09936 Filed 5–9–22; 8:45 am]

BILLING CODE 4910–13–P

[9] The FAA anticipates that any outage would be of short duration and any potential risk would be minimal because, concurrent with the outage, GPS performance would have to fall below rule values on the route of flight and radar coverage would have to be unavailable at the same time and location.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2018–C–1007]

Listing of Color Additives Exempt From Certification; Antarctic Krill Meal

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the safe use of Antarctic krill meal, composed of the ground and dried tissue of *Euphausia superba,* with or without the lipid fraction, for use in the feed of salmonid fish, to enhance the color of their flesh. We are taking this action in response to a color additive petition (CAP) submitted by Aker BioMarine Antarctic AS (Aker BioMarine or petitioner).

DATES: This rule is effective June 10, 2022. Submit either electronic or written objections and requests for a hearing on the final rule by June 9, 2022. See section XI for further information on the filing of objections.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 9, 2022. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact

information, or other information that identifies you in the body of your objection, that information will be posted on *https://www.regulations.gov.*

• If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–C–1007 for ''Listing of Color Additives Exempt From Certification; Antarctic Krill Meal.'' Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Stephen DiFranco, Office of Food Additive Safety (HFS–255), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–2710; or Alexandra Jurewitz, Office of Regulations and Policy (HFS–024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notification published in the **Federal Register** of April 9, 2018 (83 FR 15089), we announced that we filed a color additive petition (CAP 5C0303) submitted by Aker BioMarine Antarctic AS (Aker BioMarine), c/o Intertek Scientific & Regulatory Consultancy, Rm. 1036, Bldg. A8 Cody Technology Park, Ively Rd., Farnborough, Hampshire, GU14 0LX, United Kingdom. The petition proposed to amend the color additive regulations in part 73 (21 CFR part 73), *Listing of Color Additives Exempt from Certification,* to provide for the safe use of Antarctic krill meal, composed of the ground and dried tissue of *Euphausia superba,* with or without removal of the lipid fraction, for use in the feed of salmonid fish, to enhance the color of their flesh. Aker BioMarine proposed use levels not to exceed 4 percent (weight/weight or w/w) in feed for freshwater salmonids and 12 percent (w/w) in feed for marine salmonids. Antarctic krill meal is primarily intended for use as a nutrient source, partially replacing other meals (especially fish meal) used in the diet of salmonids. Antarctic krill meal is a natural source of astaxanthin, and it has been established that astaxanthin can impart color to the edible tissues of the salmonids.

Antarctic krill meal is not intended to be the sole source of pigmentation in salmonid feed, and other permitted color additives—including other permitted sources of astaxanthin—may be added to achieve the desired level of coloration in the fish flesh. In the **Federal Register** of April 13, 1995 (60 FR 18736), we published a final rule that listed astaxanthin in § 73.35 (21 CFR 73.35) for use in the feed of salmonid fish. In that final rule, we concluded that 80 milligrams (mg) of astaxanthin per kilogram (kg) of finished feed may be safely used to enhance pigmentation of the flesh of salmonid fish, and we limited the astaxanthin content of the finished feed to not more than 80 mg/kg in § 73.35(c)(2). In the **Federal Register** of July 6, 2000 (65 FR 41581 and 65 FR 41584), we published final rules that listed haematococcus algae meal in 21 CFR 73.185 and phaffia yeast in 21 CFR 73.355 as additional sources of astaxanthin permitted for use in the feed of salmonid fish, provided that the quantity of astaxanthin in finished feed from either color additive—when used alone or in combination with other astaxanthin color additive sources listed in part 73—results in no more than 80 mg/kg of astaxanthin in the finished feed. In the **Federal Register** of November 5, 2009 (74 FR 57248), and November 16, 2009 (74 FR 58845), we published final rules that listed astaxanthin dimethyldisuccinate (21 CFR 73.37) and paracoccus pigment (21 CFR 73.352), respectively, as color additive astaxanthin sources permitted in salmonid fish feed with the limitation that they impart no more than 80 mg/kg of astaxanthin when used alone or in combination with other astaxanthin sources listed in part 73 as a condition of use.

Consistent with these regulations, the petitioner proposed that the quantity of astaxanthin in the finished feed contributed by Antarctic krill meal when used under the intended conditions of use, alone or in combination with other permitted sources of astaxanthin, should not exceed 80 mg/kg astaxanthin in the finished feed.

This final rule covers only the intended use of Antarctic krill meal as a color additive in the feed of salmonid fish, as the target animal. Under 21 CFR 70.42, we apply a ''safe-for-use'' principle when evaluating a color additive petition. This approach ensures that each listed color additive will be safe for its intended use or uses in or on food, drugs, or cosmetics. In reviewing this color additive petition for the proposed intended use of Antarctic krill

meal in the feed of salmonid fish, we evaluated the safety of the petitioned use of the additive in the diet of both the target animal and humans. A discussion of this evaluation can be found in sections III and IV of this document. Approvals for other potential uses, such as in non-target animal food, were not the subject of this petition and therefore are not discussed below. However, such approvals may be subject to the provisions of section 409(b) or 721(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(b) or 21 U.S.C. 379e(b)) and 21 CFR 570.30 or 71.1.

II. Background

Antarctic krill meal is a brownish-orange powder composed of the cooked, dried, and ground tissue of *Euphausia superba.* To obtain the color additive, Antarctic krill are harvested from Antarctic waters and processed by cooking, drying, and milling to yield whole Antarctic krill meal. The manufacture of defatted Antarctic krill meal includes an additional step of lipid extraction with ethanol. Residual ethanol in the krill biomass is removed by evaporation, yielding defatted Antarctic krill meal. The petition requests approval of the whole Antarctic krill meal and the defatted form of Antarctic krill meal for use as a color additive in salmonid feed.

The primary coloring component in Antarctic krill meal is astaxanthin. Astaxanthin is an oxygenated carotenoid (xanthophyll) with the chemical name 3,3′-dihydroxy-β, β-carotene-4,4′-dione and may consist of cis, trans, and optical isomers. Astaxanthin is found as the mono- and di-astaxanthin esters and as free astaxanthin. Astaxanthin is present at levels of 80 to 170 mg/kg in the whole Antarctic krill meal and 10 to 90 mg/kg in the defatted Antarctic krill meal, calculated as free astaxanthin (Ref. 1).

Ethoxyquin, an additive approved for use in animal feed, may be added as a stabilizer to whole Antarctic krill meal. Under § 573.380 (21 CFR 573.380), ethoxyquin may be safely used in fish feeds as a chemical preservative to retard the oxidation of xanthophylls at a level not to exceed 150 parts per million (150 ppm) in the treated article. The petition proposes the optional addition of ethoxyquin into whole Antarctic krill meal at levels up to 250 mg/kg (250 ppm). When the whole krill meal is formulated with other fish feed ingredients up to a maximum level of 12 percent by weight in feed for marine salmonids and 4 percent by weight in feed for freshwater salmonids to produce a finished feed, the concentration of ethoxyquin from the whole krill meal in the finished feed would be no more than 30 ppm and 10 ppm, respectively.

III. Safety Evaluation

Under section 721(b)(4) of the FD&C Act, a color additive may not be listed for a proposed use unless the data and information available to FDA establish that the color additive is safe for that use. Our color additive regulations at 21 CFR 70.3(i) define ''safe'' to mean that there is convincing evidence establishing with reasonable certainty that no harm will result from the intended use of the color additive. As part of our safety evaluation to establish with reasonable certainty that a color additive is not harmful under its intended conditions of use, we consider the additive's manufacturing and stability; the projected human dietary exposure to the additive and any impurities resulting from the petitioned use of the additive; the additive's toxicological data; and other relevant information (such as published literature) available to us.

Because consumers are not directly exposed to Antarctic krill meal, FDA focused its review on the safety of the substances present in Antarctic krill meal that are deposited in the consumable portions of the fish. We considered the safety of astaxanthin, which is already approved for use in the feed of salmonid fish, as well as the safety of other components found in Antarctic krill meal at levels higher than that in other fish meals, for which Antarctic krill meal is intended to serve as a replacement in salmonid feed. Target animal safety was also evaluated for the salmonids consuming the Antarctic krill meal. Our review was based on the petitioned use in salmonid feed and on human consumption of the consumable portions of these salmonids.

IV. Safety of Petitioned Use of the Color Additive

A. Exposure Estimate

Astaxanthin is found in wild salmonids and is the principal pigment that imparts the pink or red coloring characteristic of the flesh of these fish. As referenced above, astaxanthin is currently approved for use as a color additive in the feed of salmonid fish at levels not to exceed 80 mg/kg of the finished feed. Antarctic krill meal is not intended to be the sole source of pigmentation in salmonid feed, and other permitted sources of astaxanthin may be added in order to achieve the desired level of coloration in the fish flesh. The quantity of astaxanthin in the finished feed contributed by Antarctic krill meal when used under the intended conditions of use, alone or in combination with other permitted sources of astaxanthin, is not to exceed 80 mg/kg astaxanthin. Therefore, the exposure to astaxanthin from the petitioned use of Antarctic krill meal is substitutional for the currently approved uses of astaxanthin, and there would be no increase in human exposure to astaxanthin from this use (Ref. 2).

Additionally, we considered the exposure to astaxanthin from the consumption of wild salmon and the exposure to astaxanthin from the consumption of farm-raised salmonid fish that have been fed approved color additive sources of these carotenoids to be comparable. We conclude that the petitioned use of Antarctic krill meal will not increase the exposure to astaxanthin (Ref. 3).

The petition notes that Antarctic krill meal contains higher levels of fluoride than are present in the fish meal it is intended to partially replace. The petitioner indicated that salmonids that consume a relatively high dietary concentration of fluoride from the petitioned use of Antarctic krill meal may exhibit elevated levels of fluoride in the kidney and bones, but no significant accumulation in the edible tissues (muscle meat and skin) is anticipated. The petitioner indicated that canned salmon may contain bones from the fish that could be consumed by humans. Therefore, we considered fluoride exposure to humans from the consumption of canned salmon (Ref. 2).

B. Toxicological Considerations

To support the safety of the petitioned use of the subject color additive, including astaxanthin, the petitioner noted that synthetically produced and naturally derived astaxanthin has been previously approved for safe use as a color additive in salmonid feed. The petitioner noted that the astaxanthin in Antarctic krill meal occurs in the same optical isomer distribution as is found in wild salmon and in the naturally occurring astaxanthin coloring additives currently permitted for use in salmonid feed. In previous safety evaluations of other sources of astaxanthin, FDA concluded that the esterified forms of astaxanthin that are present in Antarctic krill meal present no additional safety concerns as compared to free astaxanthin because they are converted to the free form during digestion in the fish (Refs. 4 and 5).

The petitioner noted that Antarctic krill meal contains a higher level of

fluoride than is typically present in the fish meal it is intended to partially replace. The petitioner indicated that salmonids that consume an increased dietary concentration of fluoride from the petitioned use of Antarctic krill meal may exhibit elevated levels of fluoride in the kidney and bones. However, no significant accumulation of fluoride in the edible tissues (muscle meat and skin) is anticipated. FDA considered a possible increase in human fluoride exposure due to the consumption of fish fed a diet containing Antarctic krill meal. We concluded that we have no safety concerns regarding the level of fluoride when humans are consuming the flesh of salmonids fed feed containing Antarctic krill meal or when humans are consuming canned salmon made from these fish (Ref. 4).

Regarding the target animal safety of the Antarctic krill meal, the petitioner included data and literature references addressing nutrition, astaxanthin content, and fluoride content of Antarctic krill meal when fed to salmonids. These studies did not reveal any toxicity to the target fish species (Ref. 3).

Based on the substitutional exposure to astaxanthin, the safety of astaxanthin to humans and the target fish species, and our consideration of the fluoride content of the additive, we conclude there is a reasonable certainty of no harm to humans or to the target fish species from the proposed use of Antarctic krill meal.

V. Labeling Requirements

In accordance with § 70.25 (21 CFR 70.25), all color additives must be labeled with sufficient information to assure their safe use and to allow a determination of compliance with any limitations imposed by FDA in other applicable regulations. Therefore, the labeling of the color additive, Antarctic krill meal, and any mixture prepared therefrom, is subject to the requirements of § 70.25.

Under § 70.25(a)(4), an expiration date for a color additive must be stated on its label if stability data require it. The petitioner determined the stability of astaxanthin as a color additive in the product to be approximately 12 months. Although the effect of imparting color may be attenuated after 12 months, the degradation of the astaxanthin-based coloring components does not form any new substances of toxicological concern. FDA finds that because of the potential impact on the stability of astaxanthin in Antarctic krill meal after 12 months, an expiration date must be stated on the label of sealed and open containers, in accordance with § 70.25(a)(4).

In addition to the requirements for labeling the color additive or color additive mixture, the ingredient list on fish feed, to which Antarctic krill meal is added, must identify the presence of the color additive under § 501.4 (21 CFR 501.4). The new regulation, § 73.32(d)(2) (21 CFR 73.32(d)(2)), references § 501.4 to ensure that the presence of Antarctic krill meal as a color additive in the fish feed will be declared on the ingredient label.

The presence of the color additive must be declared on the label of any food. This is to include a declaration on the label of salmonid fish fed feed containing added Antarctic krill meal and on the label of food containing such salmonid fish as an ingredient. Our regulations, at § 101.22(b) (21 CFR 101.22(b)), require a food that bears or contains artificial coloring, such as salmon artificially colored with Antarctic krill meal, to bear labeling even though such food is not in package form. Section 101.22(c) requires that label statements of artificial coloring be likely to be read by the ordinary person under customary conditions of purchase and use of such food. Furthermore, § 101.22(k)(2) requires, in the statement of ingredients for a food to which any coloring has been added, and for which the coloring is not subject to certification, a declaration that makes it clear that a color additive has been used in the food. In addition, the presence of a color additive in a food received in a bulk container that is held at a retail establishment must be declared on the labeling of the bulk container or on a counter card or other similar device under § 101.100(a)(2) (21 CFR 101.100(a)(2)). The ingredient label would alert the consumer that the fish is artificially colored. Without such ingredient labeling, food comprising salmonid fish fed feed with added Antarctic krill meal would be deemed to be misbranded under section 403(k) of the FD&C Act (21 U.S.C. 343(k)), which states that a food shall be deemed to be misbranded if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact.

Therefore, in accordance with §§ 101.22(b), (c), and (k)(2) and 101.100(a)(2), labeling on any salmonid fish fed feed with added Antarctic krill meal is required to declare the presence of the color additive or color additive mixture. The new regulation, at § 73.32(d)(3), references §§ 101.22(b), (c), and (k)(2) and 101.100(a)(2) to ensure that, at the retail level, the presence of Antarctic krill meal as a color additive in the fish will be declared, and that the labeling of the bulk fish container, including a list of ingredients, will be displayed on the container or on a counter card with similar information.

VI. Conclusion

Based on the data and information in the petition and other available relevant information, we conclude that the petitioned use of Antarctic krill meal, for use as a color additive is safe to the target fish species and to humans who consume this fish, at levels not to exceed 4 percent (w/w) in feed for freshwater salmonids and 12 percent (w/w) in feed for marine salmonids. We further conclude that this color additive will achieve its intended technical effect and is suitable for the petitioned use. Therefore, we are amending the color additive regulations in part 73 to provide for the safe use of this color additive as set forth in this document. In addition, based on the factors in 21 CFR 71.20(b), we conclude that batch certification of Antarctic krill meal is not necessary to protect the public health.

VII. Public Disclosure

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15, we will delete from the documents any materials that are not available for public disclosure.

VIII. Analysis of Environmental Impact

We have carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required (Ref. 6). FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

IX. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Section 301(ll) of the FD&C Act

Our review of this petition was limited to section 721 of the FD&C Act. This final rule is not a statement

regarding compliance with other sections of the FD&C Act. For example, section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1) to (4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing this color additive. Accordingly, this final rule should not be construed to be a statement that a food containing this color additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all color additive final rules that pertain to food and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

XI. Objections

This rule is effective as shown in the **DATES** section, except as to any provisions that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.* We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

XII. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.*

1. Memorandum from E. Miranda-Bermudez, Color Technology Branch, Division of Color Certification and Technology (DCCT), Office of Cosmetics and Colors (OCAC), Center for Food Safety and Applied Nutrition (CFSAN), FDA to S. DiFranco, Division of Food Ingredients (DFI), Office of Food Additive Safety (OFAS), CFSAN, FDA, March 14, 2020.

2. Memorandum from D. Doell, Chemistry Review Team, DFI, OFAS, CFSAN, FDA to S. DiFranco, DFI, OFAS, CFSAN, FDA, March 11, 2020.

3. Memorandum from L. Post, Target Animal Review, Division of Animal Feeds, Office of Surveillance and Compliance, Center for Veterinary Medicine, FDA to S. DiFranco, DFI, OFAS, CFSAN, FDA, July 30, 2019.

4. Memorandum from T. Thurmond, Toxicology Review Team, DFI, OFAS, CFSAN, FDA to S. DiFranco, DFI, OFAS, CFSAN, FDA, March 14, 2020.

5. Memorandum from T. Thurmond, Toxicology Review Team, Division of Petition Review (DPR), OFAS, CFSAN, FDA to F. Ellison, DPR, OFAS, CFSAN, FDA, February 3, 2009.

6. Memorandum from M. Pfeil, Environmental Review Team, Division of Science and Technology, OFAS, CFSAN, FDA to S. DiFranco, DFI, OFAS, CFSAN, FDA, March 23, 2020.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of the Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 2. Add § 73.32 to read as follows:

§ 73.32 Antarctic krill meal.

(a) *Identity.* (1) The color additive Antarctic krill meal consists of the cooked, dried, and ground biomass of whole *Euphausia superba* (Antarctic krill), with or without removal of the lipid fraction. The lipid fraction may be fully or partially extracted with ethanol, followed by removal of residual ethanol, to produce defatted Antarctic krill meal. Whole Antarctic krill meal, produced when the lipid fraction is not removed, may contain ethoxyquin as a preservative.

(2) Color additive mixtures for fish feed use made with Antarctic krill meal may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Antarctic krill meal must conform to the following specifications and must be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Physical state, solid.

(2) Ethoxyquin, not more than 250 milligrams per kilogram (mg/kg) (250 parts per million (ppm)) in whole Antarctic krill meal.

(3) Lead, not more than 2 mg/kg (2 ppm).

(4) Arsenic, not more than 5 mg/kg (5 ppm).

(5) Mercury, not more than 1 mg/kg (1 ppm).

(6) Cadmium, not more than 2 mg/kg (2 ppm).

(7) Fluoride, not more than 2,500 mg/kg (2,500 ppm).

(8) Astaxanthin, not more than 170 mg/kg (170 ppm) in whole Antarctic krill meal; not more than 90 mg/kg (90 ppm) in defatted Antarctic krill meal.

(c) *Uses and restrictions.* Antarctic krill meal may be safely used in salmonid feed in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish;

(2) The color additive may be used at levels not to exceed 4 percent by weight in freshwater salmonid feed and 12 percent by weight in marine salmonid feed;

(3) The quantity of the color additive incorporated in the feed is such that the finished feed meets the tolerance limitation for ethoxyquin in animal feed prescribed in § 573.380 of this chapter; and

(4) The quantity of astaxanthin in the finished feed, from Antarctic krill meal when used alone or in combination with other astaxanthin color additive sources listed in this part, must not exceed 80 mg/kg astaxanthin (72 grams per ton) in the finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any

premixes prepared therefrom must bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, a statement of the concentration of ethoxyquin contained therein (whole Antarctic krill meal only), and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section must be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing Antarctic krill meal must be declared in accordance with §§ 101.22(b), (c), and (k)(2) and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

Dated: May 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–10025 Filed 5–9–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 50

[Docket No. OAG 177; AG Order No. 5384–2022]

RIN 1105–AB62

Guidelines and Limitations for Settlement Agreements Involving Payments to Non-Governmental Third Parties

AGENCY: Department of Justice.

ACTION: Interim final rule; request for comments.

SUMMARY: This interim final rule (''rule'') revokes regulations of the Department of Justice (''Department'') that codified a prohibition, subject to limited exceptions, on the inclusion of provisions in settlement agreements directing or providing for a payment or loan, in cash or in kind, to any non-governmental person or entity that is not a party to the dispute. For further information on how the Department intends to approach such settlements going forward, interested parties should consult an Attorney General Memorandum that the Department is issuing on its website in conjunction with this rule. Comments are requested both as to this rule and as to that Memorandum.

DATES:

Effective date: This rule is effective May 10, 2022.

Applicability date: May 5, 2022.

Comments: Comments are due on or before July 11, 2022.

ADDRESSES: To ensure proper handling of comments, please reference Docket No. OAG 177 on all electronic and written correspondence. The Department encourages the electronic submission of all comments through *https://www.regulations.gov* using the electronic comment form provided on that site. For ease of reference, an electronic copy of this document is also available at that website. It is not necessary to submit paper comments that duplicate the electronic submission, as comments submitted to *https://www.regulations.gov* will be posted for public review and are part of the official docket record. However, should you wish to submit written comments through regular or express mail, they should be sent to Robert Hinchman, Senior Counsel, Office of Legal Policy, U.S. Department of Justice, Room 4252 RFK Building, 950 Pennsylvania Avenue NW, Washington, DC 20530. Comments received by mail will be considered timely if they are postmarked on or before July 11, 2022. The electronic Federal eRulemaking portal will accept comments until Midnight Eastern Time at the end of that day.

FOR FURTHER INFORMATION CONTACT: Robert Hinchman, Senior Counsel, Office of Legal Policy, U.S. Department of Justice, telephone (202) 514–8059 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at *https://www.regulations.gov.* Information made available for public inspection includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

You are not required to submit personal identifying information in order to comment on this rule. Nevertheless, if you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also locate all the personal identifying information that you do not want posted online in the first paragraph of your comment and identify what information you want the agency to redact. Personal identifying information identified and located as set forth above will be placed in the agency's public docket file, but not posted online.

If you want to submit confidential business information as part of your comment but do not want it to be posted online, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, the agency may choose not to post that comment (or to post that comment only partially) on *https://www.regulations.gov.* Confidential business information identified and located as set forth above will not be placed in the public docket file, nor will it be posted online.

If you want to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** section.

II. Discussion

A. Overview

This rule revokes the Department's regulations at 28 CFR 50.28. Going forward, the Department's approach to settlement agreements that direct or provide for a payment or a loan, in cash or in kind, to a non-governmental person or entity that is not a party to the dispute will be governed by a new Attorney General Memorandum being issued on the Department's website concurrently with this rule.

B. Background

For decades prior to 2017, Department components had entered into settlement agreements that involved payments to certain third parties as a means of addressing harms arising from violations of Federal law, particularly in the environmental context but in other contexts as well. In 2017, the Attorney General issued a memorandum prohibiting Department attorneys from ''enter[ing] into any agreement on behalf of the United States in settlement of federal claims or charges, including agreements settling civil litigation, accepting plea agreements, or deferring or declining prosecution in a criminal

matter, that directs or provides for a payment or loan to any non-governmental person or entity that is not a party to the dispute,'' subject only to certain specified exceptions. Memorandum from the Attorney General, ''Prohibition on Settlement Payments to Third Parties'' at 1 (June 5, 2017) (the ''2017 Memorandum''). Provisions reflecting the 2017 Memorandum were added to the Justice Manual (*https://www.justice.gov/jm/justice-manual*) at sections 1–17.000, 5–11.105, 9–16.325.

In December 2020, the Department amended its regulations to add a new 28 CFR 50.28, reflecting the prohibition set forth in the 2017 Memorandum ''with certain changes . . . to clarify the scope of the exceptions.'' 85 FR 81409. The Department specified that the prohibition ''applies to all civil and criminal cases litigated under the direction of the Attorney General and includes civil settlement agreements, cy pres agreements or provisions, plea agreements, non-prosecution agreements, and deferred prosecution agreements.'' 85 FR 81410.

C. Revocation of 28 CFR 50.28

After having considered the views of the Department's components and their experience with the regulations at 28 CFR 50.28, the Attorney General has concluded that the regulations at 28 CFR 50.28 are more restrictive and less tailored than necessary and should therefore be revoked.

When used appropriately, agreements providing for payments to third parties are lawful and allow the United States to more fully accomplish the primary goals of civil and criminal enforcement: Compensating victims, remedying harm, and punishing and deterring unlawful conduct.

For example, the harms caused by violations of Federal environmental statutes, including harms to communities affected by environmental crime, can be difficult to redress directly in particular cases. In such circumstances, the Environment and Natural Resources Division has previously relied upon supplemental environmental projects to help achieve an enforcement action's goals. Such projects further the aims of Federal environmental laws the Justice Department is responsible for enforcing by remedying the harms to the communities most directly impacted by violations of those laws. For this reason, they are particularly powerful tools for advancing environmental justice.

In revoking 28 CFR 50.28, the Department is not departing from the principle that the goals of settlements include compensating victims, redressing harms, and punishing and deterring unlawful conduct. 85 FR 81409. But policies in service of this principle have traditionally been addressed through memoranda from Department leadership rather than through regulations. The Department is therefore revoking 28 CFR 50.28 in its entirety, and the Attorney General is concurrently issuing a new Memorandum setting forth the Department's policy going forward. That Memorandum also directs that the current provisions of the Justice Manual at sections 1–17.000, 5–11.105, and 9–16.325 be revised to conform to the new policy.

Regulatory Certifications

A. Administrative Procedure Act

This rule relates to a matter of agency management or personnel and is a rule of agency organization, procedure, or practice. As such, this rule is exempt from the usual requirements of prior notice and comment and a 30-day delay in effective date. *See* 5 U.S.C. 553(a)(2), (b), and (d). The rule is effective upon signature. In its discretion, the Department is seeking post-promulgation public comment on this rulemaking.

B. Regulatory Flexibility Act

An analysis under the Regulatory Flexibility Act was not required for this rule because the Department was not required to publish a general notice of proposed rulemaking for this matter. *See* 5 U.S.C. 601(2), 604(a).

C. Executive Orders 12866 and 13563—Regulatory Review

This rule has been drafted and reviewed in accordance with section 1(b) of Executive Order 12866, ''Regulatory Planning and Review,'' and section 1(b) of Executive Order 13563, ''Improving Regulation and Regulatory Review.''

This rule is ''limited to agency organization, management, or personnel matters'' and thus is not a ''rule'' for purposes of review by the Office of Management and Budget under section 3(d)(3) of Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget.

D. Executive Order 12988—Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, ''Civil Justice Reform.''

E. Executive Order 13132—Federalism

This rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. It is a rule of internal agency practice and procedure. Therefore, in accordance with Executive Order 13132, ''Federalism,'' the Department has determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

F. Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*

G. Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act, 5 U.S.C. 804. This action pertains to agency management, personnel, and organization and does not substantially affect the rights or obligations of non-agency parties. Accordingly, it is not a ''rule'' as that term is used in the Congressional Review Act, 5 U.S.C. 804(3)(B), (C), and the reporting requirements of 5 U.S.C. 801 do not apply.

H. Paperwork Reduction Act of 1995

This final rule does not impose any new reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

List of Subjects in 28 CFR Part 50

Administrative practice and procedure.

Accordingly, for the reasons set forth in the preamble, and by virtue of the authority vested in me as Attorney General, including 5 U.S.C. 301 and 28 U.S.C. 509, 510, part 50 of title 28 of the Code of Federal Regulations is amended as follows:

PART 50—STATEMENTS OF POLICY

■ 1. The authority citation for part 50 continues to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 1162; 28 U.S.C. 509, 510, 516, and 519; 42 U.S.C.

1921 *et seq.,* 1973c; and Pub. L. 107–273, 116 Stat. 1758, 1824.

§ 50.28 [Removed and Reserved]

■ 2. Section 50.28 is removed and reserved.

Dated: May 5, 2022.

Merrick B. Garland,

Attorney General.

[FR Doc. 2022–10036 Filed 5–5–22; 4:15 pm]

BILLING CODE 4410–BB–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

[SATS No. KY–261–FOR; Docket ID: OSM–2019–0013; SIDIS SS08011000 SX064A000 222S180110; S2D2S SS08011000 SX064A000 22XS501520]

Kentucky Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment, and removal of a required amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are approving, subject to certain limitations discussed below, an amendment to the Kentucky regulatory program (Kentucky program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The regulatory provisions we are approving establish new bond requirements for providing sufficient financial assurances for the long-term treatment of unanticipated pollutional discharges at permitted sites. Consequently, we are removing a required amendment that we imposed in 2018 regarding financial assurance for the long-term treatment of discharges. We are also approving revisions to other various bond requirements.

DATES: Effective June 9, 2022.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Castle, Field Office Director, Lexington Field Office, Office of Surface Mining Reclamation and Enforcement, Telephone: (859) 260–3900, Email: *mcastle@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Kentucky Program
II. Submission of the Amendment
III. OSMRE's Findings
IV. Summary and Disposition of Comments
IV. OSMRE's Decision
V. Statutory and Executive Order Reviews

I. Background on the Kentucky Program

Subject to OSMRE's oversight, section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. *See* 30 U.S.C. 1253(a)(1) and (7). Based on these criteria, the Secretary of the Interior conditionally approved the Kentucky program effective May 18, 1982. You can find background information on the program, including the Secretary's findings, the disposition of comments, and conditions of approval in the May 18, 1982, **Federal Register** (47 FR 21434). You can also find later actions concerning Kentucky's program and program amendments at 30 CFR 917.11, 917.12, 917.13, 917.15, 917.16, and 917.17. The regulatory authority in Kentucky is Kentucky's Energy and Environment Cabinet (herein referred to as the Cabinet).

II. Submission of the Amendment

By letter dated November 25, 2019 (Administrative Record No. KY 2003), the Cabinet submitted an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). The amendment revises chapter 10:015 of title 405 of the Kentucky Administrative Regulations (KAR), *General bonding provisions.* The regulatory provisions at Section 8(7), *Bond Rate of Additional Areas,* establish new requirements for the calculation of additional bond amounts necessary for the long-term treatment of unanticipated pollutional discharges (hereafter referred to as ''discharges''). Other bond requirements of a non-substantive nature were also included. *See* 405 KAR 10, *Bond and Insurance Requirements,* subchapter 10:015. The submission is intended to address disapprovals we made in a 2018 decision regarding the Cabinet's proposed regulations for the long-term treatment of discharges in a final rule designated KY–256–FOR (KY–256), *see* January 29, 2018, **Federal Register** (83 FR 3948), and the resultant action we required under the authority of 30 CFR 732.17(e) and (f). The required action is codified in the Kentucky program at 30 CFR 917.16(p), *Required regulatory program amendments.* The full text of the program submission is available at *https://www.regulations.gov.*

A. Background of Kentucky Program Amendment KY–256—In May 2012, in accord with 30 CFR 733.12(b), we notified the Cabinet that we had reason to believe it was not implementing, administering, enforcing, and maintaining the reclamation bond provisions of its approved program in a manner that assured ''completion of the [applicable] reclamation plan,'' as required by section 509(a) of SMCRA, 30 U.S.C. 1259(a), *Performance bonds.* The Cabinet responded to this section 733 notice with three submissions: One in September 2012, another in July 2013, and a third in December 2013. The first submission was announced in the **Federal Register** on February 20, 2013 (78 FR 11796). Subsequently, all three submissions were combined (and public comment solicited) in a single **Federal Register** document, 80 FR 15953 (March 26, 2015), in which the proposed rule was designated State program amendment KY–256. As the document explained, KY–256–FOR was intended to address the deficiencies identified in the section 733 notice.

B. Partial Approval of KY–256—We approved most of the provisions of KY–256–FOR in a final rule published in the **Federal Register** on January 29, 2018 (83 FR 3948). One of the provisions not approved, and now under consideration in revised form, was subsection 8(7) of 405 KAR 10:015, which consisted of three subsections (8(7)(a), –(b), and –(c)). If approved, subsection 8(7)(a) would have provided that, for permitted sites requiring long-term treatment of discharges, the Cabinet must calculate an additional bond amount based on the estimated annual treatment cost provided by the permittee and multiplied by twenty years. Focusing on this twenty-year multiplier, we disapproved the provision in our January 2018 final rule because the Cabinet had not demonstrated how this provision would assure that adequate bonding would be calculated for the long-term treatment of discharges. In doing so, we reaffirmed that abatement of unanticipated water pollution is an element of reclamation and noted that a permittee's treatment obligation may extend in perpetuity. As a result, we found the provision less stringent than section 509 of SMCRA, 30 U.S.C. 1259, and less effective than the Federal regulations at 30 CFR part 800 and, on that basis, declined to approve it. We also declined to approve subsection 8(7)(b), which would have operated in conjunction with subsection 8(7)(a) by subjecting the estimate of annual treatment cost specified in subsection

(a) to verification and acceptance by the Cabinet.

Lastly, we declined to approve subsection 8(7)(c), which would have allowed permittees to submit to the Cabinet for approval a remediation plan that demonstrates that substandard discharge will be abated through land reclamation techniques, prior to phase II bond release, in lieu of the bond calculation in subsection 8(7)(a). As the final rule explained, *see* 83 FR 3948, 3955, this provision would have effectively created an exception to the requirement of SMCRA section 509 that a permittee post bond that is fully adequate to cover complete reclamation, including water treatment, and therefore could not be approved. In addition to declining to approve the three components of subsection 8(7), we also required the Cabinet to take certain regulatory action pursuant to our authority in 30 CFR 732.17(e) and (f), as more fully discussed below.

C. Litigation—Before taking this regulatory action, the Cabinet and the Kentucky Coal Association (KCA) filed separate—but similar—lawsuits against the Secretary of the Interior and the Deputy Director of OSMRE in the U.S. District Court for the Eastern District of Kentucky (case nos. 3:18–cv–19, 3:18–cv–20), challenging the partial approval of KY–256. Prior to the government's deadline to file its initial response to the lawsuits, the parties commenced settlement negotiations. The parties agreed to jointly seek a stay of proceedings in each case so that they could explore the possibility of resolving the lawsuits through rulemaking rather than litigation. Motions seeking stays were filed in each case in June and July 2018. In July 2018, the judges in the two cases granted the motions and stayed proceedings for 90 days. Through a series of similar motions and orders, the stays have been extended to the present day and remain in effect.

D. Required Amendment—The Cabinet's amendment submission is intended to satisfy the regulatory action required, as codified at 30 CFR 917.16(p), by addressing the issues identified in the final rule for KY–256, and is further intended to help resolve the pending litigation. In particular, the regulatory action we required was for the Cabinet to either: (1) Notify us how the Cabinet will require operators to address financial assurances for the long-term treatment of discharges, potentially in perpetuity, under its currently approved program, given that we did not approve new regulatory provisions in subsection 8(7) of 405 KAR 10:015; or (2) submit an amendment to its approved program that requires operators to provide sufficient financial assurances for the treatment of discharges for as long as such discharges continue to exist. In response to the required regulatory action, the Cabinet in 2018 initially elected the first option, notifying us, first verbally and then in writing on March 27, 2018, that its program already provides adequate financial assurance. Following the filing of litigation on March 31, 2018, and the subsequent agreement of the parties to pursue settlement, the Cabinet then elected the second option, submitting provisions intended to provide financial assurance for the treatment of discharges when long-term treatment is required. We describe our findings on the proposed rule, KY–261, in section III, below.

E. Additional Revisions—In addition to responding to the required amendment, the Cabinet has proposed certain non-substantive revisions at 405 KAR 10:015. These revisions include reference changes and editorial edits but do not change the administrative regulations substantively; instead, these changes clarify content or conform the regulation to drafting requirements and conventions. The non-substantive changes are found in 405 KAR 10:015, sections 1(2), 2(5), 2(5)(c)(3)(d), 2(5)(c)(3)(e), 2(6), 2(6)(b), 2(6)(c), 2(7), 2(7)(c), 4, 4(1)(b), 4(2)(a), 4(2)(f), 5(1), 5(2), 6(1), 6(1)(a), 6(1)(c), 6(3), 7(3), 8, 8(5), 9(4), 10(2), 11(1), 11(2), 11(3), 11(5), and 12(1)(g). Because the changes in these sections are non-substantive, we make no findings on them.

F. Public Notice—We announced receipt of the proposed amendment in the February 25, 2020, **Federal Register** (85 FR 10634) (Administrative Record No. KY–2003–3). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. We did not hold a public hearing or meeting because one was not requested. The public comment period ended on March 26, 2020. Public comments received are addressed in section IV of this notice.

G. Demonstration—During our review of the amendments, we requested that the Cabinet demonstrate that proposed subsection 8(7)(a) would provide sufficient financial assurances for long-term treatment sites. By letter dated August 28, 2020 (Administrative Record No. 2003–5), the Cabinet provided a demonstration of the model to be used to calculate the additional bond amounts. This demonstration included a narrative describing how the model works and three example scenarios that calculated the additional bond amounts, which are based on the total annualized capital costs and annual treatment costs multiplied by a factor of 25. The calculation is intended to result in the amount of an additional bond necessary for the regulatory authority to complete reclamation, including treatment of discharges, in the event of a forfeiture. As part of our review, we met with Cabinet representatives on January 19, 2021. During the meeting, the Cabinet provided clarifications on the adequacy of the inputs to the model and how the model processed this information. Cabinet representatives then provided a demonstration, supplemented by a narrative of the model's calculation process, that adequately addressed our questions and comments.

III. OSMRE's Findings

The Cabinet seeks to add administrative regulations at 405 KAR 10:015, subsections 8(7)(a) and (b), to address the requirement for sufficient financial assurances for the treatment of discharges, as identified in the final rule for KY–256. The following are the findings we made concerning the amendment under SMCRA and the Federal regulations at 30 CFR 732.15, *Criteria for approval or disapproval of state programs,* and 30 CFR 732.17, *State program amendments,* as described below.

A. 405 KAR 10:015 8(7)(a): The Cabinet proposes to add subsection 8(7)(a) to its approved program. As mentioned, a provision at this section was proposed earlier but disapproved in KY–256. The proposed provision states that, for any permit identified as requiring long-term treatment of a discharge, the Cabinet must calculate the amount of an additional bond or other financial assurance instrument based on the estimated annual treatment cost, provided by the permittee and verified by the Cabinet, multiplied by a factor of 25, plus any capital costs of the treatment system.

OSMRE Finding: In KY–256, the Cabinet had proposed a new regulation at subsection 8(7)(a), which provided that, for any permit that had been identified as producing long-term treatment drainage, the Cabinet would calculate the amount of an additional bond based on the estimated annual treatment cost, as provided by the permittee and verified by the Cabinet, multiplied by twenty years. We disapproved the provision because the Cabinet had not demonstrated that a twenty-year multiplier would result in an adequate bond. We stated that both SMCRA and the Federal regulations require operators to post bonds that are sufficient in amount to assure

completion of reclamation if that reclamation were to be completed by the regulatory authority. This includes abatement of any discharges. Therefore, absent such a demonstration, we found subsection 8(7)(a) less stringent than section 509 of SMCRA and less effective than the Federal regulations at 30 CFR part 800, *Bond and Insurance Requirements for Surface Coal Mining and Reclamation Operations Under Regulatory Programs,* and we did not approve it.

The proposed regulation modified the KY–256 version of 8(7)(a) in three important ways. First, when calculating the bond amount, the Cabinet would now be required to account for capital costs, something the earlier version in KY–256 did not do. Second, the bond calculation basis (annual treatment cost) would be subject to a factor of 25, not the twenty-year multiplier previously proposed. Third, the Cabinet changed the reference in the earlier version from ''additional bond'' to ''additional bond or other financial assurance instrument,'' though the change was not explained in the Cabinet's November 2019 submission.

There is no comparable Federal regulation that prescribes how financial assurance requirements for the long-term treatment of discharges should be determined. Absent such regulation, we reviewed the model provided by the Cabinet to understand how the additional bond or other financial assurance instrument is to be calculated under subsection 8(7)(a). Taken together, the provisions of the proposed regulation, the Cabinet's demonstration on the workings of its bond calculation model, and general bond provisions of the Kentucky program form the basis of our findings in determining whether the proposed provisions meet the requirements of section 509 of SMCRA and 30 CFR part 800.

Using this bond calculation model for long-term treatment costs, the Cabinet determines the amount of bond necessary to assure completion of reclamation if the work had to be performed by the regulatory authority following forfeiture. The language of subsection 8(7)(a), as proposed, leaves the verification and acceptance of the long-term treatment cost determination to the regulatory authority. We agree with this approach and, based on the Cabinet's demonstration of its use of its bond calculation model, find this method of determining the amount of bond necessary for long-term treatment of discharges no less stringent than section 509 of SMCRA and no less effective than the Federal regulations at 30 CFR part 800.

We are satisfied that any changed circumstances affecting the Cabinet's initial assumptions can be appropriately addressed through future bond adjustments, as authorized in section 10 of 405 KAR 10:015. Importantly, bond adequacy must be reassessed every two years under subsection 6(3) of 405 KAR 10:015. This approach to bond calculation is consistent with the Federal regulations at 30 CFR 800.14, *Determination of bond amount,* and 800.15, *Adjustment of amount.* Neither of these provisions spell out the precise parameters for calculation of the original bond amount or for periodic adjustments of the bond amount. Rather, those decisions are to be made by the regulatory authority. We expect that long-term treatment bonds will be reviewed biannually under subsection 6(3) of 405 KAR 10:015 and adjusted, using this bond calculation model for long-term treatment costs, as appropriate under section 10.

Finally, we are also satisfied that the Cabinet's bond calculation model for long-term treatment costs demonstrates an adequate bond amount. Recognizing the difficulty of determining an adequate bond amount covering treatment which may last in perpetuity, and that there is no specific Federal requirement or guidance on determining an adequate amount of a bond covering treatment in perpetuity, the Cabinet chose to use a surrogate of seventy-five years. We consider the Cabinet's use of the seventy-five-year surrogate acceptable considering that the nature and extent of long-term discharges can change over time, that section 10 of 405 KAR 10:015 authorizes the Cabinet to adjust bond amounts, and that section 6(3) of the same subchapter requires biannual assessments of bond adequacy.

Given these considerations, we conclude that subsection 8(7)(a)'s calculation provisions meet the requirements of section 509 of SMCRA, including the requirement in section 509(a) that the amount of the bond ''be sufficient to assure the completion of the reclamation plan if the work had to be performed by the regulatory authority in the event of forfeiture,'' and that subsection 8(7)(a) is no less stringent than section 509 of SMCRA and no less effective than the regulations at 30 CFR part 800. Because the Cabinet did not provide any explanation or justification in its submission for expanding the scope to include other financial assurance instruments beyond those already approved in section 3, we are approving the regulation but only to the extent that the phrase ''additional bond or other financial assurance instrument'' in subsection 8(7)(a) refers to the relevant performance bonds already authorized in section 3 of 405 KAR 10:015. We maintain oversight of the regulatory program and the bonding system under the approved Kentucky program. Should we become aware that the State's bonding program is insufficient, we have the authority to require the State to take appropriate action. We also note our amenability to considering, in the future, a proposed amendment seeking approval of the use of ''other financial assurance instruments,'' one that explains what they are and justifies Kentucky's legal authority to use such instruments.

B. 405 KAR 10:015 8(7)(b): The Cabinet proposes to add subsection 8(7)(b) to its approved program. A provision at this section was previously proposed but disapproved in KY–256. The proposed provision provides that the long-term treatment cost estimate is subject to verification and acceptance by the Cabinet and that the Cabinet will use its own estimate for annual treatment costs if it cannot verify the accuracy of the permittee's estimate.

OSMRE Finding: Except for the added clarification in subsection 8(7)(b) that the cost estimate called for in subsection 8(7)(a) is a ''long-term treatment'' cost estimate, the Cabinet had proposed this same language under KY–256. We did not approve this provision previously because it referenced the bond calculation in 8(7)(a) that we were not approving. Because we are approving the provisions of new subsection 8(7)(a), this reference is no longer a concern. We therefore find that subsection 8(7)(b) is no less stringent than section 509 of SMCRA and no less effective than the Federal regulations at 30 CFR part 800, including 30 CFR 800.14(a)(1), which requires that the amount of bond required be determined by the regulatory authority. On this basis, it is approved.

C. 405 KAR 10:015 8(7)(c): The Cabinet's submission includes the deletion of subsection 8(7)(c), which was proposed in KY–256 and would have provided that, in lieu of posting the additional bond amount, the permittee would submit a satisfactory reclamation and remediation plan for any area producing a discharge. As originally proposed, the reclamation plan would have to demonstrate that a pollutional discharge can be permanently abated by land reclamation techniques prior to phase II bond release.

OSMRE Finding: We did not approve the new regulation proposed in KY–256 because we found the allowance of a remediation plan that is based on land reclamation in lieu of posting adequate

bond unacceptable. As we stated, neither SMCRA nor its implementing regulations provide any exceptions to the requirement to post a bond that assures completion of reclamation, including water treatment. For this reason, we found the provision to be less stringent than section 509 of SMCRA and less effective than the Federal regulations at 30 CFR part 800. Because we never approved the provision, we are not making a finding on this deletion.

IV. Summary and Disposition of Comments

Public Comments

In the February 25, 2020, **Federal Register** document announcing our receipt of this amendment, we asked for public comments (85 FR 10634). The comment period closed on March 26, 2020. No requests for public meetings or hearings were received. By letter dated March 26, 2020, we received comments from the KCA, which represents the producers of the majority of coal mined in Kentucky and over one hundred additional businesses and organizations that depend upon or support the Kentucky coal mining industry (Administrative Record No. KY–2003–4).

In its comments, KCA supported approval of the regulations proposed by the Cabinet, noting that it has actively participated in the Kentucky rulemaking process and has been involved in the noted litigation concerning partial approval of KY–256. The KCA stated that the proposed revisions are as stringent as the requirements of SMCRA and satisfy the criteria for approval under 30 CFR 732.15 and should be approved without delay. The KCA mentioned its understanding that the Cabinet has or can provide significant evidence demonstrating that the bonding calculation methodology contained in the revised subsection 8(7) will ensure adequate bonding. The KCA emphasized that its member companies require regulatory certainty and clarity and urged approval without delay.

OSMRE Response: Because the comments are in support of the approval of the amendment, a position with which OSMRE agrees, we make no response.

Federal Agency Comments

On December 16, 2019, in accord with 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Kentucky program (Administrative Record No. 2003–1). No Federal agency comments were received.

Environmental Protection Agency (EPA) Concurrence and Comments

Under 30 CFR 732.17(h)(11)(ii), we are required to obtain written concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). None of the revisions that the Cabinet proposes to make in this amendment pertain to or affect air or water quality standards. Therefore, we did not ask EPA to concur on the amendment. However, on December 16, 2019, under 30 CFR 732.17(h)(11)(i), we requested comments from the EPA (Administrative Record No. 2003–1). The EPA did not provide any comments.

State Historical Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

Under 30 CFR 732.17(h)(4), we are required to request comments from the SHPO and ACHP on amendments that may have an effect on historic properties. On December 16, 2019, we requested comments from the Kentucky Heritage Council on this amendment (Administrative Record No. 2003–1). We did not receive any comments.

V. OSMRE's Decision

Based on the above findings, we are approving KY–261 as submitted by the Cabinet on November 25, 2019. We are approving the amendment subject to our understanding regarding the meaning of ''other financial assurance instrument,'' and removing the required amendment at 30 CFR 917.16(p).

To implement this decision, we are amending the Federal regulations, at 30 CFR part 917, which codify decisions concerning the Kentucky program. In accordance with the Administrative Procedure Act (5 U.S.C. 500 *et seq.*), this rule will take effect 30 days after the date of publication. Section 503(a) of SMCRA requires that the State's program demonstrate that the State has the capability of carrying out the provisions of the Act and meeting its purposes. SMCRA requires consistency of State and Federal standards, which this amendment achieves. For these reasons, we conclude that KY–261 satisfies the required action identified in our January 2018 final rule on KY–256. It provides a mechanism for calculating an additional bond amount at the time when the regulatory agency determines that long-term treatment is required.

VI. Statutory and Executive Order Reviews

Executive Order 12630—Governmental Actions and Interference With Constitutionality Protected Property Rights

This rule would not effect a taking of private property or otherwise have taking implications that would result in property being taken for Government use without just compensation under the law. Therefore, a takings implication assessment is not required. This determination is based on an analysis of the relevant Federal regulations.

Executive Order 12866—Regulatory Planning and Review and 13563—Improving Regulation and Regulatory Review

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB) will review all significant rules. Pursuant to OMB guidance, dated October 12, 1993, the approval of State program amendments is exempted from OMB review under Executive Order 12866. Executive Order 13563, which reaffirms and supplements Executive Order 12866, retains this exemption.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has reviewed this rule as required by section 3(a) of Executive Order 12988. The Department has determined that this **Federal Register** document meets the criteria of section 3 of Executive Order 12988, which is intended to ensure that the agency review its legislation and proposed regulations to eliminate drafting errors and ambiguity; that the agency write its legislation and regulations to minimize litigation; and that the agency's legislation and regulations provide a clear legal standard for affected conduct rather than a general standard, and promote simplification and burden reduction. Because section 3 focuses on the quality of Federal legislation and regulations, the Department limited its review under this Executive order to the quality of this **Federal Register** document and to changes to the Federal regulations. The review under this Executive order did not extend to the language of the State regulatory program or to the program amendment that the Cabinet drafted.

Executive Order 13132—Federalism

This rule has potential federalism implications as defined under section 1(a) of Executive Order 13132. Executive Order 13132 directs agencies to ''grant the States the maximum

administrative discretion possible'' with respect to Federal statutes and regulations administered by the States. Kentucky, through its approved regulatory program, implements and administers SMCRA and its implementing regulations at the State level. This rule approves an amendment to the Kentucky program submitted and drafted by the State and, thus, is consistent with the direction to provide maximum administrative discretion to States.

Executive Order 13175—Consultation and Coordination With Indian Tribal Government

The Department of the Interior strives to strengthen its government-to-government relationship with Tribes through a commitment to consultation with Tribes and recognition of their right to self-governance and tribal sovereignty. We have evaluated this rule under the Department's consultation policy and under the criteria in Executive Order 13175 and have determined that it has no substantial direct effects on federally recognized Tribes or on the distribution of power and responsibilities between the Federal Government and Tribes. Therefore, consultation under the Department's tribal consultation policy is not required. The basis for this determination is that our decision on the Kentucky program does not include Tribal lands or affect regulation of activities on Tribal lands. Tribal lands are regulated independently under the applicable approved Federal program.

Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Executive Order 13211 requires agencies to prepare a Statement of Energy Effects for a rulemaking that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not a significant energy action under the definition in Executive Order 13211, a Statement of Energy Effects is not required.

Executive Order 13045—Protection of Children From Environmental Health Risks and Safety Risks

This rule is not subject to Executive Order 13045 because this is not an economically significant regulatory action as defined by Executive Order 12866; and this action does not address environmental health or safety risks disproportionately affecting children.

National Environmental Policy Act

Consistent with sections 501(a) and 702(d) of SMCRA (30 U.S.C. 1251(a) and 1292(d), respectively) and the U.S. Department of the Interior Departmental Manual, part 516, section 13.5(A), State program amendments are not major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C).

National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 3701 *et seq.*) directs OSMRE to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. (OMB Circular A–119 at p. 14) This action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with SMCRA.

Paperwork Reduction Act

This rule does not include requests and requirements of an individual, partnership, or corporation to obtain information and report it to a Federal agency. As this rule does not contain information collection requirements, a submission to the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is not required.

Regulatory Flexibility Act

This rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon the Federal regulations setting minimum bond requirements for surface coal mining and reclamation operations under regulatory programs, for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the corresponding Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of $100 million; (b) will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based on an analysis of the corresponding Federal regulations, which were determined not to constitute a major rule.

Unfunded Mandates Reform Act

This rule will not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or Tribal governments or the private sector. This determination is based an analysis of the Federal regulations setting minimum bond requirements for surface coal mining and reclamation operations under regulatory programs, which were determined not to impose an unfunded mandate. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

List of Subjects in 30 CFR Part 917

Intergovernmental relations, Surface mining, Underground mining.

Thomas D. Shope,

Regional Director, North Atlantic-Appalachian Region.

For the reasons set out in the preamble, 30 CFR part 917 is amended as set forth below:

PART 917—KENTUCKY

■ 1. The authority citation for part 917 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Section 917.15 is amended in the table in paragraph (a) by adding an entry for ''November 25, 2019'' in chronological order by ''Date of Final Publication'' to read as follows:

§ 917.15 Approval of Kentucky regulatory program amendments.

(a) * * *

Original amendment submission date	Date of final publication	Citation/description
*	*	* * * * *
November 25, 2019	May 10, 2022	405 KAR 10:015 8(7)(a) and (b) (bonding rate of additional areas); 405 KAR 10:015, sections 1(2), 2(5), 2(5)(c)(3)(d), 2(5)(c)(3)(e), 2(6), 2(6)(b), 2(6)(c), 2(7), 2(7)(c), 4, 4(1)(b), 4(2)(a), 4(2)(f), 5(1), 5(2), 6(1), 6(1)(a), 6(1)(c), 6(3), 7(3), 8, 8(5), 9(4), 10(2), 11(1), 11(2), 11(3), 11(5), and 12(1)(g) (non-substantive revisions).

* * * * *

§ 917.16 [Amended]

■ 3. Section 917.16 is amended by removing and reserving paragraph (p).

[FR Doc. 2022–09982 Filed 5–9–22; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2022–0271]

Special Local Regulations; Annual Les Cheneaux Islands Antique Wooden Boat Show; Hessel, MI

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Annual Les Cheneaux Islands Antique Wooden Boat Show special local regulation on Marquette Bay, Hessel, MI, to protect the safety of life and property on navigable waters prior to, during, and immediately after this event. During the enforcement period, entry into, transiting, or anchoring within the regulated area is prohibited unless authorized by the Captain of the Port Sault Sainte Marie or a designated representative.

DATES: The regulations in 33 CFR 100.922 will be enforced from 6 a.m. through 8 p.m. on August 13, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LT Deaven Palenzuela, Chief of Waterways Management Division, U.S. Coast Guard; telephone 906–635–3223, email *ssmprevention@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in 33 CFR 100.922 for the Annual Les Cheneaux Islands Antique Wooden Boat Show in Hessel, MI, from 6 a.m. through 8 p.m. on August 13, 2022. This action is being taken to protect the safety of life and property on navigable waters prior to, during, and immediately after the event. Our special local regulations for the annual Les Cheneaux Islands Antique Wooden Boat Show § 100.922, specifies the location of the regulated area which encompasses portions of Marquette Bay, Hessel, MI. During the enforcement period, all vessels while in the regulated area will operate at a no wake speed and follow the directions of the on-scene patrol commander. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and/or marine information broadcasts.

Dated: May 3, 2022.

A.R. Jones,

Captain, U.S. Coast Guard, Captain of the Port Sault Sainte Marie.

[FR Doc. 2022–10007 Filed 5–9–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–0270]

Safety Zones; Annual Events in the Captain of the Port Buffalo Zone—Cleveland National Air Show

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for the Cleveland National Airshow from September 1 through September 5, 2022, to provide for the safety of life and property on navigable waters during this event. Our regulation for annual events in the Captain of the Port Buffalo Zone identifies the regulated area for this event in Cleveland, OH. During the enforcement period, no person or vessel may enter the safety zone without the permission of the Captain of the Port Buffalo.

DATES: The regulations in 33 CFR 165.939 will be enforced for the Cleveland National Airshow safety zone listed in item (d)(2) in the Table to § 165.939 from 9 a.m. through 6 p.m., each day from September 1, 2022, through September 5, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LT Jared Stevens, Waterways Management Division, Marine Safety Unit Cleveland, U.S. Coast Guard; telephone 216–937–0124, email *D09-SMB-MSUCLEVELAND-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone listed in 33 CFR 165.939 for the Cleveland National Airshow daily from 9 a.m. through 6 p.m. on September 1 through September 5, 2022. This action is being taken to provide for the safety of life on navigable waterways during this multi-day event. Our regulation for annual events in the Captain of the Port Buffalo Zone identifies the regulated area for the Cleveland National Airshow which encompasses all U.S. waters of Lake Erie and Cleveland Harbor (near Burke Lakefront Airport) from 41°30′20″ N and 081°42′20″ W to 41°30′50″ N and 081°42′49″ W, to 41°32′09″ N and 081°39′49″ W, to 41°31′53″ N and 081°39′24″ W.

Pursuant to 33 CFR 165.23, entry into, transiting, or anchoring within the safety zone during the enforcement period is prohibited unless authorized by the Captain of the Port Buffalo or their designated representative. Those seeking permission to enter the safety zone may request permission from the Captain of Port Buffalo via VHF Channel 16. Vessels and persons granted permission to enter the safety zone shall obey the directions of the Captain of the Port Buffalo or his designated representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide

notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

Dated: April 11, 2022.

L.M. Littlejohn,

Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. 2022–09994 Filed 5–9–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2022–0263]

Safety Zones; Recurring Safety Zones in Captain of the Port Sault Sainte Marie Zone for Events Beginning in June 2022

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce established safety zones for maritime events to provide for the safety of life on navigable waterways. Our regulation for safety zones within the Captain of the Port Sault Sainte Marie Zone identifies the regulated area for these safety zones. During the enforcement periods, vessels must stay out of the established safety zone and may only enter with permission from the designated representative of the Captain of the Port Sault Sainte Marie.

DATES: The regulations in 33 CFR 165.918 will be enforced for the safety zones identified in Table 1 of the **SUPPLEMENTARY INFORMATION** section below for the dates and times specified.

FOR FURTHER INFORMATION CONTACT: If you have questions about this publication, call or email Waterways Management division, LT Deaven Palenzuela, Coast Guard Sector Sault Sainte Marie, U.S. Coast Guard; telephone 906–635–3223, email *ssmprevention@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zones in 33 CFR 165.918 as per the time, dates, and locations in Table 1.

TABLE 1

[Datum NAD 1983]

Event	Location	Event date
(2) Jordan Valley Freedom Festival Fireworks, East Jordan, MI.	All U.S. navigable waters of Lake Charlevoix, near the City of East Jordan, within the arc of a circle with an approximate 1200-foot radius from the fireworks launch site in position 45°09′18″ N, 085°07′48″ W.	June 25, 2022, from 10 p.m. to 10:30 p.m.
(3) Grand Marais Splash In; Grand Marais, MI.	All U.S. navigable waters within the southern portion of West Bay bound within the following coordinates: 46°40′22.08″ N, 085°59′0.12″ W, 46°40′22.08″ N, 85°58′22.08″ W, and 46°40′14.64″ N, 85°58′19.56″ W, with the West Bay shoreline forming the South and West boundaries of the zone.	June 18, 2022, from 2 p.m. to 4 p.m.

This action is being taken to provide for the safety of life on navigable waterways during the fireworks displays. The regulations for safety zones within the Captain of the Port Sault Sainte Marie Zone, § 165.918, apply for these fireworks displays.

This notification of enforcement is issued under authority of 33 CFR 165.918 and 5 U.S.C. 552 (a). In addition to this notification of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Broadcast Notice to Mariners or Local Notice to Mariners. If the Captain of the Port Sault Sainte Marie determines that the safety zone need not be enforced for the full duration stated in this notification he or she may use a Broadcast Notice to Mariners to grant general permission to enter the respective safety zone.

Dated: May 3, 2022.

A.R. Jones,

Captain, U.S. Coast Guard, Captain of the Port Sault Sainte Marie.

[FR Doc. 2022–10009 Filed 5–9–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2022–0244]

Safety Zones; Recurring Events in Captain of the Port Duluth—LaPointe Fireworks

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the LaPointe Fireworks in the waters of Lake Superior in LaPointe, WI, on July 4, 2022. This action is necessary to protect participants and spectators during the LaPointe Fireworks. During the enforcement period, entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Duluth or designated on-scene representative.

DATES: The regulations in 33 CFR 165.943 will be enforced for the LaPointe Fireworks safety zone listed in item 6 in the table to § 165.943 from 9 p.m. through 11 p.m. on July 4, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notification of enforcement, call or email LTJG Joe McGinnis, MSU Duluth, Waterways Management Branch, U.S. Coast Guard; telephone 218–725–3823, email *DuluthWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone for the annual LaPointe Fireworks in item

6 in the table to 33 CFR 165.943 from 9 p.m. through 11 p.m. on July 4, 2022. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Ninth Coast Guard District, § 165.943, specifies the location of the safety zone for the LaPointe Fireworks, which encompasses all waters of Lake Superior in LaPointe, WI, within the arc of a circle with a 350-foot radius from the fireworks launch site with its center in position 46°46′40″ N, 090°47′22″ W. During the enforcement periods, as reflected in § 165.943(c), if you are the operator of a vessel in the safety zone, you must comply with directions from the Captain of the Port Duluth, or her on-scene representative.

Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Duluth or their designated on-scene representative. The Captain of the Port's designated on-scene representative may be contacted via VHF Channel 16. In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via a Broadcast Notice to Mariners.

Dated: April 26, 2022.

F.M. Smith,

Commander, U.S. Coast Guard, Captain of the Port Duluth.

[FR Doc. 2022–10005 Filed 5–9–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0281]

RIN 1625–AA00

Safety Zone; Celebrate Our Stars and Stripes Fireworks, Raritan Bay, Perth Amboy, NJ

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters of Raritan Bay near Perth Amboy, NJ, for a fireworks display. This temporary safety zone is necessary to protect spectators and vessel from the hazards associated with the fireworks display. This rule is intended to restrict all vessels from a portion of Raritan Bay during the fireworks unless authorized by the Captain of the Port (COTP) New York or a designated representative.

DATES: This rule is effective from 9 p.m. on July 2, 2022, until 10 p.m. on July 3, 2022. This rule will be enforced either on July 2, 2022, from 9 p.m. to 10 p.m. or on July 3, 2022, from 9 p.m. to 10 p.m.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0281 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MST1 Gutierrez, Lizette, U.S. Coast Guard; telephone (718) 354–4154, email *D01-SMB-SecNY-Waterways@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the event sponsor was late in submitting the marine event application. This late submission did not give the Coast Guard enough time to publish an NPRM followed by a final rule before the effective date thus making it impracticable to publish an NPRM. The event sponsor advised that the event is in correlation with a festival bringing together Perth Amboy and South Amboy, NJ, to honor Independence Day. Any change to the date of the event would cause economic hardship on the event sponsor, negatively impacting other activities being held in conjunction with the event.

The location of the event is centrally located between both Perth Amboy and South Amboy which is more advantageous for the event spectators and sponsors. In addition it has less of an impact on vessel traffic within Raritan Bay because the location is out of the major shipping lanes.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP New York has determined this temporary safety zone is necessary to ensure the safety of spectators and vessels from the hazards associated with the fireworks display.

IV. Discussion of the Rule

This rule establishes a temporary safety zone on the waters of Raritan Bay near Perth Amboy, NJ, for a fireworks event on July 2, 2022. If the event is unable to happen on July 2, 2022, due to inclement weather, the fireworks event will instead occur on July 3, 2022. All persons and vessels shall comply with the instruction of the COTP New York or a designated representative during the enforcement of the temporary safety zone. Entering into, transiting through, or anchoring within the temporary safety zone is prohibited unless authorized by the COTP New York or a designated representative.

Based on the inherent hazards associated with fireworks, the COTP New York has determined that fireworks launches in close proximity to water crafts pose a significant risk to public safety and property. The combination of increased number of recreational vessels, congested waterways, darkness punctuated by bright flashes of light, and debris, especially burning debris falling on passing or spectator vessels, has the potential to result in serious injuries or fatalities. This temporary safety zone will restrict vessels from a portion of Raritan Bay around the location of the fireworks launch platform before, during and immediately after the fireworks display.

The Coast Guard determined that this regulated area will not have significant impact on vessel traffic due to its temporary nature and limited size and the fact that vessels are allowed to transit the navigable waters outside of the regulated area.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and

Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

The Coast Guard's implementation of this temporary safety zone will be of short duration and is designed to minimize the impact to vessel traffic on the navigable waters. This temporary safety zone will only be enforced for approximately 60 minutes. Due to the location, vessels will be able to transit around the safety zone in a safe manner.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishment of a temporary safety zone lasting only 1 hour that will prohibit entry within a 300-yard radius of the fireworks barges located in approximate position 40°29′28″ N, 074°15′45″ W. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREA

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T01–0281 to read as follows:

§ 165.T01–0281 Safety Zone; Raritan Bay, Perth Amboy, NJ.

(a) *Location.* The following area is a safety zone: All navigable waters of Raritan Bay within a 300-yard radius of the fireworks barge located in approximate position 40°29′28″ N, 074°15′45″ W, in the vicinity of Perth Amboy, NJ, approximately 1,110 yards southeast of Ferry Point, Perth Amboy, NJ.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer

operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port New York (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative via VHF channel 16 or 718–354–4154 (Sector New York command center). Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(3) All persons and vessels shall comply with the instructions of the COTP or a designated representative. Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashlight or other means, the operator of the vessel shall proceed as directed. Failure to comply with a lawful direction may result in expulsion from the area, citation for failure to comply, or both.

(4) Spectators or other vessels shall not anchor, block, loiter, or impede the transit of the event participants or official patrol vessels in the regulated areas during the effective dates and times unless authorized by COTP or designated representative.

(5) The COTP or designated representative may delay or terminate any marine event in this subpart at any time if it is deemed necessary to ensure the safety of life or property.

(d) *Enforcement period.* This section will be subject to enforcement on either July 2, 2022, from 9 p.m. to 10 p.m. or on July 3, 2022, from 9 p.m. through 10 p.m.

Dated: May 4, 2022.

Z.E. Merchant,

Captain, U.S. Coast Guard, Captain of the Port, New York.

[FR Doc. 2022–10008 Filed 5–9–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0184]

RIN 1625–AA00

Safety Zone; Graduate Boat Parade, Sturgeon Bay, WI

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain waters of Sturgeon Bay, WI. This action is necessary to provide for the safety of life on these navigable waters during the boat parade for the Graduates of Sturgeon Bay High School on May 28, 2022. This rulemaking will restrict usage by persons and vessels within the safety zone. At no time during the effective period may non-parade vessels transit the waters of Sturgeon Bay between the Highway 42 Bridge and Michigan Street Bridge. These restrictions will apply to all vessels during the effective period unless authorized by the Captain of the Port Lake Michigan or a designated representative.

DATES: This rule is effective from 11:00 a.m. through 2:00 p.m. on May 28, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0184 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Chief Petty Officer Jeromy Sherrill, Sector Lake Michigan Waterways Management Division, U.S. Coast Guard; telephone 414–747–7148, email *Jeromy.N.Sherrill@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On March 9, 2022, the principal of Sturgeon Bay High School notified the Coast Guard that it will be conducting a boat parade for graduates of the Class of 2022 on May 28, 2022, from 11:00 a.m. through 2:00 p.m. The boat parade will begin at Madelyn Marine, NW of Highway 42 bridge, proceed NW to the Michigan Street Bridge, cross the channel towards the Maritime Museum, then proceed SE, crossing back across the channel and ending at Madelyn Marine. The Captain of the Port Sector Lake Michigan (COTP) has determined that potential hazards associated with the boat parade would be a safety concern for anyone within the safety zone that is not participating in the boat parade.

In response, on March 22, 2022, the Coast Guard published a notice of proposed rulemaking (NPRM) titled ''Safety Zone; Graduate Boat Parade, Sturgeon Bay, WI'' (87 FR 16129). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this fireworks display. During the comment period that ended April 6, 2022, we received 0 comments.

III. Legal Authority and Need for Rule

The Captain of the Port Sector Lake Michigan (COTP) has determined that potential hazards associated with the boat parade would be a safety concern for anyone within the safety zone that is not participating in the boat parade. The purpose of this rule is to ensure safety of vessels and the navigable waters in the safety zone before, during, and after the scheduled event.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published March 22, 2022. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from 11:00 a.m. through 2:00 p.m. on May 28, 2022. The safety zone would cover all navigable waters of Sturgeon Bay between the Highway 42 Bridge and Michigan Street Bridge. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the boat parade event. No vessels or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The regulatory text appears at the end of this document.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the

Office of Management and Budget (OMB).

This regulatory action determination is based on the characteristics of the safety zone. The safety zone created by this rule will relatively small and is designed to minimize its impact on navigable waters. This rule will prohibit entry into certain navigable waters of Sturgeon Bay, WI, and it is not anticipated to exceed 3 hours in duration. Thus, restrictions on vessel movement within that particular area are expected to be minimal. Moreover, under certain conditions vessels may still transit through the safety zone when permitted by the COTP Lake Michigan.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received 00 comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting 3 hours that would prohibit entry within a relatively small portion of Sturgeon Bay. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T09–0184 to read as follows:

§ 165.T09–0184 Safety Zone; Graduate Boat Parade, Sturgeon Bay, WI.

(a) *Location.* All navigable waters of Sturgeon Bay between the Highway 42 Bridge and Michigan Street Bridge.

(b) *Enforcement period.* The safety zone described in paragraph (a) of this section is effective on May 28, 2022, from 11:00 a.m. through 2:00 p.m.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Lake Michigan (COTP) or a designated representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the COTP or a designated representative.

(3) The ''designated representative'' of the COTP is any Coast Guard commissioned, warrant, or petty officer

who has been designated by the COTP to act on his or her behalf.

(4) Persons and vessel operators desiring to enter or operate within the safety zone during the boat parade must contact the COTP or an on-scene representative to obtain permission to do so. The COTP or an on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or an on-scene representative.

Dated: April 22, 2022.

D.P. Montoro,

Captain, U.S. Coast Guard, Captain of the Port Lake Michigan.

[FR Doc. 2022–09992 Filed 5–9–22; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2021–0452; FRL–8834–02–R9]

Air Quality State Implementation Plans; Approvals and Promulgations: California; Opacity Testing of Heavy-Duty Diesel Vehicles

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a revision to the California State Implementation Plan (SIP) concerning particulate matter (PM) emissions from heavy-duty (HD) diesel vehicles. We are approving state rules that regulate PM emission sources under the Clean Air Act (CAA or the Act).

DATES: This rule is effective on June 9, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2021–0452. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Jeffrey Buss, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947–4152 or by email at *buss.jeffrey@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

Table of Contents

I. Proposed Action
II. Public Comments and EPA Responses
III. EPA Action
IV. Incorporation by Reference
V. Statutory and Executive Order Reviews

I. Proposed Action

On November 5, 2021 (86 FR 61100), the EPA proposed to approve the following rules into the California SIP.

Agency	Rule No.	Rule title	Amended	Submitted
CARB	Title 13, Division 3, Chapter 3.5.	Heavy-Duty Diesel Smoke Emission Testing and Heavy-Duty Vehicle Emission Control System Inspections.	07/01/2019	02/13/2020
CARB	Title 13, Division 3, Chapter 3.6.	Periodic Smoke Inspections of Heavy-Duty Diesel-Powered Vehicles ...	07/01/2019	02/13/2020

We proposed to approve these rules because we determined that they comply with the relevant CAA requirements. Our proposed action contains more information on the rules and our evaluation.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received nine comments from members of the public. These comments were generally supportive of the action and none raised any concerns with our proposed rule.

III. EPA Action

Nine comments were submitted, and none change our assessment of the rules as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving these rules into the California SIP.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the California rules described in the amendments to 40 CFR part 52 set forth below. Therefore, these materials have been approved by the EPA for inclusion in the SIP, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[1] The EPA has made, and will continue to make, these documents available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

[1] 62 FR 27968 (May 22, 1997).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those

imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 11, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter.

Dated: April 29, 2022.

Martha Guzman Aceves,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. In § 52.220a, in paragraph (c), table 1 is amended by:

■ a. Adding a heading for ''Title 13 (Motor Vehicles), Division 3 (Air Resources Board), Chapter 3.5. (Heavy-Duty Diesel Smoke Emission Testing, and Heavy-Duty Vehicle Emission Control System Inspections)'' after the entry for ''2147(b)(3)''; and adding entries for ''2180'', ''2180.1'', ''2181'', ''2182'', ''2183'', ''2184'', ''2185'', ''2186'', ''2187'', ''2188'' and ''2189'' under the newly added heading;

■ b. Adding a heading for ''Title 13 (Motor Vehicles), Division 3 (Air Resources Board), Chapter 3.6. (Periodic Smoke Inspections of Heavy-Duty Diesel-Powered Vehicles)'' after the newly added entry for ''2189''; and adding entries for ''2190'', ''2191'', ''2192'', ''2193'', and ''2194'' under the newly added heading.

The additions read as follows:

§ 52.220a Identification of plan-in part.

* * * * *

(c) * * *

TABLE 1—EPA-APPROVED STATUTES AND STATE REGULATIONS [1]

State citation	Title/subject	State effective date	EPA approval date	Additional explanation
*	*	*	*	*
Title 13 (Motor Vehicles), Division 3 (Air Resources Board), Chapter 3.5. (Heavy-Duty Diesel Smoke Emission Testing, and Heavy-Duty Vehicle Emission Control System Inspections)			
2180	Applicability	July 1, 2019	May 10, 2022, [INSERT **Federal Register** CITATION].	Unless otherwise noted, this chapter applies to all diesel-powered and gasoline-powered heavy-duty vehicles operating in California.
2180.1	Definitions	July 1, 2019	May 10, 2022, [INSERT **Federal Register** CITATION].	Definitions for applicable vehicles, opacity standards, inspections, penalties and appeals.

TABLE 1—EPA-APPROVED STATUTES AND STATE REGULATIONS [1]—Continued

State citation	Title/subject	State effective date	EPA approval date	Additional explanation
2181	Responsibilities of the Driver and Inspector During the Inspection Procedure.	July 1, 2019	May 10, 2022, [INSERT **Federal Register** CITATION].	Sets forth the responsibilities of the vehicle inspector and driver during an inspection.
2182	Heavy-Duty Diesel Vehicle Smoke Opacity Standards and Test Procedures; Excessive Smoke.	July 1, 2019	May 10, 2022, [INSERT **Federal Register** CITATION].	Sets forth opacity standards and testing procedures.
2183	Inspection of the Emission Control System on a Heavy-Duty Vehicle.	July 1, 2019	May 10, 2022, [INSERT **Federal Register** CITATION].	Describes the inspection procedures inspector use to determine whether the emission control components on diesel vehicles have been tampered, inadequately maintained or defective.
2184	Refusal to Submit to Inspection Procedure.	July 1, 2019	May 10, 2022, [INSERT **Federal Register** CITATION].	Describes the consequences of a refusal to submit to a vehicle inspection.
2185	Civil Penalty Schedule	July 1, 2019	May 10, 2022, [INSERT **Federal Register** CITATION].	Sets for the civil penalties for failing a vehicle inspection.
2186	Demonstration of Correction and Post-Repair Test or Inspection.	July 1, 2019	May 10, 2022, [INSERT **Federal Register** CITATION].	Sets for the requirements for a vehicle owner to demonstrate correction and post-inspection repair to pass an inspection.
2187	Vehicles Removed from Service.	July 1, 2019	May 10, 2022, [INSERT **Federal Register** CITATION].	Sets for the conditions upon which a vehicle failing inspection can be removed from, and return to, service.
2188	Contesting a Citation	July 1, 2019	May 10, 2022, [INSERT **Federal Register** CITATION].	Describes how a vehicle owner may contest a citation for failing and inspection.
2189	Severability of Provisions	July 1, 2019	May 10, 2022, [INSERT **Federal Register** CITATION].	Provides that in the event any portion of the chapter is held to be invalid, unenforceable or unconstitutional, the remaining portions shall remain in effect.
Title 13 (Motor Vehicles), Division 3 (Air Resources Board), Chapter 3.6. (Periodic Smoke Inspections of Heavy-Duty Diesel-Powered Vehicles)				
2190	Vehicles Subject to the Periodic Smoke Inspection Requirements.	July 1, 2019	May 10, 2022, [INSERT **Federal Register** CITATION].	Defines the heavy-duty diesel-powered vehicles operating in California that are subject to periodic smoke inspection, as well as listing those that are exempt.
2191	Definitions	July 1, 2019	May 10, 2022, [INSERT **Federal Register** CITATION].	Defines diesel vehicle fleets subject to the regulation and applicable testing procedures.
2192	Vehicle Inspection Responsibilities.	July 1, 2019	May 10, 2022, [INSERT **Federal Register** CITATION].	Sets forth the responsibilities of diesel vehicle fleet owners to comply with the requirements of the periodic smoke inspection program.
2193	Smoke Opacity Standards, Inspection Intervals, and Test Procedures.	July 1, 2019	May 10, 2022, [INSERT **Federal Register** CITATION].	Sets forth opacity testing standards, inspection intervals, test procedures and alternate test procedures.
2194	Record Keeping Requirements.	July 1, 2019	May 10, 2022, [INSERT **Federal Register** CITATION].	Requires vehicle owners to maintain records of test or alternate test results and provide them to the California Air Resources Board upon request.

* * * * * * *

[1] Table 1 lists EPA-approved California statutes and regulations incorporated by reference in the applicable SIP. Table 2 of paragraph (c) lists approved California test procedures, test methods and specifications that are cited in certain regulations listed in Table 1. Approved California statutes that are nonregulatory or quasi-regulatory are listed in paragraph (e).

* * * * *

[FR Doc. 2022–09727 Filed 5–9–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 220502–0109; RTID 0648–XB884]

Fisheries of the Northeastern United States; Atlantic Mackerel, Squid, and Butterfish Fisheries; Final 2022 Specifications

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS is finalizing specifications for fishing year 2022 for the chub mackerel, butterfish, longfin squid, and *Illex* squid fisheries. This action is necessary to reaffirm previously approved projected allowable harvest levels that will prevent overfishing and allow harvesting of optimum yield for all the species of the Mackerel, Squid, and Butterfish Fishery Management Plan. These specifications are intended to promote the sustainable utilization and conservation of the mackerel, squid, and butterfish resources.

DATES: Effective May 10, 2022.

FOR FURTHER INFORMATION CONTACT: Aly Pitts, Fishery Management Specialist, (978) 281–9352.

SUPPLEMENTARY INFORMATION: The regulations implementing the Mackerel, Squid, and Butterfish Fishery Management Plan (FMP) require the Mid-Atlantic Fishery Management Council's Mackerel, Squid, and Butterfish Monitoring Committee to develop specification recommendations for each species based upon the acceptable biological catch (ABC) advice of the Council's Scientific and Statistical Committee (SSC).

On July 22, 2021 (86 FR 38586), we published a final rule in the **Federal Register** setting new 2021 and projected specifications for fishing year 2022 butterfish and *Illex* squid, while maintaining the current longfin squid, Atlantic mackerel, and chub mackerel specifications for 2021 and projected for 2022–2023. The proposed rule for that action included additional background on specifications and the details of how the Council derived its recommended specifications for Atlantic mackerel, chub mackerel, *Illex* squid, longfin squid, and butterfish. Those details are not repeated here; for additional information, please refer to the proposed rule for that action. This action will reaffirm the 2022 specifications for chub mackerel, *Illex* squid, longfin squid, and butterfish (Table 1, 2, 3, 4, 5, and 6). The Atlantic mackerel specifications for 2022 were set by a separate action, effective on January 7, 2022 (87 FR 1700), and are not modified by this action.

TABLE 1—LONGFIN SQUID FINAL 2022 SPECIFICATIONS

Specification	Metric tons
Overfishing Limit (OFL)	Unknown.
Acceptable Biological Catch (ABC)	23,400.
Initial Optimum Yield (IOY)	22,932.
Domestic Annual Harvest (DAH), Domestic Annual Processing (DAP)	22,932.

TABLE 2—LONGFIN QUOTA TRIMESTER ALLOCATIONS FINAL 2022 SPECIFICATIONS

Trimester	Percent	Metric tons
I (Jan–Apr)	43	9,861
II (May–Aug)	17	3,898
III (Sep–Dec)	40	9,173

TABLE 3—BUTTERFISH FINAL 2022 SPECIFICATIONS

Specification	Metric tons
OFL	24, 341
ABC	17,854
Annual Catch Target (ACT)	16,961
Assumed discards	637
Total discards	5,466
Butterfish cap in longfin fishery	3,884
DAH	11,495

TABLE 4—2022 TRIMESTER ALLOCATION OF BUTTERFISH MORTALITY CAP ON THE LONGFIN SQUID FISHERY

Trimester	Percent	Metric tons
I (Jan–Apr)	43	1,670
II (May–Aug)	17	660
III (Sep–Dec)	40	1,554
Total	100	3,844

TABLE 5—ILLEX SQUID FINAL 2022 SPECIFICATIONS

Specification	Metric tons
OFL	Unknown.
ABC	33,000.
IOY	31,478.
DAH/DAP	31,478.

TABLE 6—ATLANTIC CHUB MACKEREL FINAL 2022 SPECIFICATIONS

Specification	Metric tons
ABC	2,300
ACL	2,262
ACT	2,171

TABLE 6—ATLANTIC CHUB MACKEREL FINAL 2022 SPECIFICATIONS—Continued

Specification	Metric tons
Total Allowable Landings	2,041

Classification

The NMFS Assistant Administrator has determined that this final rule is consistent with the Mackerel, Squid, and Butterfish Fishery Management Plan, the Magnuson-Stevens Fishery Conservation and Management Act, and other applicable law.

This rule is exempt from review under Executive Order 12866 because this action contains no implementing regulations.

Pursuant to 5 U.S.C. 553(b)(B), we find good cause to waive prior public notice and opportunity for public comment on the catch limit and allocation adjustments, because allowing time for notice and comment would be unnecessary and contrary to the public interest. The proposed rule for the 2021–2023 specifications provided the public with the opportunity to comment on the

specifications, including the projected 2022 through 2023 specifications (86 FR 28323, May 26, 2021). The 2022 specifications presented here were previously approved through the 2021–2023 specifications and this final rule is intended to officially reaffirm these specifications. Further, this final rule contains no changes from the projected 2022 specifications that were included in both the May 26, 2021, proposed rule and the July 22, 2021, final rule. The butterfish specifications were decreased by 72 percent in 2021 from 2020, but this rule increases the allowable catch by 53 percent. Implementing these specifications will reduce the likelihood of an unnecessary closure of the butterfish fishery and will avoid confusion. The public and industry participants expect this action. Through both the proposed rule and final rules for the 2021–2023 specifications, we alerted the public that we would conduct a review of the latest available data in each of the interim years of the multi-year specifications and may make changes if warranted. Thus, the proposed and final rules that contained the projected 2021–2023 specifications provided a full opportunity for the public to comment on the substance and process of this action. Based on these considerations, we further find, pursuant to 5 U.S.C. 553 (d)(3), good cause to waive the 30-day delayed effectiveness period for the reasons stated above.

The Chief Counsel for Regulation, Department of Commerce, previously certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that the 2022 chub mackerel, *Illex* squid, longfin quid, and butterfish specifications would not have a significant economic impact on a substantial number of small entities. Implementing the 2022 specifications will not change the conclusions drawn in that previous certification to the SBA. Because advance notice and the opportunity for public comment are not required for this action under the Administrative Procedure Act, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* do not apply to this rule. Therefore, no new regulatory flexibility analysis is required and none has been prepared.

This action does not contain a collection of information requirement for the purposes of the Paperwork Reduction Act.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 2, 2022.

Samuel D. Rauch, III

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2022–09686 Filed 5–9–22; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 87, No. 90
Tuesday, May 10, 2022

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0510; Project Identifier MCAI–2022–00158–R]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH (AHD) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Airbus Helicopters Deutschland GmbH (AHD) Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, and EC135T3 helicopters. This proposed AD was prompted by reports of the air conditioning system (ACS) malfunctioning. This proposed AD would require deactivating the ACS and prohibit installing the affected parts, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by June 24, 2022.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For EASA material that is proposed for IBR in this NPRM, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find the EASA material on the EASA website at *https://ad.easa.europa.eu.* For Airbus Helicopters service information identified in this NPRM, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *https://www.airbus.com/helicopters/services/technical-support.html.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. The EASA material is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0510.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0510; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the EASA AD, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Stephanie Sunderbruch, Aerospace Engineer, Safety Risk Management Section, Systems Policy Branch, Policy & Innovation Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–4659; email *Stephanie.L.Sunderbruch@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0510; Project Identifier MCAI–2022–00158–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Stephanie Sunderbruch, Aerospace Engineer, Safety Risk Management Section, Systems Policy Branch, Policy & Innovation Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–4659; email *Stephanie.L.Sunderbruch@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2022–0023, dated February 3, 2022 (EASA AD 2022–0023), to correct an unsafe condition for Airbus Helicopters Deutschland GmbH (AHD) (formerly Eurocopter Deutschland GmbH, Eurocopter España S.A.) Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2,

EC135T2+, EC135T3, EC635T2+, EC635P2+, EC635P3, EC635T1, and EC635T3 helicopters, all variants, serial numbers (S/N) from 0008 to 0869 inclusive, except S/N 0831 and S/N 0864.

This proposed AD was prompted by reports of the ACS malfunctioning; investigation into the malfunction has identified that certain ACS soft start units are the root cause. The FAA is proposing this AD to address malfunctioning ACSs. The unsafe condition, if not addressed, could result in an overvoltage of the ACS, resulting in overheating of the surrounding area, failure of the helicopter electrical system connected to the ACS, and a subsequent loss of electrical power which could result in increased pilot workload and reduced helicopter control. See EASA AD 2022–0023 for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0023 requires deactivating the ACS soft start unit part number (P/N) ES59185–2 on helicopters with a compressor/condenser pallet P/N 135–0553–1 or P/N 135–0566–2 installed. EASA AD 2022–0023 also prohibits installing soft start unit P/N ES59185–2 or a compressor/condenser pallet P/N 135–0553–1 or P/N 135–0566–2 on any helicopter.

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Related Service Information

The FAA reviewed Airbus Helicopters Alert Service Bulletin ASB EC135–21A–024, Revision 0, dated February 2, 2022. This service information specifies procedures for deactivating the soft part unit of the compressor/condenser pallet and specifies that compressor/condenser pallet P/N 135–0553–1 or 135–0566–2 with soft start unit P/N ES59185–2 installed must not be installed on any helicopter.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is proposing this AD after evaluating all known relevant information and determining that the unsafe condition described previously is likely to exist or develop on other helicopters of the same type designs.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2022–0023, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD and except as discussed under ''Differences Between this Proposed AD and the EASA AD.''

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2022–0023 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2022–0023 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2022–0023 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2022–0023. Service information referenced in EASA AD 2022–0023 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0510 after the FAA final rule is published.

Differences Between This Proposed AD and the EASA AD

EASA 2022–0023 applies to Model EC635P2+, EC635P3, EC635T1, EC635T2+, and EC635T3 helicopters, whereas this proposed AD would not because these models are not FAA type-certificated and are not included on the U.S. type certificate data sheet except where the U.S. type certificate data sheet explains that the Model EC635T2+ helicopter having serial number 0858 was converted from Model EC635T2+ to Model EC135T2+.

Interim Action

The FAA considers this proposed AD would be an interim action. The design approval holder is currently developing a modification that will address the unsafe condition identified in this AD. Once this modification is developed, approved, and available, the FAA might consider additional rulemaking.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 341 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this proposed AD.

Deactivating the ACS would take about 1 work-hour, for an estimated cost of $85 per helicopter and up to $28,985 for the U.S. fleet.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

Airbus Helicopters Deutschland GmbH (AHD): Docket No. FAA–2022–0510; Project Identifier MCAI–2022–00158–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by June 24, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Helicopters Deutschland GmbH (AHD) Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, and EC135T3 helicopters, serial numbers (S/N) from 0008 to 0869 inclusive, except S/N 0831 and S/N 0864, certificated in any category.

(d) Subject

Joint Aircraft Service Component (JASC) Code 2100, Air Conditioning System.

(e) Unsafe Condition

This AD was prompted by reports of the air conditioning system (ACS) malfunctioning. The FAA is issuing this AD to prevent possible overheating of the ACS. The unsafe condition, if not addressed, could result in an overvoltage of the ACS, resulting in overheating of the surrounding area, failure of the helicopter electrical system connected to the ACS, and a subsequent loss of electrical power which could result in increased pilot workload and reduced helicopter control.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0023, dated February 3, 2022 (EASA AD 2022–0023).

(h) Exceptions to EASA AD 2022–0023

(1) Where EASA AD 2022–0023 requires compliance in terms of flight hours, this AD requires using hours time-in-service.

(2) Where EASA AD 2022–0023 refers to its effective date, this AD requires using the effective date of this AD.

(3) This AD does not mandate compliance with the ''Remarks'' section of EASA AD 2022–0023.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2022–0023 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Related Information

(1) For EASA AD 2022–0023, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu*. You may find the EASA material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0510.

(2) For more information about this AD, contact Stephanie Sunderbruch, Aerospace Engineer, Safety Risk Management Section, Systems Policy Branch, Policy & Innovation Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–4659; email *Stephanie.L.Sunderbruch@faa.gov.*

Issued on April 30, 2022.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–09683 Filed 5–9–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0475; Airspace Docket No. 21–AEA–16]

RIN 2120–AA66

Proposed Establishment of Area Navigation (RNAV) Routes; Northeast United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish six low altitude United States Area Navigation (RNAV) routes (T-routes) in support of the VHF Omnidirectional Range (VOR) Minimum Operational Network (MON) Program. The purpose is to enhance the efficiency of the National Airspace System (NAS) by transitioning from a ground-based to a satellite-based navigation system.

DATES: Comments must be received on or before June 24, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: (800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2022–0475; Airspace Docket No. 21–AEA–16 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the

agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would expand the availability of RNAV in the northeast United States and improve the efficient flow of air traffic within the NAS by lessening the dependency on ground-based navigation.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2022–0475; Airspace Docket No. 21–AEA–16) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2022–0475; Airspace Docket No. 21–AEA–16.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.* You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA, 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to establish six low altitude RNAV T-routes, designated T–416, T–428, T–430, T–434, T–436, and T–438, in the northeast United States to support the VOR MON Program.

T–416: T–416 would extend between the Smyrna, DE, (ENO) VHF Omnidirectional Range/Tactical Air Navigational System (VORTAC), and the PREPI, OA, Fix (OA means ''Offshore Atlantic''). The route would overlie VOR Federal airway V–312 between the ALBEK, NJ, Fix, and the PREPI Fix. At PREPI, T–416 would connect with the oceanic route structure.

T–428: T–428 would extend between the Selinsgrove, PA, (SEG) VOR/Distance Measuring Equipment (VOR/DME), and the NECCK, NJ, Waypoint (WP). The route would overlie VOR Federal airway V–6 from Selinsgrove to the Solberg, NJ, (SBJ) VOR/DME. T–428 would also overlie VOR Federal airway V–232 from Solberg to the TYKES, NJ, Fix, then to the NECCK, NJ, WP, that will replace the Colts Neck, NJ, (COL) VOR/DME.

T–430: T–430 would extend between the Philipsburg, PA, VORTAC (PSB), and the Solberg, NJ, (SBJ) VOR/DME. The route would overlie VOR Federal airway V–30 between Philipsburg and Solberg.

T–434: T–434 would extend between the SCAAM, PA, WP, and the NECCK, NJ, WP. The SCAAM WP would replace the Keating, PA, (ETG) VORTAC. The HYATT, PA, WP would replace the Milton, PA, (MIP) VORTAC. The NECCK, NJ, WP, would replace the Colts Neck, NJ, (COL) VOR/DME. T–434 would overlie VOR Federal airway V–232 from the SCAAM WP to the NECCK WP.

T–436: T–436 would extend between the Robbinsville, NJ, (RBV) VORTAC, and the Martha's Vineyard, MA, (MVY) VOR/DME. It would overlie VOR Federal airway V–249 from Robbinsville to the Sparta, NJ, (SAX) VORTAC. T–436 would overlie VOR Federal airway V–623 from Sparta to the BIZEX, NY, WP. The BIZEX WP will replace the Carmel, NY, (CMK) VOR/DME. Additionally, T–436 would overlie VOR Federal airway V–188 from the BIZEX WP to the Groton, CT, (GON) VOR/DME; and, it would overlie VOR Federal airway V–374 from Groton to Martha's Vineyard.

T–438: T–438 would extend between the RASHE, PA, Fix and the PREPI, OA, Fix. It would overlie VOR Federal airway V–276 between RASHE and PREPI.

United States RNAV T-routes are published in paragraph 6011 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The RNAV routes listed in this document would be subsequently published in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 14 CFR 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–416 Smyrna, DE (ENO) to PREPI, OA [New]

Smyrna, DE (ENO)	VORTAC	(Lat. 39°13′53.93″ N, long. 075°30′57.49″ W)
TEBEE, NJ	Fix	(Lat. 39°30′13.97″ N, long. 075°19′37.19″ W)
LULOO, NJ	WP	(Lat. 39°36′35.96″ N, long. 075°12′57.43″ W)
RIDNG, NJ	WP	(Lat. 39°45′30.23″ N, long. 075°05′59.95″ W)
ALBEK, NJ	Fix	(Lat. 39°46′39.92″ N, long. 074°54′25.99″ W)
Coyle, NJ (CYN)	VORTAC	(Lat. 39°49′02.42″ N, long. 074°25′53.85″ W)
PREPI, OA	Fix	(Lat. 39°48′41.06″ N, long. 073°15′40.70″ W)

* * * * * * *

T–428 Selinsgrove, PA (SEG) to NECCK, NJ [New]

Selinsgrove, PA (SEG)	VOR/DME	(Lat. 40°47′27.09″ N, long. 076°53′02.55″ W)
EESTN, PA	WP	(Lat. 40°43′36.50″ N, long. 075°27′16.55″ W)
Solberg, NJ (SBJ)	VOR/DME	(Lat. 40°34′58.96″ N, long. 074°44′30.45″ W)
TYKES, NJ	Fix	(Lat. 40°17′22.38″ N, long. 074°23′06.13″ W)
NECCK, NJ	WP	(Lat. 40°18′41.79″ N, long. 074°09′35.79″ W)

* * * * * * *

T–430 Philipsburg, PA (PSB) to Solberg, NJ (SBJ) [New]

Philipsburg, PA (PSB)	VORTAC	(Lat. 40°54′58.53″ N, long. 077°59′33.78″ W)
Selinsgrove, PA (SEG)	VOR/DME	(Lat. 40°47′27.09″ N, long. 076°53′02.55″ W)
East Texas, PA (ETX)	VOR/DME	(Lat. 40°34′51.74″ N, long. 075°41′02.51″ W)
BOPLY, PA	Fix	(Lat. 40°32′47.79″ N, long. 075°11′07.06″ W)
Solberg, NJ (SBJ)	VOR/DME	(Lat. 40°34′58.96″ N, long. 074°44′30.45″ W)

* * * * * * *

T–434 SCAAM, PA to NECCK, NJ [New]

SCAAM, PA	WP	(Lat. 41°11′37.46″ N, long. 077°58′15.20″ W)
WATSO, PA	Fix	(Lat. 41°02′46.31″ N, long. 076°50′00.10″ W)
HYATT, PA	WP	(Lat. 41°01′24.47″ N, long. 076°39′54.34″ W)
LYTEL, PA	Fix	(Lat. 40°55′48.79″ N, long. 075°52′14.42″ W)
BEERS, PA	Fix	(Lat. 40°52′47.50″ N, long. 075°27′37.36″ W)
HOPPS, PA	Fix	(Lat. 40°51′10.41″ N, long. 075°23′39.31″ W)
Solberg, NJ (SBJ)	VOR/DME	(Lat. 40°34′58.96″ N, long. 074°44′30.45″ W)
TYKES, NJ	Fix	(Lat. 40°17′22.38″ N, long. 074°23′06.13″ W)
NECCK, NJ	WP	(Lat. 40°18′41.79″ N, long. 074°09′35.79″ W)

* * * * * * *

T–436 Robbinsville, NJ (RBV) to Martha's Vineyard, MA (MVY) [New]

Robbinsville, NJ (RBV)	VORTAC	(Lat. 40°12′08.65″ N, long. 074°29′42.09″ W)
JERYY, NJ	Fix	(Lat. 40°19′10.38″ N, long. 074°37′23.66″ W)
Solberg, NJ (SBJ)	VOR/DME	(Lat. 40°34′58.96″ N, long. 074°44′30.45″ W)
Sparta, NJ (SAX)	VORTAC	(Lat. 41°04′03.15″ N, long. 074°32′17.91″ W)
SEAVY, NJ	Fix	(Lat. 41°12′30.76″ N, long. 074°19′35.62″ W)
BIZEX, NY	WP	(Lat. 41°17′02.86″ N, long. 073°34′50.20″ W)
SEALL, CT	INT	(Lat. 41°23′33.74″ N, long. 072°50′50.56″ W)
Groton, CT (GON)	VOR/DME	(Lat. 41°19′49.45″ N, long. 072°03′07.14″ W)
Martha's Vineyard, MA (MVY)	VOR/DME	(Lat. 41°23′46.37″ N, long. 070°36′45.78″ W)

* * * * * * *

T–438 RASHE, PA to PREPI, OA [New]

RASHE, PA	Fix	(Lat. 40°40′36.04″ N, long. 077°38′38.94″ W)
Ravine, PA (RAV)	VORTAC	(Lat. 40°33′12.21″ N, long. 076°35′57.77″ W)
HIKES, PA	Fix	(Lat. 40°22′55.93″ N, long. 075°36′54.90″ W)
MAZIE, PA	Fix	(Lat. 40°19′19.55″ N, long. 075°06′35.28″ W)
Yardley, PA (ARD)	VOR/DME	(Lat. 40°15′12.03″ N, long. 074°54′27.41″ W)
Robbinsville, NJ (RBV)	VORTAC	(Lat. 40°12′08.65″ N, long. 074°29′42.09″ W)
PREPI, OA	Fix	(Lat. 39°48′41.06″ N, long. 073°15′40.70″ W)

* * * * *

Issued in Washington, DC, on May 3, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–09922 Filed 5–9–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0284]

RIN 1625–AA00

Safety Zone; Ohio River, Miles 90.3 to 91.8 Wheeling, WV

AGENCY: Coast Guard, Homeland Security (DHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary safety zone for all navigable waters of the Ohio River from Mile 90.3 to Mile 91.8 from 6 p.m. to 8 p.m. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a floating lantern festival. Entry of vessels or persons into this zone is prohibited unless specifically authorized by Captain of the Port Marine Safety Unit Pittsburgh. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before June 9, 2022.

ADDRESSES: You may submit comments identified by docket number USCG–2022–0284 using the Federal Decision Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rulemaking, call or email MSTC Kevin Schneider, Marine Safety Unit Pittsburgh, U.S. Coast Guard, at telephone 412–221–0807, email *Kevin.L.Schneider@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On March 30, 2022, the Alzheimer's Association West Viginia Chapter notified the Coast Guard that it will be releasing biodegradable water lanterns onto the Ohio Rivert at Heritage Port 1 Water Street Wheeling, WV, 26003 from 6 p.m. to 8 p.m. on August 22, 2022. Participants can purchase the water lanterns in honor of someone they know who is currently battling Alzheimer's or some form of dementia, write the person's name, a message, or whatever they'd like on the lantern, and place the lantern on the river in that person's honor.

The purpose of this rulemaking is to ensure the protection of personnel, vessels, and the marine environment in the navigable waters within the safety zone while the floating. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231).

III. Discussion of Proposed Rule

The Captain of the Port Marine Safety Unit Pittsburgh (COTP) is proposing to establish a safety zone from 6 p.m. to 8 p.m. on August 22, 2022. The safety zone would cover all navigable waters on the Ohio River from Mile 90.3 to Mile 91.8. The duration of the safety zone is intended to protect personnel, vessels, and the marine environment from potential hazards created by a floating lantern festival.

No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on size, location, and duration of the temporary safety zone. This safety zone impacts only a one-and-a-half-mile stretch of the Ohio River for a short amount of time of two hours on one evening. Vessel traffic will be informed about the safety zone through local notices to mariners. Moreover, the Coast Guard will issue Local Notice to Mariners, Marine Safety Information Bulletins, and Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone and the rule allows vessels to seek permission from the COTP to transit the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the temporary safety zone may be small entities, for the reasons stated in section IV.A above, this rule will not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132 (Federalism), if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the potential effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves This rulemaking involves a safety zone lasting two hours that will prohibit entry on the Ohio River from mile 90.3 to mile 91.8, during the floating lantern festival. Normally such actions are categorically excluded from further review under paragraph L60 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2022–0284 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T08–0284 to read as follows:

§ 165.T08–0284 Safety Zone; Ohio River, Miles 90.3–91.8, Wheeling, WV.

(a) *Location.* The following area is a temporary safety zone: All navigable waters of the Ohio River from Mile 90.3 to Mile 91.8.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Pittsburgh (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry of persons and vessels into the zone in paragraph (a) of this section is prohibited unless authorized by the COTP or a designated representative.

(2) Persons or vessels requiring entry into or passage through the zone must request permission from the COTP or a designated representative. The COTP's representative may be contacted at 412–670–4288.

(d) *Enforcement period.* This section is effective from 6 p.m. through 8 p.m. on August 22, 2022.

Dated: May 5, 2022.

Eric J. Velez,

Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Pittsburgh.

[FR Doc. 2022–10024 Filed 5–9–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[Docket No. CDC–2022–0052; NIOSH–347]

RIN 0920–AA82

World Trade Center (WTC) Health Program; Addition of Uterine Cancer to the List of WTC-Related Health Conditions

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 amended the Public Health Service Act (PHS Act) to establish the World Trade Center (WTC) Health Program. The WTC Health Program (Program), which is administered by the Director of the National Institute for Occupational Safety and Health (NIOSH), within CDC, provides medical monitoring and treatment to eligible responders to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania, and to eligible survivors of the New York City attacks. In accordance with the WTC Health Program's regulations, which establish procedures for adding a new condition to the list of health conditions covered by the Program, this proposed rule would add malignant neoplasms of corpus uteri and uterus, part unspecified (uterine cancer) to the List of WTC-Related Health Conditions (List).

DATES: Comments must be received by June 24, 2022.

ADDRESSES: You may submit comments identified by Docket No. CDC–2022–0052 and NIOSH–347 by either of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS C–34, 1090 Tusculum Avenue, Cincinnati, Ohio 45226–1998.

Instructions: All written submissions received in response to this document must include the agency name and docket number (CDC–2022–0052; NIOSH–347) for this action. All relevant comments, including any personal information provided, will be posted without change to *https://www.regulations.gov.* Do not submit comments by email. CDC does not accept comments by email.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst, National Institute for Occupational Safety and Health, 1090 Tusculum Avenue, MS: C–46, Cincinnati, OH 45226; telephone (855) 818–1629 (this is a toll-free number); email *NIOSHregs@cdc.gov.*

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- B. Methods Used by the Administrator To Determine Whether To Add Cancers to the List of WTC-Related Health Conditions
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- D. Review of Evidence Supporting the Proposed Addition of Uterine Cancer to the List of WTC-Related Health Conditions
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I. Executive Summary

A. Purpose of Regulatory Action

With this rulemaking, the Administrator of the WTC Health Program (Administrator) and the Secretary of HHS propose the addition of uterine cancer [1] to the List. The Administrator received requests from WTC responders and survivors as well as a September 2020 letter from five of the WTC Health Program Clinical Centers of Excellence (CCEs) asking the Administrator to add ''uterine cancer'' to the List. The Administrator subsequently directed the WTC Health Program's Science Team to review the available scientific evidence for adding uterine cancer to the List under existing Program policy and procedures. A white paper issued by the Program's Science Team in September 2021 (White Paper) found that the available scientific evidence provided sufficient support to add uterine cancer to the List but only for Program members who have a certified WTC-related estrogen-secreting tumor. The Administrator asked the WTC Health Program Scientific/Technical Advisory Committee (STAC) for a recommendation on whether a reasonable basis exists for adding uterine cancer to the List. Between September and November 2021, the STAC reviewed the White Paper and other available scientific information, considered public comment, and deliberated on whether there is a reasonable basis to recommend the addition of uterine cancer to the List. Ultimately, the STAC recommended that uterine cancer be added to the List and provided the Administrator its recommendation and rationale. Upon review, the Administrator decided that the STAC provided a reasonable basis for its recommendation to add uterine cancer to the List. Based on the STAC's recommendation and the scientific literature, including the White Paper, the Administrator has determined that the available information provides a sufficient evidentiary basis to propose the addition of uterine cancer to the List.

B. Summary of Major Provisions

This rule proposes the addition of malignant neoplasms of corpus uteri and uterus, part unspecified (uterine cancer) to the List of WTC-Related Health Conditions in 42 CFR 88.15(d).

C. Costs and Benefits

The addition of uterine cancer to the List through this rulemaking is estimated to cost the WTC Health Program from $1,718,691 to $2,199,808 annually, between 2022 and 2025. All of the costs to the WTC Health Program are transfers.[2] Benefits to current and future

[1] For the purposes of this action, the WTC Health Program defines the term ''uterine cancer'' as ICD–10 code C54, including the following specific malignant neoplasms: Isthmus uteri (C54.0), endometrium (C54.1), myometrium (C54.2), fundus uteri (C54.3), overlapping sites of corpus uteri (C54.8), and corpus uteri, unspecified (C54.9); and ICD–10 code C55, including only a single sub-category, malignant neoplasm of uterus, part unspecified.

[2] Due to the implementation of the Affordable Care Act in 2014, and as required under the authorizing statute for the WTC Health Program, all current and future Program members are assumed to have or have access to medical insurance

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WTC Health Program members are expected to include improved access to care and better treatment outcomes than members would have in the absence of Program coverage.

II. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, opinions, recommendations, and data. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Comments are invited on any topic related to this proposed rule. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Comments submitted electronically or by mail should be titled ''Docket No. CDC–2022–0052; NIOSH–347'' and should identify the author(s) and contact information in case clarification is needed. Written comments can be submitted to the address provided in the **ADDRESSES** section, above. All communications received on or before the closing date for comments will be fully considered by the Administrator.

Upon publication of this notice of proposed rulemaking, the Administrator has requested an independent peer review from three subject-matter experts of the scientific and technical evidence that comprises the basis of this action.[3] The peer reviews will be posted, without attribution, in the rulemaking docket 30 days after the publication of this proposed rulemaking.

To provide interested parties adequate time to review the proposed rule, supporting scientific literature, and peer reviews, and to submit written comments to the docket, the Administrator has determined that good cause exists to extend the 30-day comment period required by the Program's authorizing statute[4] to 45 days.

III. Background

In this action, the Administrator and the Secretary of HHS propose to amend 42 CFR 88.15 to add malignant neoplasms of corpus uteri and uterus, part unspecified (uterine cancer)[5] to the List.

A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347, as amended by Pub. L. 114–113 and Pub. L. 116–59), added Title XXXIII to the PHS Act[6] establishing the WTC Health Program within HHS. The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator in this document mean the Director of NIOSH, within CDC, or his or her designee. Section 3312(a)(6) of the PHS Act requires the Administrator to conduct rulemaking to propose the addition of a health condition to the List codified in 42 CFR 88.15.

B. Methods Used by the Administrator To Determine Whether To Add Cancers to the List of WTC-Related Health Conditions

In accordance with the Program's authorizing statute as well as regulations in 42 CFR part 88, the Administrator may decide to propose the addition of a health condition to the List in response to a petition from an interested party[7] or at his or her own discretion.[8] Under 42 CFR 88.16, the Administrator has established a process by which health conditions may be considered for addition to the List in § 88.15. Pursuant to sec. 3312(a)(6)(D) of the PHS Act, whenever the Administrator determines that a condition should be proposed for addition to the List, the Administrator is required to publish a notice of proposed rulemaking and allow interested parties to comment on the proposed rule.

The Program also developed the *Policy and Procedures for Adding Types of Cancer to the List of WTC-Related Health Conditions* (*Policy and Procedures*) to describe the evaluation of evidence of a causal association between 9/11 exposures and a type of cancer. Pursuant to these procedures, a type of cancer may be proposed for addition to the List if the available evidence meets at least one of the following four methods:[9]

Method 1. Epidemiologic Studies of September 11, 2001-Exposed Populations.

The peer-reviewed, published epidemiologic studies of 9/11-exposed populations are assessed by applying the following criteria extrapolated from the Bradford Hill criteria,[10] as appropriate:

a. Strength of the association between a 9/11 exposure and a type of cancer (including the precision of the risk estimate);[11]

b. Consistency of the findings across multiple studies. If only a single published epidemiologic study is available for assessment, the consistency of findings cannot be evaluated, and more emphasis will be placed on evaluating the strength of the association and the precision of the risk estimate;

c. Biological gradient, or dose-response relationships between 9/11 exposures and the type of cancer; and

d. Plausibility and coherence with known facts about the biology of the type of cancer.

Method 2. Established Causal Associations.

A type of cancer may be added to the List if there is well-established scientific support published in multiple peer-reviewed epidemiologic studies for a causal association between a condition already on the List and that cancer.

Method 3. Review of Evaluations of Carcinogenicity in Humans.

A type of cancer may be added to the List under Method 3 only if both of the following criteria are satisfied:

3A. *Published Exposure Assessment Information.* A 9/11 agent[12] included in

coverage other than through the WTC Health Program; therefore, all projected treatment costs to be paid by the WTC Health Program are considered transfers.

[3] *See* Public Health Service Act, sec. 3312(a)(6)(F).

[4] *See* Public Health Service Act, sec. 3312(a)(6)(D)(ii).

[5] *See supra* note 1.

[6] Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm–61. Those portions of the Zadroga Act found in Titles II and III of Public Law 111–347 do not pertain to the WTC Health Program and are codified elsewhere.

[7] PHS Act, sec. 3312(a)(6)(B); 42 CFR 88.16(a).

[8] PHS Act, sec. 3312(a)(6)(A); 42 CFR 88.16(b).

[9] John Howard, Administrator of the WTC Health Program, *Policy and Procedures for Adding Types of Cancer Conditions to the List of WTC-Related Health Conditions,* revised Nov. 18, 2021, *https://www.cdc.gov/wtc/pdfs/policies/WTCHP_PP_Addn_Cancer_11182021-508.pdf.*

[10] *See* Hill AB [1965], *The Environment and Disease: Association or Causation?* Proc R Soc Med 58:295–300.

[11] Precision of the risk estimate describes the uncertainty inherent in estimating the strength of association (the effect size) between exposure and health effect from observational data. It is often expressed as a confidence interval illustrating a range of values that contains the true effect size. A narrow confidence interval indicates a more precise measure of the effect size and a wider interval indicates greater uncertainty.

[12] Chemical, physical, biological, or other hazards reported in a published, peer-reviewed exposure assessment study of responders, recovery workers, or survivors who were present in the New York City disaster area, or at the Pentagon site, or the

the Inventory of 9/11 Agents [13] is identified; and

3B. *Evaluation of Carcinogenicity in Humans from Scientific Studies.* NTP [the National Toxicology Program] has determined that the 9/11 agent is *known to be a human carcinogen* or is *reasonably anticipated to be a human carcinogen,* and the IARC [the World Health Organization's International Agency for Research on Cancer] has determined that there is *sufficient* or *limited* evidence in humans that the 9/11 agent causes the type of cancer.

Method 4. Review of Information by the WTC Health Program Scientific/Technical Advisory Committee (STAC).

A type of cancer may be added to the List if the STAC recommends the addition and provides a reasonable basis for the recommendation.[14] To assist the Administrator in understanding whether the STAC's recommendation has a reasonable basis, the STAC must describe in detail the basis for its recommendation and, if applicable, any evidentiary sources it has used to support its recommendation.

C. History and Scope of Rulemaking

In September 2012, the Administrator published a final rule adding most types of cancer to the List,[15] codified at 42 CFR 88.15(d). The 2012 rulemaking added malignant neoplasm of the ovary (ovarian cancer) to the List pursuant to Method 3, described above; rare cancers were also added to the List pursuant to Method 4. In a follow-up rulemaking conducted in February 2014,[16] the Program clarified the definition of ''rare cancers'' to include any type of cancer that occurs in less than 15 cases per 100,000 persons.[17] As a result of this rulemaking other—but not all—types of malignant neoplasms of female genital organs,[18] including cervix uteri (invasive cervical cancer) and uterine sarcomas, were found to meet the revised definition of rare cancers.[19] Uterine cancer [20] was not added to the List because the scientific evidence available at the time of the 2012 and 2014 rulemakings did not provide sufficient support for its inclusion; nor did it meet the definition of rare cancer.

Since 2012, the WTC Health Program has received eight submissions requesting the addition of endometrial or uterine cancer to the List. Only one of these submissions, Petition 023, received in 2019 and requesting the addition of ''endometrial cancer,'' [21] was determined to be a valid petition.[22] In response, the Program conducted a literature search and identified and evaluated seven published, peer-reviewed, epidemiologic studies about uterine cancer, including endometrial cancer, in the 9/11-exposed population. Ultimately, in 2019, the Administrator determined that the evidence was insufficient to support adding uterine cancer, including endometrial cancer, to the List.[23]

On September 11, 2020, the Administrator received a submission from five of the Program's CCEs, requesting the addition of uterine cancer to the List. Although the Program determined that the submission was not a valid petition, the Administrator thought that it raised important questions about the potential association between endocrine disrupting chemicals (EDCs) and hormone-related tumors such as endometrial cancer. The CCEs noted that the WTC Health Program's scientific literature evaluation conducted for Petition 023 did not include consideration of the relationship between EDCs and uterine cancer, despite some EDCs being included in the *Inventory of 9/11 Agents.*[24] The CCEs argued that research that has emerged since 2012 suggests EDCs may have a role in the development of estrogen-related diseases such as endometrial cancer. Moreover, the CCEs noted the low numbers of female [25] WTC responders in the occupational studies of the health effects of 9/11 exposure and expressed concern that this may lead to gaps in the research.

The Administrator determined that a more thorough evaluation of the scientific information regarding uterine cancer available since 2012 was needed and asked the WTC Health Program Science Team (Science Team) to conduct a review of the available scientific evidence to determine whether it might now support adding uterine cancer to the List. The Science Team conducted a literature review and issued a White Paper (discussed below) documenting its findings in September 2021. The White Paper describes the

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Shanksville, Pennsylvania site, as those locations are defined in 42 CFR 88.1, as well as those hazards not identified in a published, peer-reviewed exposure assessment study, but which are reasonably assumed to have been present at any of the three sites. WTC Health Program, *Development of the Inventory of 9/11 Agents,* published Jul. 17, 2018, *https://wwwn.cdc.gov/ResearchGateway/Content/pdfs/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf.*

[13] The *Inventory of 9/11 Agents* is composed of those agents identified in Tables 1–4 of the document, *Development of the Inventory of 9/11 Agents. Id.*

[14] The STAC may base its recommendation and reasonable basis on criteria other than those outlined in Methods 1–3.

[15] WTC Health Program final rule, *Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions,* 77 FR 56138 (Sept. 12, 2012).

[16] WTC Health Program interim final rule, *Amendments to List of WTC-Related Health Condition; Cancer; Revision,* 79 FR 9100 (Feb. 18, 2014).

[17] A cancer is considered to be on the List if it meets the definition of rare cancers in 42 CFR 88.15(d)(24), which is any type of cancer * that occurs in less than 15 cases per 100,000 persons per year in the United States.

* Based on 2005–2009 average annual data age-adjusted to the 2000 U.S. population. *See* Glenn Copeland, Andrew Lake, Rick Firth, *et al.* (eds), *Cancer in North America: 2005–2009. Volume One: Combined Cancer Incidence for the United States, Canada and North America,* Springfield, IL: North American Association of Central Cancer Registries, Inc., June 2012.

See also the Administrator's *Policy and Procedures for Rare Cancers, https://www.cdc.gov/wtc/pdfs/policies/WTCHP_PP_RareCancers05052014-508.pdf.*

[18] Although the List does not identify health condition medical diagnostic codes, the Program uses ICD–10 codes internally to track certified conditions. Malignant neoplasms of female genital organs comprise ICD–10 codes C51–C58 and include malignant neoplasms of the female genital organs: Vulva (C51), vagina (C52), cervix uteri (C53), corpus uteri (C54), uterus, part unspecified (C55), ovary (C56), other and unspecified female genital organs (C57), and placenta (C58). Uterine sarcomas are included in ICD–10 C55. ICD–10 codes C54 and C55 are not currently considered WTC-related health conditions. World Health Organization (WHO) [1997], *International Classification of Diseases, Tenth Edition.*

[19] *See supra* note 17.

[20] *See supra* note 1.

[21] The endometrium is the layer of tissue that lines the uterus. National Cancer Institute, *Dictionary of Cancer Terms, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/endometrium. Endometrial cancer accounts for nearly 90 percent of uterine cancer cases. See also* American Society of Clinical Oncology [2021], *Uterine Cancer: Statistics, https://www.cancer.net/cancer-types/uterine-cancer/statistics.*

[22] Interested parties may petition the Administrator to add health conditions to the List. To be considered a valid petition, a submission must meet the criteria established in 42 CFR 88.16(a)(1) and further described in the *Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions, https://www.cdc.gov/wtc/pdfs/policies/WTCHPPPPetitionHandlingProcedures14May2014-508.pdf.*

[23] WTC Health Program **Federal Register** document, *Petition 023-Uterine Cancer, Including Endometrial Cancer; Finding of Insufficient Evidence,* 84 FR 49954 (Sept. 24, 2019).

[24] *Inventory of 9/11 Agents* means those 9/11 agents identified as being present at a 9/11 site and included in Tables 1–4 of the WTC Health Program publication, *Development of the Inventory of 9/11 Agents,* Jul. 17, 2018, *https://wwwn.cdc.gov/ResearchGateway/Content/pdfs/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf.* EDCs in the *Inventory of 9/11 Agents* include persistent organic pollutants and other industrial substances such as cadmium, dioxins, perfluoroalkyl and poly fluoroalkyl substances (PFAS), phthalates, polybrominated diphenyl ethers (PBDE), and polychlorinated biphenyls (PCB). None of these 9/11 agents have been found by NTP or IARC to be known to cause or reasonably anticipated to cause uterine cancer.

[25] Although this rulemaking refers to uterine cancer in females, the WTC Health Program recognizes that some individuals who identify as male may also be at risk for uterine cancer.

Science Team's conclusion that insufficient evidence exists to support a decision to add uterine cancer to the List under Methods 1 or 3 of the *Policy and Procedures* described above; evidence considered under Method 2 supports adding uterine cancer to the List, but only for those Program members who have a certified WTC-related estrogen-secreting tumor.

Pursuant to Method 4 of the *Policy and Procedures,* the Administrator exercised his discretion to request a recommendation from the STAC [26] regarding whether the available evidence provides a reasonable basis exists for adding uterine cancer to the List. The Administrator convened the STAC on September 28–29, 2021, and gave the Committee the following charge:

> As you are aware, the WTC Health Program currently covers all major types of cancer, except for uterine cancer. I welcome the Committee's evaluation and recommendation on whether there is a reasonable scientific basis to support adding uterine cancer to the List of WTC-Related Health Conditions.[27]

At the September 2021 meeting, the Science Team presented the White Paper describing the available scientific evidence for an association between uterine cancer and 9/11 exposures. The STAC heard public comment and deliberated on the evidence presented in the White Paper. The Committee ultimately decided to create a workgroup to ''write a report describing the committee's conclusion, scientific rationale, and supporting evidence for adding uterine cancer as a WTC-related health condition.'' [28] At a follow-up meeting on November 18, 2021, the workgroup presented their draft report to the Committee. Following deliberation, the 12 STAC members present [29] voted unanimously to approve the report and recommend that the Administrator add uterine cancer to the List. Both the White Paper and the STAC recommendation are discussed below.

D. Review of Evidence Supporting the Proposed Addition of Uterine Cancer to the List

1. WTC Health Program Science Team Review

As discussed above, the Administrator asked the Science Team to assess the scientific evidence currently available to determine whether a basis exists under the *Policy and Procedures* for proposing the addition of uterine cancer to the List. The Science Team reported its findings in the White Paper entitled, *Scientific Considerations for Potential Addition of Uterine Cancer to the List of Covered Conditions by the World Trade Center Health Program (Revised): Preliminary Assessment for the World Trade Center Health Program Scientific/Technical Advisory Committee.*[30] The White Paper describes the scope of the Science Team's query as well as the literature search and inclusion criteria, and summarizes the studies identified that describe the available evidence on causal relationships between 9/11 exposures and uterine cancer.

Pursuant to Method 1, the Science Team conducted a literature search in April 2021. As described in the White Paper, the Science Team identified and summarized nine studies: Six which were previously evaluated in the Petition 023 **Federal Register** document,[31] one that recapitulated the results of two of those previously evaluated studies, and two additional studies published since the Petition 023 literature search and evaluation were conducted. Ultimately, five studies were found to be relevant for further evaluation, including some of the earlier studies which have been recently updated by their authors.[32] With regard to Method 1, the Science Team concluded:

> Five relevant peer-reviewed, published, epidemiologic studies were identified and reviewed. The studies do not provide consistent evidence of elevated uterine cancer incidence or mortality among WTC responders and survivors. The studies also do not report a dose-response relationship between 9/11 exposures and uterine cancer and the study designs may be susceptible to selection bias. As a result, collectively, these studies do not demonstrate a potential to provide a basis for a decision on whether to add uterine cancer to the List.[33]

Pursuant to Method 2, the Science Team explored whether a causal association exists between uterine cancer and a health condition already on the List. The Science Team found that uterine cancer may be medically associated with estrogen-secreting tumors, which are considered rare cancers in the Program. Studies reviewed by the Science Team demonstrate support for a causal association between granulosa cell tumors of the ovary (the most common type of estrogen-secreting tumor) and uterine cancer.[34] With regard to Method 2, the Science Team concluded:

> A thorough review of the scientific literature found that estrogen-secreting tumors are associated with endometrial cancer, but that these estrogen-secreting tumors are rare. Because estrogen-secreting tumors fall under the category of ''rare cancers'' in the List, uterine cancer [may be considered a medically associated condition and thus] . . . added to the List only for members who have a certified estrogen-secreting tumor.[35]

Pursuant to Method 3, the Science Team considered the evaluations of carcinogenicity published by NTP and IARC of those EDCs that are 9/11 agents identified in the *Inventory of 9/11 Agents.* With regard to Method 3, the Science Team concluded:

> Four EDCs listed in the Inventory of 9/11 Agents are considered carcinogenic to humans by NTP or IARC: (1) 2,3,7,8-tetrachlorodibenzodioxin (TCDD); (2) 2,3,4,7,8-pentachlorodibenzofuran; (3) polychlorinated biphenyls (PCB); and (4) cadmium. None of these agents is considered to have sufficient or even limited evidence of uterine carcinogenicity [based on IARC's *Monographs*]. Further review of epidemiologic studies published after . . . [IARC's *Monographs*] did not identify additional evidence of carcinogenicity to the uterus.[36]

In addition, since Method 4 allows a cancer to be proposed for addition to the List if the STAC provides a reasonable basis, the Science Team presented

[26] *See* PHS Act, sec. 3312(a)(6)(A).

[27] *Administrator's Charge to the World Trade Center Health Program Scientific/Technical Advisory Committee, https://www.cdc.gov/wtc/pdfs/stac/STAC_AdmCharge_Revised20210928-P.pdf.*

[28] World Trade Center Health Program Scientific/Technical Advisory Committee, *Executive Summary of Meeting, September 28–29, 2021, https://www.cdc.gov/wtc/pdfs/stac/WTCHP_STACmeetingMinutes_20210928-29.pdf.*

[29] Per STAC bylaws, a quorum consists of a majority of the committee's membership. Based on the membership at the time of the meeting, the required number of members for a quorum was nine. Four members were unable to attend the November 18, 2021, meeting, however 12 members were in attendance and quorum was maintained throughout the meeting.

[30] WTC Health Program [2021], *Scientific Considerations for Potential Addition of Uterine Cancer to the List of Covered Conditions by the World Trade Center Health Program (Revised): Preliminary Assessment for the World Trade Center Health Program Scientific/Technical Advisory Committee.* The Science Team's White Paper is available in the docket for this rulemaking and on the WTC Health Program website, at *https://www.cdc.gov/wtc/pdfs/stac/ScientificConsiderationsUterineCancer_STAC_20210928.pdf.*

[31] A seventh study was evaluated in the Petition 023 review but was not considered in the Science Team's evaluation for reasons described in the White Paper, *id.* at 8.

[32] *See* full discussion of the Science Team's literature review and findings regarding Method 1 in the White Paper, *id.* at 8–17.

[33] *Id.* at 6–7.

[34] *See* full discussion of the Science Team's review of the scientific literature and findings regarding Method 2 in the White Paper, *supra* note 30, at 17–18.

[35] *Id.* at 7.

[36] *Id.* at 7.

supplementary evidence that was reviewed but found not to be applicable to Methods 1, 2, or 3 for the STAC's consideration. First, the Science Team described the commonalities between the mechanisms of development for uterine cancer and other types of cancer, including ''estrogen, an abnormal mismatch repair (MMR) system, genetic abnormalities, and aberrant methylation of DNA and microRNA.'' [37] Next, the Science Team presented evidence from studies in non-9/11-exposed populations that demonstrate associations between uterine cancer and the 9/11 agents TCDD, PCBs, cadmium, and asbestos (known EDCs). Additionally, the Science Team noted that most studies of EDC exposure are conducted among occupational cohorts, including few or no women. Finally, the Science Team presented evidence that some EDCs in the *Inventory of 9/11 Agents,* including 2,3,7,8-tetrachlorodibenzodioxin and PCBs, are considered by NTP and IARC to be known or probable human carcinogens associated with types of cancer other than uterine cancer (*e.g.,* melanoma, breast cancer, lymphoma, and leukemia), supporting the inference that some EDC 9/11 agents may also be linked to uterine cancer.

2. WTC Health Program Scientific/Technical Advisory Committee Review

After being presented with the White Paper at the September 28–29, 2021, STAC meeting, the Committee created a workgroup to ''write a report describing the committee's conclusion, scientific rationale, and supporting evidence for adding uterine cancer as a WTC-related health condition.'' [38] Following the deliberation of the full committee at the November 18, 2021, meeting, the STAC voted to recommend that uterine cancer be added to the List. The Chair of the STAC sent a letter with the Committee's formal recommendation and rationale to the Administrator, which he received on November 29, 2021.[39]

The STAC recommendation is grounded in evidence and principles first developed by the STAC in its 2012 recommendation to the Administrator concerning the addition of cancers to the List.[40] The 2021 STAC recommendation quotes the 2012 STAC recommendation, which described those principles as including an understanding that ''exposures resulting from the collapse of the World Trade Center were unlike any other exposures in intensity and variety in history. . . . Compounding the uniqueness of the exposures is the absence of any data on air contaminant levels or the composition of the dust and fumes in the first four days after the attack, and the presence of multiple and complex exposures.'' [41] Further, the STAC found in 2012 that ''both responder populations and area residents and workers had potential for significant exposures to toxic and carcinogenic components of WTC dust and smoke.'' [42]

The STAC also revisited the arguments presented in the 2012 STAC recommendation for the addition of all cancer types, adding that:

> . . . we believe that the arguments for adding all cancers can apply to the question of whether to include all types of uterine cancer. Other than uterine cancer, all cancer types now are covered as WTC-related conditions. Mechanisms for carcinogenesis resulting from endogenous and exogenous exposures are similar for most cancer types. It is therefore highly implausible that uterine cancer would be the *only* cancer not related to WTC exposures.[43]

In fact, in reviewing the literature, the STAC found that uterine cancer ''shares many of the same genetic mechanisms with cancers already included in [the] List of WTC-Related Health Conditions.'' [44] Because exposure to endogenous and exogenous estrogen is strongly associated with both endometrial [45] and breast cancer, the STAC found exposure to EDCs in WTC dust to be ''particularly relevant.'' Noting that the 2012 STAC recommendation did not review evidence supporting an association between EDCs and cancer types, the November 2021 recommendation summarized the STAC's understanding of exposures to EDCs and their possible association with uterine cancer.[46]

The STAC acknowledged that ''[s]tudying the potential health effects of exposure to EDCs is inherently challenging and much remains unknown despite decade[s] of research,'' and quoted a recent review which described EDCs' multiple mechanisms of action, acting ''simultaneously at the level of the receptor, hormone synthesis, and hormone degradation.'' [47]

The STAC noted that the *Inventory of 9/11 Agents* includes certain 9/11 agents which are recognized as EDCs. Specifically, the STAC noted that elevated levels of polychlorinated dibenzo-para-dioxins and polychlorinated dibenzofurans (PCDD/F) were found on window surfaces from locations in lower Manhattan and Brooklyn six weeks after September 11, 2001. Other EDCs were found in WTC dust and smoke samples and in runoff samples from Rector Street on September 14 and 20, 2001. Two biomonitoring studies demonstrated significantly elevated levels of EDCs in 9/11-exposed cohorts: A study of perfluorochemicals in plasma from WTC responders working near Ground Zero between September 11 and December 23, 2001 found levels of perfluorooctanoic acid (PFOA) and perfluorohexanesulfonate (PFHxS) twice as high as in the U.S. general population; and a study comparing 9/11-exposed adolescents to non-9/11-exposed adolescents found that PCDD/F levels were statistically significantly higher among the 9/11-exposed cohort.[48] The STAC found that PBDEs, high levels of which were found in WTC dust, in particular have been shown to ''interfere with estrogen- . . . mediated processes'' and that ''some toxicologic studies provide indirect evidence'' for an association between PBDE exposures and uterine cancer.[49]

The STAC found that EDC exposure-related imbalances in sex steroid hormones are a ''plausible mechanism'' for the development of uterine cancer among WTC responders and survivors. Hormone-related cancers thought to be caused by EDC exposure include thyroid cancer, breast cancer, testicular and prostate cancers, and all female reproductive organ cancers, all of which are included on the List with the exception of uterine cancer.

[37] *Id.* at 27.

[38] WTC Health Program STAC, Executive Summary of Meeting, September 28–29, 2021, *https://www.cdc.gov/wtc/stac_meeting.html,* at 2.

[39] Letter from Dr. Elizabeth Ward, Chair of the STAC, to the Administrator, regarding the STAC's resolution on the addition of uterine cancer to the List of WTCHP Covered Conditions, received November 29, 2021. The letter from Dr. Ward, including the STAC's recommendation is available in the docket for this rulemaking and on the WTC Health Program website, at *https://www.cdc.gov/wtc/pdfs/stac/STAC.Recommendation.Received.29.November.2021.pdf.*

[40] Letter from Dr. Elizabeth Ward, Chair of the STAC, to the Administrator, regarding the STAC's resolution on the addition of cancer to the List of WTC-Related Health Conditions, received Apr. 2, 2012, *https://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-248/0248-040212-Letter.pdf.*

[41] *Supra* note 39, at 6.

[42] *Id.* at 7.

[43] *Id.* at 2.

[44] *Id.*

[45] In footnote 1 of its recommendation, the STAC clarifies that ''endometrial'' and ''uterine'' cancer are used synonymously and that most of the literature reviewed by the STAC relates specifically to endometrial cancer. The STAC recommendations pertain to all types of uterine cancer, including endometrial cancer.

[46] *See supra* note 39, at Attachment 1.

[47] *Id.* at 8.

[48] *See* full discussion of the STAC's review of the scientific literature and findings in Attachment 1, sec. 2 of the STAC recommendation, *supra* note 39.

[49] *Id.* at 10.

The STAC also commented on the likely inability of existing and future epidemiologic studies in the 9/11-exposed responder population—the most studied 9/11-exposure cohort—to accurately capture uterine cancer incidence because of the small number of female responders. Moreover, the STAC noted that studies of carcinogens reviewed by IARC and other authoritative bodies typically represent industrial cohorts, which often include few or no females, making finding an association between a 9/11 agent and uterine cancer highly unlikely and thus potentially foreclosing Method 3 as a basis for adding uterine cancer to the List.

Finally, the STAC considered public comment as well as the strong support of the WTC Health Program CCEs for the addition of uterine cancer to the List, noting that many Program members and advocates feel the exclusion of uterine cancer from the List is ''illogical and unfair and may cause tangible harm.'' The STAC cited a recent study [50] supporting the argument that WTC responders and survivors diagnosed with uterine cancer will experience better cancer survival if uterine cancer is covered by the Program due to treatment coverage and high-quality care.

After reviewing the available evidence and hearing comment from both the public and the WTC Health Program's CCEs, the STAC concluded that:

> In view of the strong rationale for adding all types of uterine cancer to the list of WTC-related cancers and the potential benefits to affected WTC responders, WTC survivors, and providers caring for these patients, we recommend that all types of uterine cancer be added to the list of WTC-related cancers and urge the Administrator to make all feasible efforts to do so as quickly as policies and procedures allow.[51]

E. Administrator's Decision Regarding Uterine Cancer

After reviewing the available body of scientific evidence describing the causal relationship between 9/11 exposures and uterine cancer, including certain 9/11 agents which are known EDCs, as well as evaluating the STAC's comprehensive rationale and recommendation, the Administrator concludes that the totality of available information provides a sufficient evidentiary basis to propose adding uterine cancer [52] to the List.

In accordance with the Program's *Policy and Procedures,* the Administrator evaluated the available information under the four methods developed for determining whether to add a type of cancer to the List. First, he assessed whether there was sufficient evidence in peer-reviewed, published, epidemiologic studies of 9/11-exposed populations to support adding uterine cancer to the List under Method 1. The Administrator concurs with the Science Team's evaluation of the literature pursuant to Method 1 and finds that the available literature does not provide sufficient support for the addition of uterine cancer to the List under Method 1.

Next, he looked at Method 2 which permits an addition to the List if multiple peer-reviewed epidemiologic studies establish a causal association between a condition already on the List and that cancer. The Administrator agrees with the Science Team's finding that there is evidence of a causal association between estrogen-secreting tumors, which are considered rare cancers in the Program, and uterine cancer. Thus, the Administrator finds that uterine cancer may be proposed for addition to the List pursuant to Method 2, but such an addition would be limited to only those Program members who have a certified WTC-related estrogen-secreting tumor.

The Administrator also examined NTP and IARC evaluations of carcinogenicity under Method 3, which permits an addition to the List if NTP has determined that a specific 9/11 agent is known to be a human carcinogen or is reasonably anticipated to be a human carcinogen, and IARC has determined that there is sufficient or limited evidence in humans that the 9/11 agent causes the type of cancer. The Administrator reviewed the NTP and IARC evaluations of those EDCs that are on the *Inventory on 9/11 Agents* (*i.e.,* TCDD, 2,3,4,7,8-pentachlorodibenzofuran, PCB, and cadmium) and concurs with the Science Team's finding that there is insufficient support for the addition of uterine cancer pursuant to Method 3.

Finally, the Administrator reviewed the recommendation of the STAC to determine if uterine cancer could be added to the List pursuant to Method 4, which permits an addition where the STAC recommends such an addition and provides a reasonable basis for the recommendation. The Administrator finds that the STAC's recommendation provides a reasonable basis for the addition of uterine cancer under Method 4 and this recommendation is further supported by the supplemental information presented by the Science Team in the White Paper.

Specifically, the Administrator agrees with the STAC's finding that mechanisms of initiation and progression of uterine cancer are similar to those for several other cancers on the List.[53] In particular, the evidence showing similar gene mutations and abnormal mismatch repair proteins among many cancers, including uterine cancer, strongly supports shared etiology and pathogenesis between uterine cancer and other cancer types on the List. For example, gene mutations found in low-grade, endometrioid endometrial cancer (which accounts for 80 percent of all endometrial cancers) include those in *PTEN* (phosphatase and tensin homolog deleted on chromosome 10), *CTNNB1* (β-catenin), and *K–RAS. PTEN* inactivation is similarly found in malignant melanoma, brain tumors, and ovarian, thyroid, breast, and prostate cancers, while *CTNNB1* and *K–RAS* mutations are found in a variety of human cancers. High-grade endometrial cancers are associated with mutations in oncogene *ERBB2* (HER–2/neu) and tumor suppressor gene *TP53. ERBB2* gene mutations are also found in breast and ovarian cancers; likewise, *TP53* is frequently mutated in a variety of human cancers, including high-grade serous ovarian and basal-like breast cancers.[54] Finally, studies have shown that several microRNAs (miRNAs), including miR–152 which plays a role as a tumor suppressor, can be epigenetically silenced by hyper-methylation of their respective DNA locus in endometrial cancer.[55] Aberrant methylation of miR–152 has also been reported for other cancers, including acute lymphoblastic leukemia, gastrointestinal cancer, and cholangiocarcinoma. Recent pan-cancer molecular studies [56] have found shared

[50] *See* full discussion of the STAC's review of the scientific literature and findings in Attachment 1, sec. 2 of the STAC recommendation, *supra* note 39.

[51] *Id.* at 5.

[52] ICD–10 codes C54 and C55. *See supra* note 1.

[53] Banno K, Yanokura M, Iida M, Masuda K, Aoki D [2014], *Carcinogenic Mechanisms of Endometrial Cancer: Involvement of Genetics and Epigenetics,* J Obstet Gynaecol Res 40(8):1957–1967; Urick ME and Bell DW [2019], *Clinical Actionability of Molecular Targets in Endometrial Cancer,* Nat Rev Cancer 19, 510–521.

[54] Levine DA and the Cancer Genome Atlas Research Network [2013], *Integrated Genomic Characterization of Endometrial Carcinoma,* Nature 497(7447):67–73.

[55] Favier A, Rocher G, Larsen AK, Delangle R, Uzan C, Sabbah M, Castela M, Duval A, Mehats C, Canlorbe G [2021], *MicroRNA as Epigenetic Modifiers in Endometrial Cancer: A Systematic Review,* Cancers (Basel) 6;13(5):1137.

[56] Pan-cancer molecular studies examine the similarities and differences among the genomic and cellular alterations found across diverse tumor types. Weinstein JN, Collisson EA, Mills GB, Mills Shaw KR, Ozenberger BA, Ellrott K, Shmulevich I, Sander C, Stuart JM [2013]. *The Cancer Genome*

molecular features among invasive breast carcinoma and several gynecologic tumors, such as high-grade serous ovarian cystadenocarcinoma, uterine corpus endometrial carcinoma, cervical squamous cell carcinoma and endocervical adenocarcinoma, and uterine carcinosarcoma.[57] The Administrator agrees with the STAC's finding that the shared etiology and pathogenesis described in the scientific literature suggest it would be unlikely that uterine cancer would be the only cancer type not related to 9/11 exposures.

The Administrator also finds that an association between exposure to EDCs in WTC dust and uterine cancer risk is plausible. EDCs can mimic endogenous hormones and interfere with endogenous hormone homeostasis, which may lead to a variety of adverse health outcomes, including cancer (*e.g.,* estrogen imbalances are a key risk factor for uterine cancer). There is extensive evidence from human studies of an etiologic role of estrogens in cancer. However, finding a causal association between an EDC 9/11 agent and uterine cancer is highly unlikely given the potentially long latency between exposure and disease. Moreover, the low number of women included in epidemiologic studies examining EDC carcinogenic risks in occupational cohorts increases the difficulty in finding conclusive evidence of a causal association with uterine cancer. Given the growing body of scientific evidence suggesting that exposure to EDCs may be a risk factor for female reproductive organ cancers (*e.g.,* breast, ovarian, and endometrial cancers), it is reasonable to assume that exposure to EDCs in WTC dust may contribute to uterine cancer risk.

Finally, the Administrator recognizes that the disproportionally low representation of women in the most studied cohorts of exposed responders makes it epidemiologically unlikely that a definitive association between 9/11 exposures and the occurrence of uterine cancer will be identified during the lifetime of even the most highly exposed Program members.

The Administrator has determined that the available scientific evidence and rationale provided by the STAC in its recommendation, supported by the supplemental information presented by the Science Team in the White Paper, offers a plausible rationale for an association between uterine cancer and EDCs in the *Inventory of 9/11 Agents.* Moreover, the cohorts relevant to understanding uterine cancer in the 9/11-exposed population are too small to allow a definitive decision about whether uterine cancer is causally associated with 9/11 exposure. For these reasons, the Administrator finds that a reasonable basis has been provided by the STAC under Method 4 and, accordingly, proposes to add uterine cancer to the List of WTC-Related Health Conditions.

IV. Summary of Proposed Rule

For the reasons discussed above, the Administrator proposes to amend 42 CFR 88.15 by adding a new paragraph (d)(15) to include malignant neoplasms of corpus uteri and uterus, part unspecified [58] on the List of WTC-Related Health Conditions. The existing paragraph (d)(15)—malignant neoplasm of the ovary—and the remainder of the cancer types identified in existing paragraphs (d)(16) through (24)—rare cancers—are renumbered paragraphs (d)(16) through (25), accordingly. Adding uterine cancer to the List would allow the WTC Health Program to offer treatment services to members whose uterine cancers are certified as WTC-related.

V. Required Regulatory Analyses

A. Executive Order 12866 (Regulatory Planning and Review) and Executive Order 13563 (Improving Regulation and Regulatory Review)

Executive Orders (E.O.) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

This proposed rule has been determined not to be a significant regulatory action under sec. 3(f) of E.O. 12866, and therefore has not been reviewed by the Office of Management and Budget (OMB). The addition of uterine cancer proposed by this rulemaking is estimated to cost the WTC Health Program between $1,718,691 and $2,199,808 per annum for 2022–2025.[59] All costs to the WTC Health Program will be transfers due to the implementation of provisions of the Patient Protection and Affordable Care Act (Pub. L. 111–148) in 2014 and as required under the authorizing statute for the WTC Health Program.[60] The rule would not interfere with state, local, or tribal governments in the exercise of their governmental functions.

Population Estimates

The WTC Health Program has, as of September 30, 2021, enrolled approximately 82,000 WTC responders and approximately 32,000 survivors, or approximately 114,000 individuals in total. Of that total population, approximately 60,000 individuals were participants in previous WTC medical programs and were enrolled as ''Legacy'' members in the WTC Health Program established by Title XXXIII of the PHS Act. For the purpose of calculating a baseline estimate of cancer prevalence only, the Administrator assumed that a steady rate of enrollment would continue, based on the trend in enrollees through September 2021.

According to WTC Health Program data, 12 percent of the current responder members (approximately 10,000 individuals) and 50 percent of survivor members (approximately 16,000 individuals) are female.[61] The Administrator acknowledges that some uterine cancer cases in this population may not have been caused by 9/11 exposures. The certification of individual cancer diagnoses will be conducted on a case-by-case basis, as required by the Zadroga Act. For the purpose of this economic analysis, however, the Administrator assumes that all diagnosed uterine cancers will be certified for treatment by the WTC Health Program. Finally, because there are no existing data on cancer rates related to 9/11 exposures at either the Pentagon or in Shanksville, Pennsylvania, the Administrator has

Atlas Pan-Cancer analysis project, Nature Genetics. 45 (10): 1113–1120.

[57] Berger AC *et al.* [2018], A *Comprehensive Pan-Cancer Molecular Study of Gynecologic and Breast Cancers,* Cancer Cell 33(4):690–705.

[58] *See supra* note 1.

[59] As discussed in this section, NIOSH estimated lower and upper bound estimates to reflect the uncertainty in the Agency's ability to predict the expected number of cancer cases in three years after this rulemaking. The low bound reflects the general U.S. population cancer rate and uses undiscounted costs for 2022 and costs for 2023–2025 discounted at the 7% discount rate. The upper bound reflects the U.S. population cancer rate + 21%, based on a study by Li *et al.* [2021], *infra* note 69, and uses undiscounted rates for 2022 and costs for 2023–2025 discounted at the 3% discount rate. Although, if added to the List, uterine cancer would be considered a covered condition for the duration of the WTC Health Program (currently authorized through FY 2090), the dates 2022–2025 were chosen in order to provide a snapshot of uterine cancer costs in the coming years.

[60] Because sec. 3331(c)(3) of the PHS Act requires WTC Health Program members to maintain minimum essential insurance coverage all treatment costs to be paid by the WTC Health Program are considered transfers.

[61] *See supra* note 25.

used only data from studies of individuals who were responders or survivors in the New York City disaster area.

Cost of Uterine Cancer Treatment

The Administrator estimated the treatment costs associated with covering uterine cancer in this rulemaking. The costs of treatment are divided into three treatment phases: The first year of treatment following diagnosis; the intervening years or continuing treatment after the first year; and treatment during the last year of life. The first-year costs of cancer treatment are higher due to the initial need for aggressive medical care (*e.g.,* radiation or chemotherapy) and surgical care. The costs during the last year of life are often dominated by increased hospitalization costs.[62] Therefore, three different treatment phase costs were used to provide a best estimate of treatment costs in conjunction with expected incidence and long-term survival rates for uterine cancer. Average treatment costs for uterine cancer are in Table A, below.

TABLE A—AVERAGE COSTS OF TREATMENT FOR UTERINE CANCER, 2021$

Stage of treatment:	
Initial (first 12 months after diagnosis)	$39,638
Continuing (annual)	2,066
Last year of life (last 12 months of life)	118,058

These cost figures were based on a study of cancer patients from the Surveillance, Epidemiology, and End Results (SEER) program maintained by the National Cancer Institute and using Medicare files.[63] The average costs of treatment described above are given in 2021 prices adjusted using the Medical Consumer Price Index for all urban consumers.[64]

Incident Cases of Cancer

The Administrator estimated the expected number of cases of cancer that would be observed in a cohort of responders and survivors followed for cancer incidence after September 11, 2001, using U.S. population cancer rates. Demographic characteristics of the cohort were assigned since the actual data are not available for individuals in the responder and survivor populations who have not yet enrolled in the WTC Health Program. Sex and age (at the time of exposure) distributions for responders and survivors were assumed to be the same as current members in the WTC Health Program. Because uterine cancer occurs only in females,[65] all calculations only consider female WTC Health Program members.

The Administrator assumed race and ethnic origin distributions for responders and survivors, respectively, according to distributions in the WTC Health Registry cohort: [66] 57 percent non-Hispanic white, 15 percent non-Hispanic black, 21 percent Hispanic, and 8 percent other race/ethnicity for responders; 50 percent non-Hispanic white, 17 percent non-Hispanic black, 15 percent Hispanic, and 18 percent other race/ethnicity for survivors. Registry follow-up for cancer morbidity for each person began on January 1, 2002, or age 15 years, whichever was later. Age 15 was considered because the cancer incidence rate file did not include rates for persons less than 15 years of age. Follow-up ended on December 31, 2016, or the estimated last year of life, whichever was earlier. The estimated last year of life was used since not all persons would be expected to remain alive at the end of 2016. The estimated last year of life was based on U.S. gender, race, age, and year-specific death rates from CDC WONDER.[67] A life-table analysis program, LTAS.NET, was used to estimate the expected number of incident cancers for uterine cancer.[68] The Administrator calculated cancer incidence rates using data through 2018 from the SEER Program and estimated rates for 2002–2025.[69] The Program applied the resulting gender, race, age, and year-specific cancer incidence rates to the estimated person-years at risk to estimate the expected number of cancer cases for uterine cancer starting from year 2002, the first full year following the September 11, 2001, terrorist attacks, to 2025.

Prevalence of Cancer

To determine the potential number of persons in the responder and survivor populations with cancer, the Administrator used the number of incident uterine cancer cases described above for each year starting with 2002 and estimated the prevalence of uterine cancer using survival rate statistics for each incident cancer group through 2025.[70] Using the incident cases and survival rate statistics, the Administrator estimated the prevalence (number of persons living with cancer) of cases during the 23-year period (2002–2025) since September 11, 2001. For the purposes of illustrating an upper bound incidence rate and prevalence estimate, the Administrator assumed that the rate of cancer in the WTC Health Program exceeds the general U.S. population rate by 21 percent due to 9/11 exposures. The peer-reviewed literature supports the use of a 21 percent excess risk of cancer in the 9/11-exposed population over the U.S. population cancer rate; a 2021 study by Li *et al.*[71] reported an adjusted hazard ratio of 1.21 (95 percent CI: 1.12, 1.31) for all cancer sites and used a within-cohort comparison less affected by healthy worker selection bias. The resulting Table B summarizes those results for each year from 2022 through 2025, the number of new cases occurring in that year (incidence), the number of persons surviving up to 23 years beyond their first diagnosis (prevalence), and the number of individuals who might be expected to die from their cancer in that year.[72]

[62] Yabroff KR, Lamont EB, Mariotto A, Warren JL, Topor M, Meekins A, Brown ML [2008], *Cost of Care for Elderly Cancer Patients in the United States,* J Natl Cancer Inst 100(9):630–41.

[63] Surveillance, Epidemiology, and End Results (SEER) Program (*www.seer.cancer.gov*) SEER*Stat Database: Incidence—SEER 9 Regs Research Data, Nov 2020 Sub (1975–2018), National Cancer Institute, DCCPS, Surveillance Research Program, Surveillance Systems Branch, released Apr. 2021, based on the Nov. 2020 submission. Although patients who are Medicare members are age 65 and older, cancer treatment costs are not expected to vary with age.

[64] Bureau of Labor Statistics, *Consumer Price Index, https://fred.stlouisfed.org.* Accessed on Apr. 28, 2021.

[65] *See supra* note 25.

[66] Jordan HT, Brackbill RM, Cone JE, Debchoudhury I, Farfel MR, Greene CM, Hadler JL, Kennedy J, Li J, Liff J, Stayner L, Stellman SD [2011], *Mortality Among Survivors of the Sept 11, 2001, Word Trade Center Disaster: Results from the World Trade Center Health Registry Cohort,* Lancet 378:879–887. Note: percentages may not sum to 100 percent due to rounding.

[67] Centers for Disease Control and Prevention, National Center for Health Statistics, Compressed Mortality File 1999–2016 on CDC WONDER Online Database, released June 2017. Data are from the Compressed Mortality File 1999–2016 Series 20 No. 2U, 2016, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. *http://wonder.cdc.gov/cmf-icd10.html.* Accessed May 29, 2021.

[68] Schubauer-Berigan MK, Hein MJ, Raudabaugh WM, Ruder AM, Silver SR, Spaeth S, Steenland K, Petersen MR, and Waters KM [2011], *Update of the NIOSH Life Table Analysis System: A Person-Years Analysis program for the Windows Computing Environment,* Am J Ind Med 54:915–924.

[69] *See supra* note 62.

[70] *Id.*

[71] Li J, Yung J, Qiao B, Takemoto E, Goldfarb DG, Zeig-Owens R, Cone JE, Brackbill RM, Farfel MR, Kahn AR, Schymura MJ, Shapiro MZ, Dasaro CR, Todd AC, Kristjansson D, Prezant DJ, Boffetta P, Hall CB [2021], *Cancer Incidence in World Trade Center Rescue and Recovery Workers: 14 Years of Follow-Up,* J Natl Cancer Inst *https://doi.org/10.1093/jnci/djab165.*

[72] The 23-year survival limit is imposed based on the analytic time horizon.

TABLE B—ESTIMATED INCIDENCE AND PREVALENCE OF UTERINE CANCER
[2022–2025]

	2022	2023	2024	2025
Responders (based on ~10,000 female members)				
New cases	6.69	6.92	7.14	7.27
Live cases from previous years	29.46	30.78	32.09	33.33
Deaths	5.09	5.37	5.61	5.90
Total cases	36.15	37.70	39.23	40.60
Survivors (based on ~16,000 female members)				
New cases	10.91	10.91	10.91	10.91
Live cases from previous years	53.70	54.72	55.49	56.17
Deaths	9.60	9.90	10.17	10.31
Total cases	64.61	65.63	66.40	67.08
Total (based on ~26,000 female WTC responder and survivor members)				
New cases	17.6	17.83	18.05	18.18
Live cases from previous years	83.16	85.50	87.58	89.50
Deaths	14.69	15.27	15.78	16.21
Total cases	100.76	103.33	105.63	107.68

Cost Computation

To compute the costs for uterine cancer, the Administrator assumes that the individuals diagnosed with uterine cancer will be certified by the WTC Health Program for treatment and monitoring services. The treatment costs for the first year of treatment (Table A, year adjusted) were applied to the predicted newly incident (Year 1) cases for each year. Likewise, the costs of treatment for the last year of life were applied in each year to the number of people predicted to die from their cancer in that year. The costs of continuing treatment from Table A were applied to the number of prevalent cases who had survived their cancers beyond their year of diagnosis, for each year of survival (Year 2–23).

The estimated treatment costs for responders and survivors were re-computed under the following two assumptions: (1) The rate of cancer in the WTC Health Program is equal to the rate of cancer observed in the general U.S. population; and (2) the rate of cancer in the WTC Health Program exceeds the general U.S. population rate by 21 percent, as discussed above. Costs for future years are discounted at both 7 percent and 3 percent to reflect net present value.[73]

The sum of the annual costs in the table for the years 2022 through 2025 represents the estimated treatment costs to the WTC Health Program for coverage of uterine cancer for the 12 percent of approximately 82,000 WTC responders who are female and the 50 percent of approximately 32,000 WTC survivors who are female.

Summary of Costs

Because HHS lacks data to account for recoupment from workers' compensation insurance or primary payment by either private health insurance or Medicare/Medicaid payments, the estimates offered here are reflective of estimated WTC Health Program costs only and assume the Program is the primary payer. This analysis offers an assumption about the number of individuals who might enroll in the WTC Health Program and estimates the impact of both a low rate of cancer (U.S. population average rate) and an increased rate (21 percent greater than the U.S. population average) on the number of cases and the resulting estimated treatment costs to the WTC Health Program. This analysis does not include administrative costs associated with certifying additional WTC-related uterine cancers that might result from this action.

Since the implementation of provisions of the Affordable Care Act on January 1, 2014, all members and future members are assumed to have or have access to medical insurance coverage other than through the WTC Health Program.[74] Therefore, all treatment costs to be paid by the WTC Health Program from 2022 through 2025 are considered transfers.

TABLE C—MEDICAL TREATMENT COST FOR UTERINE CANCER CASES DURING 2022–2025, 2021$

	2022 costs, undiscounted, 2021$		2023–2025 costs,* 7% discount rate	2023–2025 costs, 3% discount rate
	Cancer rate		Cancer rate	
	U.S. average	U.S. average + 21%	U.S. average	U.S. average + 21%
Responders	$749,741	$907,187	$2,145,844	$2,801,474

[73] *See* OMB Circular A–94, *Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs. https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A94/a094.pdf.*

[74] Sec. 3331(c)(3) of the PHS Act requires WTC Health Program members to maintain minimum essential insurance coverage.

TABLE C—MEDICAL TREATMENT COST FOR UTERINE CANCER CASES DURING 2022–2025, 2021$—Continued

Survivors	1,067,098	1,291,189	2,912,084	3,799,381
Total	1,816,839	2,198,376	5,057,928	6,600,855

* Since this table summarizes the lowest and highest cost estimates for treatment of uterine cancer, values representing 2023–2025 costs at the 7% discount rate and at the increased cancer rate and 2023–2025 costs at the 3% discount rate and at the U.S. population average rate were not included.

The Administrator found the cost estimate range by adding the low 2023–2025 estimate in Table C (7 percent discount rate, U.S. cancer rate average) and the low estimate for 2022 (U.S. cancer rate average) and dividing the sum by four to find the annual low-cost estimate (*i.e.,* $1,718,691). The same calculation was done for the annual high-cost estimates, adding the higher numbers in Table C (3 percent discount rate, U.S. cancer rate average +21 percent) to the high estimate for 2022 (U.S. cancer rate average +21 percent) and dividing the sum by four (*i.e.,* $2,199,808).

Examination of Benefits (Health Impact)

This section qualitatively describes the potential benefits of this rulemaking to add uterine cancer to the List of WTC-Related Health Conditions in terms of the expected improvements in the health and health-related quality of life of potential uterine cancer patients treated through the WTC Health Program, compared to not conducting the rulemaking.

The Administrator does not have information on the health of the population that may have experienced 9/11 exposures and is not currently enrolled in the WTC Health Program. In addition, the Administrator has only limited information about health insurance and healthcare services for uterine cancers potentially caused by 9/11 exposures and suffered by any population of responders and survivors, including responders and survivors currently enrolled in the WTC Health Program and responders and survivors not enrolled in the Program. For the purposes of this analysis, the Administrator assumes that all unenrolled responders and survivors are now covered by health insurance due to access provided by the Affordable Care Act and may be receiving treatment outside the WTC Health Program.

Although the Administrator cannot quantify the benefits associated with the WTC Health Program, members with uterine cancer are expected to experience better treatment outcomes as Program members than non-members. A recent study found that ''WTC-exposed responder cancer patients enrolled in the MMTP [WTC Medical Monitoring and Treatment Program, a predecessor to the WTC Health Program] had higher survival rates compared with those not enrolled in the MMTP.'' [75] Moreover, under other insurance plans, patients would have deductibles and copays, which impact access to care and, particularly, its timeliness.[76] WTC Health Program members have first-dollar coverage and hence are likely to seek care sooner, when indicated, resulting in improved treatment outcomes.

Finally, during public meetings, Program members have expressed that the lack of social and clinical support, and lack of recognition that their diagnosed uterine cancer is a WTC-related health condition, have had a significant negative impact on their morale and quality of life.

Limitations

The analysis presented here was limited by the dearth of verifiable data on the uterine cancer status of responders and survivors who have yet to apply for enrollment in the WTC Health Program. Because of the limited data, the Administrator was not able to estimate benefits in terms of averted healthcare costs; nor was the Administrator able to estimate administrative costs, or indirect costs, such as averted absenteeism, short- and long-term disability, and productivity losses averted due to premature mortality.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* requires each agency to consider the potential impact of its regulations on small entities, including small businesses, small governmental units, and small not-for-profit organizations. The Administrator certifies that this proposed rule has ''no significant economic impact upon a substantial number of small entities'' within the meaning of the RFA.

C. Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* requires an agency to invite public comment on, and to obtain OMB approval of, any regulation that requires 10 or more people to report information to the agency or to keep certain records. The Administrator has determined that this rulemaking does not contain any new information collection requirements or recordkeeping requirements; thus, the PRA does not apply to this rulemaking. Data collection and recordkeeping requirements for the WTC Health Program are approved by OMB under ''World Trade Center Health Program Enrollment, Appeals & Reimbursement'' (OMB Control No. 0920–0891, exp. December 31, 2021, currently under OMB review).

D. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801 *et seq.,* HHS will report the promulgation of this rule to Congress prior to its effective date.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531 *et seq.,* directs agencies to assess the effects of Federal regulatory actions on state, local, and tribal governments, and the private sector ''other than to the extent that such regulations incorporate requirements specifically set forth in law.'' For purposes of the Unfunded Mandates Reform Act, this proposed rule does not include any Federal mandate that may result in increased annual expenditures in excess of $100 million in 1995 dollars by state, local, or tribal governments in the aggregate, or by the private sector.

F. Executive Order 12988 (Civil Justice)

This proposed rule has been drafted and reviewed in accordance with Executive Order 12988, ''Civil Justice Reform,'' and will not unduly burden the Federal court system. This rule has

[75] Goldfarb DG, Zeig-Owens R, Kristjansson D, Li J, Brackbill RM, Farfel MR, Cone JE, Kahn AR, Qiao B, Schymura MJ, Webber MP, Dasaro CR, Lucchini RG, Todd AC, Prezant DJ, Hall CB, Boffetta P [2021], *Cancer Survival among World Trade Center Rescue and Recovery Workers: A Collaborative Cohort Study,* Am J Ind Med 64(10):815–826.

[76] Wharam JF, Galbraith AA, Kleinman KP, Soumerai SB, Ross-Degnan D, Landon BE [2008], *Cancer Screening before and after Switching to a High-Deductible Health Plan,* Ann Intern Med 148(9):647–655.

been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

The Administrator has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism and has determined that it does not have ''Federalism implications.'' The rule does not ''have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.''

H. Executive Order 13045 (Protection of Children From Environmental Health Risks and Safety Risks)

In accordance with Executive Order 13045, the Administrator has evaluated the environmental health and safety effects of this proposed rule on children. The Administrator has determined that the rule would have no environmental health and safety effect on children.

I. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, the Administrator has evaluated the effects of this proposed rule on energy supply, distribution, or use, and has determined that the rule will not have a significant adverse effect.

J. Plain Writing Act of 2010

Under Public Law 111–274 (October 13, 2010), Executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. The Administrator has attempted to use plain language in promulgating the proposed rule consistent with the Federal Plain Writing Act guidelines and requests public comment on this effort.

List of Subjects in 42 CFR Part 88

Aerodigestive disorders, Appeal procedures, Cancer, Healthcare, Mental health conditions, Musculoskeletal disorders, Respiratory and pulmonary diseases.

For the reasons discussed in the preamble, the Administrator and HHS Secretary propose to amend 42 CFR part 88 as follows:

PART 88—WORLD TRADE CENTER HEALTH PROGRAM

■ 1. The authority citation for part 88 is revised to read as follows:

Authority: 42 U.S.C. 300mm to 300mm–61.

■ 2. Amend § 88.15 as follows:
■ a. Redesignate paragraphs (d)(15) through (24) as paragraphs (d)(16) through (25).
■ b. Add new paragraph (d)(15).
■ c. In newly redesignated paragraph (d)(24), remove ''*Childhood cancers:*'' and add ''Childhood cancers:'' in its place.
■ d. In newly redesignated paragraph (d)(25), remove ''*Rare cancers:*'' and add ''Rare cancers:'' in its place.

The addition reads as follows:

§ 88.15 List of WTC-Related Health Conditions.

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(d) * * *

(15) Malignant neoplasms of corpus uteri and uterus, part unspecified.

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John J. Howard,

Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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FEDERAL MARITIME COMMISSION

46 CFR Part 520

[Docket No. 21–03]

RIN 3072–AC86

Carrier Automated Tariffs

AGENCY: Federal Maritime Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Maritime Commission (Commission) is seeking public comment on proposed modifications to its rules governing Carrier Automated Tariffs through this notice of proposed rulemaking (NPRM). The proposed rule would remove the option for ocean common carriers to charge a fee to access their tariff; allow non-vessel operating common carriers (NVOCCs) to cross reference certain aspects of other carriers' terms in their tariffs; clarify the ability for NVOCCs to reflect increases in certain charges passed-through by other entities without notice; update the definition of co-loading to apply only to less than container loads; require that documentation be annotated with the names of all NVOCCs involved in a shipping transaction; and make other miscellaneous updates and clarifications to the regulation.

DATES: Submit comments on or before June 9, 2022.

ADDRESSES: You may submit comments by email to *secretary@fmc.gov.* For comments, include in the subject line: ''Docket No. 21–03, Comments on Carrier Automated Tariffs Rulemaking.'' Comments should be attached to the email as a Microsoft Word or text-searchable PDF document.

Instructions: For detailed instructions on submitting comments, including requesting confidential treatment of comments, and additional information on the rulemaking process, see the Public Participation heading of the Supplementary Information section of this document. Note that all comments received will be posted without change to the Commission's website unless the commenter has requested confidential treatment.

Docket: For access to the docket to read background documents or comments received, go to the Commission's Electronic Reading Room at: *https://www2.fmc.gov/readingroom/proceeding/21-03/.*

FOR FURTHER INFORMATION CONTACT: William Cody, Secretary; Phone: (202) 523–5725; Email: *secretary@fmc.gov.*

SUPPLEMENTARY INFORMATION:

I. Discussion

On April 8, 2021, the Commission issued an Advance Notice of Proposed Rulemaking (ANPRM) seeking information on how common carriers interpret and apply certain Commission regulations in 46 CFR part 520.[1] In response to the ANPRM, the Commission received three sets of comments from interested parties: The National Customs Brokers and Forwarders Association of America, Inc (NCBFAA); New York New Jersey Foreign Freight Forwarders & Brokers Association, Inc. (NYNJFFF&BA); and the Association of Food Industries, Inc. (AFI). NCBFAA and NYNJFFF&BA are trade associations whose members include non-vessel operating common carriers (NVOCCs), and AFI is a trade association for the U.S. food import industry. These comments are addressed later in this proposed rule.

A. Tariff Access Fees

Before the passage of the Ocean Shipping Reform Act of 1998 (OSRA), which became effective May 1, 1999, vessel operating common carrier (VOCC) and conference tariffs were filed

[1] Advance notice of proposed rulemaking—Carrier Automated Tariffs, 86 FR 18240 (April 8, 2021).

with the Commission through the Commission's Automated Tariff Filing and Information system. OSRA eliminated the requirement that tariffs be filed with the Commission, and instead, directed carriers and conferences to publish tariffs in carrier automated tariff systems.

The statute at 46 U.S.C. 40501(c) states that ''[a] reasonable fee may be charged for'' access to tariffs.[2] The statute and the implementing regulations do not, however, state what is considered ''reasonable'' in the context of tariff access.[3] In response to complaints from potential tariff users that certain tariff access fees and minimum subscription requirements were excessive, the Commission subsequently issued guidance to stakeholders through a Circular Letter which advised that tariff access fees should recover only costs and expenses incurred by carriers in making their tariffs accessible to the public.[4] More recent experience indicates that, contrary to the Shipping Act and to the guidance provided in the Circular Letter, some tariff access fees may be so high as to effectively prevent tariff users from reviewing certain carrier tariffs. Comments received by the Commission in response to its ANPRM asserted that some carriers charge tariff access fees that ''appear to be exorbitant and thus tend to discourage the public access to VOCC rates[.]'' [5]

A competitive and efficient ocean transportation system is dependent on transparency and availability of price information to the shipping public. It is the belief of the Commission that any unnecessary roadblocks to that transparency, including cost barriers to tariff access, are contrary to that goal. The Commission has learned that a limited number of carriers are charging unreasonably high fees that prevent public access to tariffs. The Commission's implementing regulations were written at a time when dialup internet via public switched telephone networks was the norm and information was not as easily posted or located as is the case now.[6] Intervening technological developments and efficiencies have made it nearly essential for businesses to operate a free, publicly accessible website. Seven of the top ten carriers that serve the U.S. make their tariffs available on their websites at no cost. With the ubiquity of websites among carriers, the decreases in the cost of providing information online, the efficiency of providing public access through a website, and the prevalence of free and open access to tariffs among the largest carriers, the Commission believes that free public access to tariffs is reasonable.

While the Commission does not wish to place an undue burden on common carriers to make their tariffs available to the public, the Commission proposes to require carriers and conferences to provide free access to tariffs by removing the option to assess a fee for tariff access currently found at 46 CFR 520.9(e)(3). The Commission welcomes comments on what specific costs the carriers would incur in order to provide free access to tariffs and comments from carriers who do not charge access on their rationale for that decision.

B. Cross Referencing Tariffs

In contrast to the current regulations in part 520, the Commission has granted broad flexibility to NVOCCs with regard to increases in charges passed through by VOCCs in 46 CFR part 531—Negotiated Service Arrangements (NSAs), and 46 CFR part 532—NVOCC Negotiated Rate Arrangements (NRAs). These regulations allow an increase in a VOCC charge to be passed through, without markup of the charges, by an NVOCC to its shipper if the shipper agrees to this arrangement, provided the underlying charge is listed in an NRA or NSA, or included in the NVOCC's rules tariff.

The Commission is persuaded that it is beneficial to address the pass through of charges by the NVOCC to the shipper in its rules governing carrier automated tariffs to align the regulations more closely in part 520 with those regulations in part 531 (NSAs) and part 532 (NRAs) by allowing NVOCCs to cross reference an existing VOCC tariff in their NVOCC tariff. The Commission notes that, beyond the flexibility this regulation will grant to NVOCCs in their performance of transportation service, it also will clarify for shippers where certain charges originate, and will track when and how those charges may increase.

Any increases in VOCC-originated surcharges and assessorials must be published in the VOCC tariff 30 days prior to taking effect. Although VOCCs are required to file 30-day notice of increases, NVOCCs commented in response to the ANPRM that, particularly in the current environment of high demand for vessel capacity, the number of new charges and frequent increases to existing charges make it impracticable for NVOCCs to provide same-day notice of those charges in their own tariffs. Therefore, NVOCCs may be unable to recover increases in VOCC surcharges and assessorials assessed to the NVOCC. Furthermore, NVOCC customers may have difficulty keeping up with new charges and increases in existing charges as they are imposed by various parties in the ocean shipping supply chain.

To facilitate the transparency and application of VOCC-originated charges which are passed through from the NVOCC to its shipper, the Commission proposes to add a new § 520.7(a)(3)(iv) to allow an NVOCC to cross reference a VOCC's tariff for certain specified surcharges and assessorials. The Commission notes that it is not the intent of this regulation to waive the application of § 520.8(a)(1) to any charge or increase in charge being published in a carrier tariff. This cross referencing of another tariff is to be used only for those charges which are being passed through to the shipper at cost. The Commission believes that this proposed rule will allow for greater transparency in the sourcing of various fees and assessorials in the ocean shipping market, which will in turn foster a more competitive marketplace.

The Commission proposes to add § 520.7(a)(3)(iv) to the regulations to allow NVOCCs to cross reference a VOCC's tariff for certain specified surcharges and assessorials.

C. Charges Passed Through by VOCCs

NVOCCs are periodically assessed increases in charges by a VOCC that are ''passed through'' after being imposed on the VOCC by an outside entity, such as canal tolls, taxes, or other third-party levies over which the VOCC has no control. In recognition of the fact that the entity collecting these types of charges is not necessarily subject to an obligation to provide 30-day notice of increases to the carrier, current regulations allow increases in these types of existing charges to take effect upon publication in the VOCC's tariff. Commission regulations stipulate at 46 CFR 520.8(b)(4) that this exemption only applies when the collecting agency has not given advance notice of the change to the common carrier.

Currently, Commission regulations do not explicitly allow NVOCCs to pass through increases in these charges outside of the control of a common carrier, thereby preventing them from passing through to their customer an increase in a charge imposed by an outside entity and then subsequently passed through by a VOCC without the

[2] 46 U.S.C. 40501(c).

[3] 46 CFR 520.9(e)(3).

[4] Circular Letter No. 00–2, *Charges for Access to Tariffs and Tariff Systems* (October 6, 2000) at *https://www.fmc.gov/about-the-fmc/circulars/*.

[5] Docket No. 21–03, Comments of the National Customs Brokers and Forwarders Association of America, Inc., June 4, 2021, at 2.

[6] 46 CFR 520.9(a).

required 30-day notice. For this reason, an NVOCC may not be able to recover an increase in these types of charges if it is does not publish the increase in its own tariff sufficiently in advance of any such charge becoming effective in the tariff of the VOCC.

The Commission is persuaded that it is beneficial to address the pass through of charges by the NVOCC to its shipper in its rules governing carrier automated tariffs to more closely align the regulations with the flexibilities afforded VOCCs. The Commission notes that, beyond the flexibility this regulation will grant NVOCCs in their performance of transportation service, it will also clarify for shippers the types of increases in charges that can be posted in an NVOCC's tariff without a 30-day waiting period.

The Commission proposes to add a new § 520.7(h) which would explicitly state that NVOCCs can pass through charges not under the control of an ocean carrier in the same manner as VOCCs.

The Commission interprets the passing through of a charge to mean it is assessed with no markup to the charge imposed on the common carrier by the underlying collecting agency. The proposed regulations which reference charges that may be passed through explicitly prohibit marking up these charges. However, current regulations at 46 CFR 520.8(b)(4) do not address the mark up of the charges listed. Therefore, the Commission proposes to revise regulations at 46 CFR 520.8(b)(4) to specify that these charges may not be marked up above cost to be considered a pass-through cost.

The Commission believes that clarity facilitates consistency in the application of regulations, which in turn provides a measure of assurance to the shipper that certain practices will be carried out uniformly among common carriers. The nature of pass-through charges, such that a shipper may not know the amount of a particular charge in advance, can deny full transparency to the shipper prior to being invoiced for such a charge. More recently, as expressed by all commenters, there is an increased number and variety of additional fees, and frequent changes to those fees, which has escalated the chances that a shipper is unaware of the final cost of transportation when tendering cargo for shipment. To address these inconsistencies, the Commission offers the following guidance as to the intended application of the proposed regulations at 46 CFR 520.7(a)(3)(iv) and (h), and the existing regulations at 520.8(b)(4).

1. General Rate Increases

Some NVOCC commenters expressed concern that General Rate Increases (GRIs), when originating from an underlying VOCC, can appear similar to surcharges. Historically, the Commission has classified GRIs as a component of the base ocean freight assessed by the common carrier and are therefore not surcharges and not subject to any exemption under 46 CFR 520.8(b)(4). The Commission declines to categorize GRIs as surcharges because they apply to the base freight rate for carriage, not a separate fee for ancillary costs associated with that transportation. Thus, in this proposed rule, GRIs will continue to be classified as a component of the base ocean freight assessed by the common carrier and will not be considered exempted from the regulations at § 520.8(a).

2. Fees Connected to Pass-Through Charges

Some of the comments reference ''administrative fees'' in connection with the pass through of charges from the NVOCC to its shipper. Current regulations, at 46 CFR 520.8(b)(4) and proposed regulations at 520.7(a)(3)(iv) would relieve the common carrier from the requirement to provide a shipper with advance notice of an increase in a charge, under the condition that the common carrier itself was not advised of the increase in advance. This exemption is not intended to allow a markup of the charge above what the third party has billed to the NVOCC, which includes not allowing administrative or other named fees assessed by the NVOCC that apply only to charges passed through by that NVOCC, whether through a cross-referenced tariff or by name.

3. Demurrage and Detention

The Commission notes that comments included references to demurrage and detention charges levied by an underlying VOCC. Although demurrage and detention practices are not within the scope of this rulemaking, the Commission has issued guidance on how it assesses the reasonableness of demurrage and detention practices.[7] Also, it has issued an Advance Notice of Proposed Rulemaking to seek comment on whether the Commission should require common carriers and marine terminal operators to include certain minimum information on or with demurrage and detention billings.[8] The Commission is interested in receiving comments on whether it should require common carriers and marine terminal operators to adhere to certain practices regarding the timing of demurrage and detention billings. These changes were recommended by the Fact Finding Officer in Commission Fact Finding 29: International Ocean Transportation Supply Chain Engagement. The Commission welcomes additional comments on demurrage and detention practices in the docket for the Advance Notice of Proposed Rulemaking.[9]

4. Application of Exemption at 46 CFR 520.8(b)(4) to NVOCCs

The current regulations at 46 CFR 520.8(b)(4) have exempted VOCCs from notifying shippers in advance of changes in charges for terminal services, canal tolls, additional charges, or other provisions which are not under the control of the common carriers or conferences when it acts as a collection agent for such charges, and it received no notice for such changes. This exemption from the waiting period set forth at § 520.8(a)(1) has been applied to VOCCs, but its application to NVOCC tariffs has been unclear. The Commission interprets the § 520.8(b)(4) exemption to apply to NVOCCs as well, provided that the underlying charge originates with an entity that is not subject to the requirements of § 520.8(a)(1), and that the change was made without notification from the owner of the originating tariff.

D. Definition of Co-Loading

The Commission considered but declined to limit the definition of co-loading to less-than-container load (LCL) (as opposed to full container load (FCL)) cargo in its 1984 rulemaking because ''coloading FCLs was less prevalent and less likely than coloading LCL cargo.'' [10] Although the definition of co-loading and its practices was revisited by the Commission in 1993 and 1994, these docketed items were discontinued without further action.[11]

[7] Interpretive Rule on Demurrage and Detention Under the Shipping Act, 85 FR 29638 (May 18, 2020).

[8] Doc. No. 22–04: Demurrage and Detention Billing Requirements Advance Notice of Proposed Rulemaking, 87 FR 8506 (February 15, 2022); *https://www2.fmc.gov/readingroom/proceeding/22-04/.*

[9] *Id.*

[10] Docket No. 84–27, Publishing and Filing Tariffs by Common Carriers in the Foreign Commerce of the United States—Co-Loading Practices by NVOCCs, 49 FR 29980, 29982 (July 25, 1984).

[11] *https://www2.fmc.gov/readingroom/docs/93-22/93-22_003716807.pdf/* and *https://www2.fmc.gov/readingroom/docs/94-26/94-26_003718346.pdf/.* (Nov. 1, 2004).

OSRA also continued the co-loading definition without substantive change.[12]

In order to align regulations with current industry practices, the Commission proposes to amend the definition of co-loading to state specifically that co-loading applies to LCL cargo. The Commission proposes to add the term ''less than container loads of'' to the existing co-loading definition at § 520.2.

E. Documentation for Co-Loading and Other NVOCC Arrangements

Shipments involving multiple NVOCCs encompass a wide and complex range of interactions between parties in the supply chain. The various arrangements made among NVOCCs can provide efficiencies and result in lower transportation costs to the beneficial cargo owner (BCO). On the other hand, co-loading practices have the potential to reduce transparency in the shipping process and can lead to NVOCCs controlling cargo without the knowledge of the BCO.

The current definition of co-loading at 46 CFR 520.2 is ''the combining of cargo by two or more NVOCCs for tendering to an ocean common carrier under the name of one or more of the NVOCCs.'' As discussed above, this definition applies to the physical combining of LCL shipments in a single shipping container. Regulations at 46 CFR 520.11(c)(2) require that the applicable bill of lading for co-loaded cargo be annotated with the identity of any other NVOCC to which the shipment has been tendered for co-loading. Since the promulgation of co-loading regulations, practices have evolved among NVOCCs that include the tender for transport of FCL shipments by one NVOCC to another NVOCC without the knowledge or consent of the BCO. This practice is often referred to in the industry as co-loading, despite not conforming to the definition set forth by the Commission.

The Commission proposes to add a regulation at 46 CFR 520.11(d) to require that the documentation accompanying FCL shipments is annotated with the name of all NVOCCs associated with the cargo. This annotation requirement ensures that, for either co-loaded cargo or full container loads, the BCO has the information required to contact any NVOCC which may have control of its cargo. This information is critical to the BCO, particularly in cases of failure to perform by the NVOCC with which the BCO contracted to transport its cargo.

F. Other Proposed Changes to Part 520

1. Clarifying Revisions

The Commission proposes to revise several provisions within part 520 to clarify when the regulations are expressing a requirement or obligation. For example, the Commission proposes to replace the term ''shall'' with the term ''must'' to clearly indicate that certain acts are required and to identify regulatory obligations. In addition, the Commission proposes similar revisions by either deleting the word ''shall'' or other clarifying edits. Similarly, the Commission also proposes replacing certain usages of the term ''may'' with the term ''must'' to identify requirements or obligations.

2. § 520.2 Definitions

The proposed rule would: Add clarifying language to the definition of ''bulk cargo'' to explain that bulk ''containerized cargo tendered by the shipper'' is subject to mark and count and is, therefore, subject to the requirements of this part; amend the definition of combination rate to spell out the abbreviation for Tariff Rate Item; amend the definition of harmonized system to remove an outdated reference to the U.S. Customs Service; amend the definition of publisher to mean a person rather than an organization, and specify that a publisher is authorized to act by a common carrier; amend the definition of retrieval to remove outdated references to dial-up telecommunications and a network link; amend the definition of rules to clarify that a common carrier or a conference of common carriers govern the application of tariff matters; amend the definition of shipper to specify that ocean transportation refers to the transportation of cargo, and to specify that the person to whom delivery is to be made may be a consignee; amend the definition of shippers' association to make a grammatical change; and amend the definition of through transportation to remove wording which does not affect the meaning of the definition. The Commission also proposes to add definitions for destination scope and inland division. Finally, the Commission proposes to remove as unnecessary the definitions of joint rates, commodity description number, local rates, points of rest, and shippers' association.

3. § 520.3 Publication Responsibilities

Pursuant to § 520.3(d), the Commission requires that all common carriers publish a tariff in an automated tariff system and provide the location of that tariff to the Commission prior to the commencement of common carrier service. However, some NVOCCs will publish a tariff upon initially being licensed, but later allow the tariff to lapse and fall out of compliance. The Commission believes adding notice in § 520.3 of the consequences which already exist pursuant to 46 CFR 515.1 and 515.14 for failure to maintain a tariff could improve tariff compliance. The Commission therefore proposes to add a provision to § 520.3 that specifies the failure to maintain a tariff will result in the revocation of an NVOCC's license or suspension of a foreign-based NVOCC's registration. In addition, the Commission proposes to change the term used for the person a common carrier may use to meet their publication requirements from ''agent'' to ''publisher''; include the common carrier's email address in the list of items provided to the Commission prior to commencement of common carrier service pursuant to a published tariff; and define the time period allowed for the common carrier to provide changes to its Form FMC–1 to the Commission to within 30 calendar days.

4. § 520.4 Tariff Contents

The Commission proposes to revise § 520.4(a)(3) to clarify that the ocean transportation intermediary that may receive compensation paid by a carrier or conference is an ocean freight forwarder as defined by section 3(17)(A) of the Shipping Act. In addition, the Commission proposes to: Use plain language to reword the regulation at § 520.4(a)(4) requiring that a tariff state each charge separately; revise § 520.4(a)(5) to state that sample copies of bills of lading must be legible; and revise § 520.4(a)(8) to state that commodity tariffs must contain a retrievable commodity index.

The Commission also proposes to delete § 520.4(e)(1) which describes voluntary coding for commodity descriptions. To streamline the rule and remove a non-mandatory regulation, the Commission proposes to delete paragraph (e)(1). Tariff publishers are still not required to use any numeric code to identify commodities and the Commission still encourages the use of the Harmonized Tariff Schedule of the United States for both the commodity coding and associated terminology (definitions). In addition, the regulations still address the use of numeric codes to identify commodities.

5. § 520.5 Standard Tariff Terminology

The Commission proposes to update the source for geographic names listed in tariffs because they are currently out of date and inaccurate.

[12] Docket No. 98–29, Final Rule and Interim Final Rule: Carrier Automated Tariff Systems, 64 FR 11225 (Mar. 8, 1999).

6. § 520.6 Retrieval of Information

The Commission proposes to revise the search capability requirement for the retrieval of tariff information to specify that a search for a commodity description must result in a commodity or retrievable commodity index list.

7. § 520.7 Tariff Limitations

The Commission proposes to revise for clarity the date on which a new conference member's participation in the conference tariff becomes effective and specify that the minimum time allowed to file an overage claim with a common carrier applies to claims filed by a shipper. The Commission also proposes to remove the regulation stipulating the methods to be used to compute the weight of green salted hides, in light of requirements mandated by the International Maritime Organization. In addition, the Commission proposes to add paragraph (h) to § 520.7 that states that NVOCCs may pass through certain charges received from ocean common carriers that are not under the control of the common carrier or conferences. The Commission clarifies that the charges must be clearly listed in the NVOCC's tariffs and not marked up above cost.

8. § 520.8 Effective Dates

The Commission proposes to change ''destination grouping'' to ''destination scope'' in § 520.8(b)(3), consistent with other references to ''destination scope'' in 46 CFR part 520.

9. § 520.9 Access to Tariffs

The Commission proposes to update the regulations under this section to remove references to obsolete technologies.

10. § 520.10 Integrity of Tariffs

The Commission proposes to revise the requirement to maintain historical tariff data in § 520.10(a) to define the time period that data must be made available to the Commission to within 45 days of a request. The Commission believes 45 days is a reasonable period of time for a carrier or a conference to respond to a request for archived data. The Commission also proposes grammatical corrections to the requirement that carriers provide tariff access to the Commission.

11. § 520.11 Non-Vessel-Operating Common Carriers

The Commission proposes to remove the current regulation that an NVOCC must note in its tariff that it does not tender cargo for co-loading. This regulation is considered to be an unnecessary burden on an NVOCC that does not co-load. The Commission also proposes to remove the current regulation that an NVOCC may not offer special co-loading rates for the exclusive use of other NVOCCs. This regulation is outdated in light of 46 CFR part 531—Negotiated Service Arrangements, and 46 CFR part 532—NVOCC Negotiated Rate Arrangements which allow an NVOCC to negotiate rates for the exclusive use of another NVOCC.

12. § 520.12 Time/Volume Rates

The Commission proposes to clarify the requirements applicable to time/volume rates. The Commission also proposes revisions that clarify that common carriers or conferences may cancel time/volume rates when no shipper accepts these rates within thirty (30) days after the rates are published.

13. § 520.13 Exemptions and Exceptions

The Commission proposes to make change to update the governing rules of this part, and the requirements for Department of Defense cargo. The Commission also proposes to remove references to a business no longer in existence.

14. § 520.14 Special Permission

The Commission proposes to add a regulation which specifies the documents required when requesting confidential treatment of an application for special permission and update the process for submission and payment of applications for special permission.

II. Public Participation

How do I prepare and submit comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the docket, please include the docket number of this document in your comments.

You may submit your comments via email to the email address listed above under **ADDRESSES**. Please include the docket number associated with this notice and the subject matter in the subject line of the email. Comments should be attached to the email as a Microsoft Word or text-searchable PDF document.

How do I submit confidential business information?

The Commission will provide confidential treatment for identified confidential information to the extent allowed by law. If your comments contain confidential information, you must submit the following by email to the address listed above under **ADDRESSES**:

1. A transmittal letter requesting confidential treatment that identifies the specific information in the comments for which protection is sought and demonstrates that the information is a trade secret or other confidential research, development, or commercial information.

2. A confidential copy of your comments, consisting of the complete filing with a cover page marked ''Confidential-Restricted,'' and the confidential material clearly marked on each page.

3. A public version of your comments with the confidential information excluded. The public version must state ''Public Version—confidential materials excluded'' on the cover page and on each affected page and must clearly indicate any information withheld.

Will the Commission consider late comments?

The Commission will consider all comments received before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments received after that date.

How can I read comments submitted by other people?

You may read the comments received by the Commission at the Commission's Electronic Reading Room at the addresses listed above under **ADDRESSES**.

III. Rulemaking Analyses and Notices

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601–612, provides that whenever an agency is required to publish a notice of proposed rulemaking under the Administrative Procedure Act (APA), 5 U.S.C. 553, the agency must prepare and make available for public comment an initial regulatory flexibility analysis (IRFA) describing the impact of the proposed rule on small entities, unless the head of the agency certifies that the rulemaking will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 603, 605.

The proposed rule would require all common carriers to provide free tariff access, which the Commission believes will provide a benefit by ensuring there are minimal constraints to inhibit the shipping public from obtaining pricing information for ocean transportation. As referenced earlier, advancements in technology have significantly eased the burden on common carriers to make

their tariffs available to the public, and many carriers are already providing their tariffs to the public free of charge. The rule also provides flexibility for NVOCCs to pass through to their customers charges assessed by other entities, which allows the NVOCC to recover payments made on behalf of its shipper. In addition, the rule provides a documentation annotation requirement for shipments arranged by two or more NVOCCs. This requirement provides information to the beneficial cargo owner which allows for a more expedient determination of cargo status and location and places no additional burden on the NVOCC.

Because the costs to comply with this rule are minimal and few small entities are currently non-compliant, the proposed rule would not have a significant economic impact on a substantial number of small entities. For these reasons, the Chairman of the Federal Maritime Commission certifies that if this rule is promulgated, it would not have a significant economic impact on a substantial number of small entities.

Congressional Review Act

The rule is not a ''major rule'' as defined by the Congressional Review Act, codified at 5 U.S.C. 801 *et seq*. The rule will not result in: (1) An annual effect on the economy of $100,000,000 or more; (2) a major increase in costs or prices; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign based companies. 5 U.S.C. 804(2).

National Environmental Policy Act

The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4347) requires Federal agencies to consider the environmental impacts of proposed major Federal actions significantly affecting the quality of the human environment, as well as the impacts of alternatives to the proposed action. When a Federal agency prepares an environmental assessment, the Council on Environmental Quality (CEQ) NEPA implementing regulations (40 CFR parts 1500 through 1508) require it to ''include brief discussions of the need for the proposal, of alternatives [. . .], of the environmental impacts of the proposed action and alternatives, and a listing of agencies and persons consulted.'' 40 CFR 1508.9(b). This section serves as the Commission's Draft Environmental Assessment (Draft EA) for the proposed changes to 46 CFR part 520.

Upon completion of an environmental assessment, it was determined that the proposed rule will not constitute a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.,* and that preparation of an environmental impact statement is not required. This Finding of No Significant Impact (''FONSI'') will become final within 10 days of publication of this notice in the **Federal Register** unless a petition for review is filed by any of the methods described in the **ADDRESSES** section of the document. The FONSI and environmental assessment are available for inspection at the Commission's Electronic Reading Room at: *https://www2.fmc.gov/readingroom/proceeding/21-03/.*

This document sets forth the purpose of and need for this action. The purpose of this rulemaking is to update current regulations to reflect changes in industry practices. The rulemaking also proposes to remove the cost burden to the public associated with access to Carrier Automated Tariffs. Lastly, the rulemaking makes updates and clarifications to current regulations, which are largely technical.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) (PRA) requires an agency to seek and receive approval from the Office of Management and Budget (OMB) before collecting information from the public.[13] The agency must submit collections of information in proposed rules to OMB in conjunction with the publication of the notice of proposed rulemaking.[14]

The information collection requirements associated with the carrier automated tariffs requirements in part 520 are currently authorized under OMB Control Number 3072–0064. In compliance with the PRA, the Commission has submitted the proposed revised information collection to the Office of Management and Budget and is requesting comment on the proposed revision.

With the proposed addition of a new 46 CFR 520.7(a)(3)(iv), there will be a shift in burden when NVOCCs can potentially direct shippers to existing VOCC tariffs for certain specific surcharges as opposed to listing those surcharges individually. However, the Commission believes that this shift in burden will not increase or decrease the overall industry burden. Although under the proposed rule shippers may be required to review a VOCC tariff alongside an NVOCC tariff, the NVOCC will no longer need to maintain a tariff precisely matching the terms of the chosen VOCC. It will not have a significant impact on members of the shipping public.

In its proposed addition of a new 46 CFR 520.11(d), the Commission is proposing an information collection burden for those NVOCCs issuing bills of lading on FCL shipments where they would place the cargo in the control of a different NVOCC. This requirement of placing this information in the document is *de minimis,* and the Commission believes that current industry best practices already in place mean that this change would not impact NVOCCs.

Title: 46 CFR part 520—Carrier Automated Tariff Systems and Related Form FMC–1.

OMB Control Number: 3072–0064.

Abstract: 46 U.S.C. 40502 and 46 CFR part 520 requires common carriers and conferences of common carriers to publish tariffs to be made available to the public in automated tariff systems.

Current Action: The proposed rule would clarify, modernize and update the current regulations.

Type of Request: Revision of a previously approved collection.

Needs and Uses: The Commission requires tariffs to be made available to ensure compliance with the Shipping Act of 1984.

Frequency: The frequency of publishing and maintaining data in tariffs is determined by the common carrier and its customers. It is the common carrier's responsibility to ensure that the rates and terms applicable to a shipment are published prior to the receipt of cargo for that shipment.

Type of Respondents: Common carriers or their duly appointed agents are required make tariffs available to the public for inspection.

Number of Annual Respondents: The Commission does not anticipate that the proposed revisions would affect the number of respondents. The Commission anticipates an annual respondent universe of 6,331 common carriers.

Estimated Time per Response: The Commission does not anticipate that the proposed revisions would affect the estimated time per response, which would continue to range from .0167 to 2 person-hours for tariff content requirements, notification and filing requirements, and reporting and recordkeeping requirements contained in the regulations, and 0.5 person-hours for completing Form FMC–81.

[13] 44 U.S.C. 3507.

[14] 5 CFR 1320.11.

Total Annual Burden: The Commission does not anticipate that the proposed revisions would affect the number of tariffs made publicly available or the burden associated with each tariff and, therefore, would not affect the total annual burden The Commission estimates the total person-hour burden at 2,509 person-hours.

Comments are invited on:

- Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility;
- Whether the Commission's estimate for the burden of the information collection is accurate;
- Ways to enhance the quality, utility, and clarity of the information to be collected;
- Ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Please submit any comments, identified by the docket number in the heading of this document, by the methods described in the **ADDRESSES** section of this document.

Executive Order 12988 (Civil Justice Reform)

This proposed rule meets the applicable standards in E.O. 12988 titled, ''Civil Justice Reform,'' to minimize litigation, eliminate ambiguity, and reduce burden. Section 3(b) of E.O. 12988 requires agencies to make every reasonable effort to ensure that each new regulation: (1) Clearly specifies the preemptive effect; (2) clearly specifies the effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct, while promoting simplification and burden reduction; (4) clearly specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. This document is consistent with that requirement.

Regulation Identifier Number

The Commission assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda). The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda, available at *https://www.reginfo.gov/public/do/eAgendaMain.*

List of Subjects in 46 CFR Part 520

Freight, Maritime carriers, Intermodal transportation, Report and recordkeeping requirements.

For the reasons set forth in the preamble, the Federal Maritime Commission proposes to amend 46 CFR part 520 as follows:

PART 520—CARRIER AUTOMATED TARIFFS

■ 1. The authority citation for part 520 continues to read as follows:

Authority: 5 U.S.C. 553; 46 U.S.C. 305, 40101–40102, 40501–40503, 40701–40706, 41101–41109.

■ 2. Amend § 520.2 by:
■ a. Removing the word ''shall'' from the introductory text paragraph;
■ b. Revising the definitions of ''Bulk cargo'', ''Co-loading'', ''Combination rate'', ''Commodity description'', ''Controlled carrier'', ''Harmonized system'', ''Location group'', ''Publisher'', ''Retrieval'', ''Rules'', ''Shipper'', ''Tariff number'', ''Tariff rate item(''TRI'')'' and ''Through transportation'';
■ c. Adding in alphabetical order the definitions of ''destination scope'', ''inland division'' and ''Through date'';
■ d. Removing definitions of ''cCommodity description number'', ''Joint rates'', ''Local rates'', ''Point of rest'', ''Shippers' association''; ''Thru date''.

The revisions and additions read as follows:

§ 520.2 Definitions.

The following definitions apply to this part:

* * * * *

Bulk cargo means cargo that is loaded and carried in bulk without mark or count in a loose unpackaged form, having homogeneous characteristics. Bulk containerized cargo tendered by the shipper is subject to mark and count and is, therefore, subject to the requirements of this part.

Co-loading means the combining of less than container loads of cargo by two or more NVOCCs for tendering to an ocean common carrier under the name of one or more of the NVOCCs.

Combination rate means a rate for a shipment moving under intermodal transportation which is computed by the addition of a Tariff Rate Item (''TRI'') and an inland rate applicable from/to inland points not covered by the TRI.

* * * * *

Commodity description means a comprehensive description of a commodity listed in a tariff, including a brief definition of the commodity, that may be identified by a specific number.

* * * * *

Controlled carrier means an ocean common carrier that is, or whose operating assets are, directly or indirectly owned or controlled by a government; ownership or control by a government will be deemed to exist with respect to any common carrier if:

* * * * *

Destination scope means a location group defining the geographic range of cargo destinations covered by a tariff.

* * * * *

Harmonized System means the Harmonized Tariff Schedule of the United States, published by the U.S. International Trade Commission, and Schedule B, administered by the U.S. Census Bureau.

Inland division means the amount paid by a common carrier to an inland carrier for the inland portion of through transportation offered to the public by the common carrier.

* * * * *

Location group means a logical collection of geographic points, ports, states/provinces, countries, or combinations thereof, which is primarily used to identify, by location group name, a group that represents tariff origin and/or destination scope and TRI origin and/or destination.

* * * * *

Publisher means a person authorized by a common carrier to publish or amend tariff information.

* * * * *

Retrieval means the process by which a person accesses a tariff and interacts with the carrier's or publisher's system on a transaction-by-transaction basis to retrieve published tariff matter.

* * * * *

Rules means the stated terms and conditions set by *a common carrier or a conference of common carriers* which govern the application of tariff rates, charges and other matters.

* * * * *

Shipper means:

(1) A cargo owner;

(2) The person for whose account the ocean transportation of cargo is provided;

(3) The person to whom delivery is to be made

(4) A shipper's association meaning a group of shippers that consolidates or distributes freight on a nonprofit basis for the members of the group to obtain carload, truckload, or other volume rates or service contracts; or

(5) An NVOCC that accepts responsibility for payment of all charges applicable under the tariff or service contract.

* * * * *

Tariff number means a unique 3-digit number assigned by the publisher to distinguish it from other tariffs. Tariffs must be identified by the 6-digit organization number plus the user-assigned tariff number (*e.g.,* 999999–001) or a Standard Carrier Alpha Code (''SCAC'') plus the user-assigned tariff number.

Tariff rate item (''TRI'') means a single freight rate, in effect on and after a specific date or for a specific time period, for the transportation of a stated cargo quantity, which moves from origin to destination under a single specified set of transportation conditions, such as container size or temperature.

* * * * *

Through date means the date after which an amendment to a tariff element is designated by the publisher to be unavailable for use and the previously effective tariff element automatically goes back into effect.

* * * * *

Through transportation means continuous transportation between origin and destination, for which a through rate is assessed and which is offered or performed by one or more carriers, at least one of which is a common carrier, between a United States *port or point* and a foreign *port or point.*

* * * * *

■ 3. Revise § 520.3 to read as follows:

§ 520.3 Publication responsibilities.

(a) *General.* Unless otherwise exempted or excepted by § 520.13, all common carriers and conferences must keep open for public inspection, in automated tariff systems, tariffs showing all rates, charges, classifications, rules, and practices between all points or ports on their own routes and on any through transportation route that has been established.

(b) *Conferences.* Conferences must publish, in their automated tariff systems, rates offered pursuant to independent action by their members and may publish any open rates offered by their members. Alternatively, open rates may be published in individual tariffs of conference members.

(c) *Publishers.* Common carriers or conferences can use publishers to meet their publication requirements under this part.

(d) *Notification.* (i) Prior to the commencement of common carrier service pursuant to a published tariff, each common carrier and conference must electronically submit to BTA, Form FMC–1 via the Commission's website at *www.fmc.gov.* (ii) The common carrier and conference must include on Form FMC–1 its organization name, organization number, home office address, name, email address and telephone number of firm's representative, the location of its tariffs, and the publisher, if any, used to maintain its tariffs. (iii) Any changes to the above information must be transmitted to BTA within 30 calendar days. (iv) The Commission will provide a unique organization number to new entities operating as common carriers or conferences in the U.S. foreign commerce.

(e) *Location of tariffs.* The Commission will publish on its website, *www.fmc.gov,* a list of the locations of all common carrier and conference tariffs.

(f) *NVOCC failure to update tariff.* Failure to maintain a tariff will result in revocation of an NVOCC's license or suspension of a foreign-based NVOCC's registration.

■ 4. Amend § 520.4 by:

■ a. Removing in introductory paragraph (a), paragraphs (b) through (d), and (h) the word ''shall'' and adding in its place the word ''must'';

■ b. Revising paragraphs (a)(3) through (5), (8), (f)(5), (g), and (i);

■ c. Removing paragraph (e)(1);

■ d. Redesignating paragraphs (e)(2) and (3) as paragraphs (e)(1) and (2) respectively;

■ e. Replacing the word ''shall'' in newly redesignated paragraphs (e)(1), (e)(2)(ii), and (iii) with the word ''must''; and

■ f. Revising newly redesignated paragraph (e)(2)(i).

The revisions read as follows:

§ 520.4 Tariff contents.

(a) * * *

(3) State the level of compensation, if any, to be paid by a carrier or conference to an ocean freight forwarder, as defined by section 3(17)(A) of the Act (46 U.S.C. 40102(19));

(4) State separately each terminal or other charge, privilege, or facility under the control of the carrier or conference and any rules that in any way change, affect, or determine any part or the total of the rates or charges;

(5) Include sample copies of any bill of lading showing legible terms and conditions, contract of affreightment and/or other document evidencing the transportation agreement;

* * * * *

(8) For commodity tariffs, also contain a retrievable commodity index, commodity descriptions and tariff rate items.

* * * * *

(e) * * *

(2) *Commodity index.* (i) Common carriers or their publishers must have at least one similar index entry which will logically represent the commodity within the alphabetical index for each commodity description it creates under this section. Common carriers or their publishers must create multiple entries in the index for articles with equally valid common use names, such as, ''Sodium Chloride,'' ''Salt, common,'' etc.

* * * * *

(f) * * *

(5) Origin and destination scopes or location groups;

* * * * *

(g) *Location groups.* In the primary tariff, or in a governing tariff, a publisher may define and create groups of cities, states, provinces, and countries (*e.g.,* location groups) or groups of ports (*e.g.,* port groups), which can be used in the construction of TRIs and other tariff objects, in lieu of specifying particular place names in each tariff item, or creating multiple tariff items which are identical in all ways except for place names.

* * * * *

(i) *Shipper requests.* Conference tariffs must contain clear and complete instructions, in accordance with the agreement's provisions, stating where and by what method shippers can file requests and complaints and how they can engage in consultation pursuant to section 5(b)(6)–(7) of the Act (46 U.S.C. 40303(b)(6)–(7)), together with a sample rate request form or a description of the information necessary for processing the request or complaint.

* * * * *

■ 5. Amend § 520.5 by

■ a. Removing in paragraph (a) the word ''may'' in the third sentence and adding it its place the word ''can''; and

■ b. Revising paragraph (b) to read as follows:

§ 520.5 Standard tariff terminology.

* * * * *

(b) *Geographic names.* Tariffs should employ locations (points) that are provided by the National Geospatial-Intelligence Agency or the Geographic Names Information System developed by the U.S. Geological Survey. Ports published or approved for publication in the World Port Index (Pub. 150) should also be used in tariffs. Tariff publishers can use geographic names

that are currently in use and have not yet been included in these publications.

■ 6. Amend § 520.6 by:

■ a. Removing in paragraphs (a), (c), and (d) the word ''shall'' and adding in its place the word ''must''; and

■ b. Revising paragraphs (b), (e), and (f) to read as follows:

§ 520.6 Retrieval of information.

* * * * *

(b) *Search capability.* Publisher must provide the capability to search for tariff matter by non-case sensitive text search. Text search matches for commodity descriptions must result in a commodity or retrievable commodity index list.

* * * * *

(e) *Basic ocean freight.* The minimum rate display for tariffs must consist of the basic ocean freight rate and a list of all assessorial charges that apply for the retriever-entered shipment parameters. The tariff must indicate when other rules or charges apply to a shipment under certain circumstances.

(f) *Displays.* All displays of individual tariff matter must include the publication date, effective date, amendment code (use codes in Appendix A of this part) and object name or number. When applicable, a through date or expiration date must also be displayed. Use of ''S'' as an amendment code must be accompanied by a Commission issued special permission number.

■ 7. Amend § 520.7 by:

■ a. Removing in paragraphs (a), (b), and (c) the word ''shall'' and adding in its place the word ''must'';

■ b. Removing in paragraphs (a)(3)(ii) and (iii) the word ''may'' and adding in its place the word ''can'';

■ c. Adding a new paragraph (a)(3)(iv);

■ d. Removing paragraph (e).

■ e. Redesignating paragraphs (f) through (h) as paragraphs (e) through (g);

■ f. Revising newly redesignated paragraphs (e) and (f); and

■ g. Adding a new paragraph (h).

The additions and revisions read as follows:

§ 520.7 Tariff limitations.

(a) * * *

(3) * * *

(iv) An NVOCC may cross-reference an ocean common carrier tariff for the purpose of charging its shipper the ocean common carrier's surcharges and assessorial charges, provided the named charges are clearly listed in the NVOCC's tariff, and not marked up above cost.

* * * * *

(e) *Conference situations.* (1) New members of a conference must cancel any independent tariffs applicable to the trades served by the conference, within ninety (90) days of membership in the conference. Individual conference members can publish their own separate open rate tariffs. A new member's participation in the conference tariff is effective on the date notice of membership is published in the conference tariff, unless a later effective date is specified.

* * * * *

(f) *Overcharge claims.* (1) A tariff must not limit the filing of overcharge claims by a shipper with a common carrier to a period of less than three (3) years from the accrual of the cause of action.

(2) The acceptance of any overcharge claim cannot be conditioned upon the payment of a fee or charge.

(3) A tariff must not require that overcharge claims based on alleged errors in weight, measurement, or description of cargo be filed before the cargo has left the custody of the common carrier.

* * * * *

(h) *Charges assessed by ocean common carriers to non-vessel operating common carriers.* NVOCCs may pass through charges received from ocean common carriers for terminal services, canal tolls, additional charges, or other provisions which are not under the control of the common carrier or conferences, and for which the ocean common carrier merely acts as a collection agent. The charges must be clearly listed in the NVOCC's tariffs, and not marked up above cost.

■ 8. Amend § 520.8 by:

■ a. Revising paragraph (b)(3) and (4); and

■ b. Removing in paragraph (c) the wording ''shall be'' and adding in its place the word ''are''.

The revisions read as follows:

§ 520.8 Effective dates.

* * * * *

(b) * * *

(3) The addition of a port or point to a previously existing origin or destination scope; or

(4) Changes in charges which are not under the control of the common carrier or conference (including terminal services, canal tolls, additional charges, or other provisions), for which the carrier or conference merely act as a collection agent for such charges, and the agency making such changes does so without notifying the tariff owner. The carrier must not mark up these charges above cost.

* * * * *

■ 9. Revise § 520.9 to read as follows:

§ 520.9 Access to tariffs.

(a) *Methods to access.* Carriers and conferences must provide access to their published tariffs, via the internet.

(b) *Internet connection.* (1) The internet connection requires that systems provide a uniform resource locator (''URL'') internet address (*e.g., https://www.tariffsrus.com* or *https://1.2.3.4*). (2) Carriers or conferences must ensure that their internet service providers provide static internet addresses.

(c) *Tariff availability.* (1) Tariffs must be made available to any person without time, quantity, or other limitations.

(2) Carriers and conferences must provide free access to their tariff publication system.

(3) Tariff publication systems must provide user instructions for access to tariff information.

(d) *Federal agencies.* Carriers and conferences must not assess any access charges against the Commission or any other Federal agency.

(e) *User identifications.* Carriers and conferences must provide the Commission with the requisite documentation and the number of user identifications and passwords required to facilitate the Commission's access to their systems, if those systems require such identifications and passwords.

■ 10. Amend § 520.10 by revising paragraphs (a), (b), and (d) to read as follows:

§ 520.10 Integrity of tariffs.

(a) *Historical data.* Carriers and conferences must keep the data that appeared in their tariff publication systems for a period of five (5) years from the date such information is superseded, canceled or withdrawn, and must provide on-line access to such data for two (2) years. After two (2) years, such data must be retained on-line or in other electronic form, and must be made available to any person or the Commission upon request within 45 days, unless otherwise agreed. Carriers and conferences may charge a reasonable fee for the provision of historical data, not to exceed the fees for obtaining such data on-line. Carriers and conferences must not charge a fee to the Commission or any other Federal agency.

(b) *Access date capability.* Each tariff must provide the capability for a retriever to enter an access date, *i.e.,* a specific date for the retrieval of tariff data, so that only data in effect on that date would be directly retrievable. This capability would also align any rate adjustments and assessorial charges that were effective on the access date for rate calculations and designation of

applicable surcharges. The access date also applies to the alignment of tariff objects for any governing tariffs.

* * * * *

(d) *Access to systems.* Carriers and conferences must provide the Commission reasonable access to their automated systems and records for the Commission's review.

■ 11. Amend § 520.11 by:

■ a. Removing in the introductory text in paragraphs (a) and (c) the word ''shall'' and adding in its place the word ''must'';

■ b. Revising paragraphs (a)(5) and (b);

■ c. Removing paragraph (c)(1)(i);

■ d. Redesignating paragraphs (c)(1)(ii) and (iii) as (c)(1)(i) and (ii), respectively;

■ e. Removing in newly redesignated paragraph (c)(1)(i) the word ''shall'' and adding in its place the word ''must'';

■ f. Revising newly redesignated paragraph (c)(1)(ii);

■ g. Removing paragraphs (c)(2) and (3); and

■ h. Adding paragraph (d).

The revisions and addition read as follows:

§ 520.11 Non-vessel-operating common carriers.

(a) * * *

(5) The number of its bond, insurance policy, or guaranty; and

* * * * *

(b) *Agent for service.* Every NVOCC not in the United States must state the name and address of the person in the United States designated under part 515 of this chapter as its legal agent for service of process, including subpoenas. The NVOCC must also state that in any instance in which the designated legal agent cannot be served because of death, disability, or unavailability, the Commission's Secretary will be deemed to be its legal agent for service of process.

(c)(1) * * *

(ii) If two NVOCCs enter into a co-loading arrangement which results in a shipper-to-carrier relationship, the tendering NVOCC must describe its co-loading practices and specify its responsibility to pay any charges for the transportation of the cargo. A shipper-to-carrier relationship is presumed to exist where the receiving NVOCC issues a bill of lading to the tendering NVOCC for carriage of the co-loaded cargo.

(d) *Annotation.* An NVOCC which tenders cargo to another NVOCC must annotate each applicable bill of lading with the identity of any other NVOCC to which the shipment has been tendered. Such annotation must be shown on the face of the bill of lading in a clear and legible manner.

■ 12. Amend § 520.12 by:

■ a. Revising paragraphs (a), (c), and (e); and

■ b. Removing in paragraphs (b)(2) and (d) the word ''shall'' and adding in its place the word ''must''.

The revisions read as follows:

§ 520.12 Time/Volume rates.

(a) *General.* Common carriers or conferences must publish in their tariffs, rates that are conditioned upon the receipt of a specified aggregate volume of cargo or aggregate freight revenue over a specified period of time.

* * * * *

(c) *Accepted rates.* Once a time/volume rate is accepted by one shipper, it will remain in effect for the time specified, without amendment. If no shipper gives notice within 30 days of publication, a common carrier or conference may cancel the time/volume rate.

* * * * *

(e) *Liquidated damages.* Time/volume rates must not impose or attempt to impose liquidated damages on any shipper that moves cargo under the rate. Carriers and agreements must rerate cargo moved at the applicable tariff rate, if a shipper fails to meet the requirements of the time/volume offer.

■ 13. Amend § 520.13 by:

■ a. Revising paragraphs (a), (b)(2), (c)(4), (d)(2)(ii)(A), and (d)(2)(ii)(B)(1); and

■ b. Removing paragraph (d)(2)(iii).

The revisions read as follows:

§ 520.13 Exemptions and exceptions.

(a) *General.* Exemptions from the requirements of this part are governed by section 16 of the Act (46 U.S.C. 40103) and the Commission's Rules of Practice and Procedure, § 502.92, of this chapter.

(b) * * *

(2) *Controlled carriers in foreign commerce.* A controlled common carrier is exempt from the provisions of this part exclusively applicable to controlled carriers when:

* * * * *

(c) * * *

(4) *Department of Defense cargo.* Transportation of U.S. Department of Defense cargo moving in foreign commerce under terms and conditions negotiated and approved by the Surface Deployment and Distribution Command and published in a universal service contract. An exact copy of the universal service contract, including any amendments thereto, must be provided to the Commission in electronic format upon request.

* * * * *

(d) * * *

(2) * * *

(ii) *British Columbia and Puget Sound Ports; rail cars*—(A) *Through rates.* Transportation by water of cargo moving in rail cars between British Columbia, Canada and United States ports on Puget Sound, and between British Columbia, Canada and ports or points in Alaska, if the cargo does not originate in or is not destined to foreign countries other than Canada, and if:

* * * * *

(B)(*1*) This exemption does not apply to cargo originating in or destined to foreign countries other than Canada; and

* * * * *

■ 14. Amend § 520.14 by:

■ a. Revising paragraphs (b), (c)(1) through (3), and (d); and

■ b. Adding paragraph (c)(3)(iv).

The revisions and addition read as follows:

§ 520.14 Special permission

* * * * *

(b) *Clerical errors.* Typographical and/or clerical errors constitute good cause for the exercise of special permission authority. Every special permission application must plainly specify the error and present clear evidence of its existence. The special permission application must also include a full statement of the attending circumstances. The special permission application must be submitted with reasonable promptness after publishing the defective tariff material.

(c) *Application.* (1) Applications for special permission to establish rate increases or decreases on less than statutory notice or for waiver of the provisions of this part must be made by the common carrier, conference, or agent for publishing. Every such application must be submitted to the Bureau of Trade Analysis and be accompanied by a filing fee of $313.

(2) Applications for special permission must be made by letter, submitted via mail or email, followed promptly by electronic payment of the filing fee.

(3) Applications for special permission must contain the following information:

* * * * *

(iv) A statement that identifies any part(s) of the application for which confidential treatment is sought and a justification for such confidential treatment. In such cases, the applicant must provide both a confidential version and a public version of the application.

(d) *Implementation.* The authority granted by the Commission must be

used in its entirety, including the prompt publishing of the material for which permission was requested. Applicants must use the special case number assigned by the Commission with the symbol ''S.''

By the Commission.

William Cody,

Secretary.

[FR Doc. 2022–09592 Filed 5–9–22; 8:45 am]

BILLING CODE 6730–02–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 350

[Docket No. FMCSA–2022–0079]

State Inspection Programs for Passenger-Carrier Vehicles

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Request for comment on withdrawn advance notice of proposed rulemaking.

SUMMARY: On November 15, 2021, the Infrastructure Investment and Jobs Act (IIJA) was enacted, directing FMCSA to solicit additional comment on the Agency's April 27, 2016 advance notice of proposed rulemaking (ANPRM) concerning the potential establishment of requirements for States to implement annual inspection programs for commercial motor vehicles (CMVs) designed or used to transport passengers (passenger-carrying CMVs).

DATES: Comments must be received on or before June 9, 2022.

ADDRESSES: You may submit comments identified by Docket Number FMCSA–2022–0079 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov/docket/FMCSA-2022-0079/document.* Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Loretta Bitner, Chief, Passenger Carrier Safety Division, Office of Safety, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 385–2428, *Loretta.Bitner@dot.gov.* If you have questions on viewing or submitting material to the docket, call Dockets Operations at (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

A. Submitting Comments

If you submit a comment, please include the docket number for this request for comment (FMCSA–2022–0079), indicate the specific section of this document to which your comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *https://www.regulations.gov/docket/FMCSA-2022-0079/document,* click on this request for comment, click ''Comment,'' and type your comment into the text box on the following screen.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the request for comment, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as ''PROPIN'' to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket. Submissions containing CBI should be sent to Mr. Brian Dahlin, Chief, Regulatory Analysis Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket.

B. Viewing Comments and Documents

To view any documents mentioned as being available in the docket, go to *https://www.regulations.gov/docket/FMCSA-2022-0079/document* and choose the document to review. To view comments, click this request for comment, then click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy

DOT solicits comments from the public to better inform its regulatory process, in accordance with 5 U.S.C. 553(c). DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL 14—Federal Docket Management System), which can be reviewed at *www.transportation.gov/privacy.*

II. Background

On April 27, 2016, in accordance with section 32710 of the Moving Ahead for Progress in the 21st Century Act (Pub. L. 112–141, 126 Stat. 405, 815), FMCSA published in the **Federal Register**, an ANPRM titled ''State Inspection Programs for Passenger-Carrier Vehicles'' (Docket No. FMCSA–2014–0470, 81 FR 24769). The ANPRM

announced that FMCSA was considering a requirement that States establish a program for annual inspections of passenger-carrying CMVs. FMCSA requested information from all interested parties that would enable the Agency to assess the risks associated with improperly maintained or improperly inspected passenger-carrying CMVs. The ANPRM also sought public comments concerning the effectiveness of the current FMCSA annual inspection standards, and data on the potential costs and benefits of a Federal requirement for each State to implement a mandatory inspection program. FMCSA inquired about how the Agency might incentivize States to adopt such programs.

The comment period closed on June 27, 2016, and 22 comments were received, with a plurality (10 of 22) of commenters expressing general opposition to the mandatory State inspection requirement discussed in the ANPRM. After reviewing all the public comments, FMCSA determined there was not enough data and information available to support moving forward with a rulemaking action. As a result, on May 1, 2017, the Agency withdrew the ANPRM.[1] (82 FR 20311)

On November 15, 2021, the IIJA was enacted, Public Law 117–58, 135 Stat. 429 (H.R. 3684, Nov. 15, 2021). Section 23008(a) directed the Agency, within 1 year after the date of enactment, to solicit additional comments on the ANPRM to determine if data and information exist to support moving forward with a rulemaking.

III. Request for Public Comment

As discussed above, FMCSA will use information gathered through this request for comment to further consider the issues associated with State inspections of passenger-carrying CMVs. Questions from the 2016 ANPRM are reprinted here to guide commenters in their responses.[2] The Agency encourages interested parties to provide information about the impact that such a rulemaking would have on State agencies that would be compelled to establish inspection programs, motor carriers' safety performance, operating costs, business practices, and any other aspects of transportation services provided by interstate passenger carriers.

FMCSA requests data on and responses to the following issues and questions. The Agency also encourages commenters to describe any applicable regulatory inspection process under which they operate.

Existing State Mandatory Vehicle Inspection Programs for Passenger-Carrying CMVs

1. Does your State or the States in which you register your passenger-carrying CMV conduct mandatory inspections of such vehicles? Please indicate the State(s) in which your passenger-carrying CMVs are registered.

2. What vehicle types are included in the mandatory passenger-carrying CMV inspection program (*e.g.,* motorcoaches, school buses, mini-buses, 9- to 15-passenger vans, etc.) and which are not included?

3. If your State has a mandatory program, briefly describe your inspection procedures and indicate which vehicle components are inspected.

4. How many total inspections are performed by your State annually for each of the following types of vehicles?

a. Motorcoaches
b. School buses
c. Mini-buses
d. 9- to 15-passenger vans
e. Other

5. What is the estimated time required to complete each vehicle inspection?

6. What procedures are used to record the vehicle inspection?

7. If a vehicle does not pass an inspection, who addresses the issues? If it is done by someone other than the inspecting entity, is there a second inspection after the issues are addressed? On average, how many follow up inspections does it take to pass a vehicle?

8. Are mandatory vehicle inspections performed by State employees, by third-party inspectors authorized by the State, or by passenger carrier employees through a State-authorized self-inspection program?

9. If vehicle inspections are conducted by a State-authorized third party or by passenger-carrier employees authorized by the State, are there differences in safety outcomes between those conducted by State employees and those conducted by third-party inspectors or through a passenger carrier's State-authorized self-inspection facilities?

10. Are there any specific benefits or concerns related to using third-party inspectors or by others?

11. If inspections are conducted by third-party inspectors or by passenger carrier-employed mechanics or technicians, what oversight is or should be required?

12. Should self-inspection or third-party inspections be options for compliance with a mandatory State inspection?

13. How does/would the cost of inspections differ between those conducted by State employees or by third-party inspectors?

14. What might be other preferable options?

Measuring Effectiveness of Inspection Programs

15. Does your State have information on violations discovered during inspections that are attributable to maintenance issues that should have been found during a required vehicle inspection?

16. Has your State considered implementing a mandatory passenger-carrying CMV inspection program, but declined to do so? If so, what are your State's reasons for not implementing a program?

17. If your State imposes mandatory inspection of passenger-carrying CMVs, how is the effectiveness of that program measured?

18. What are the most common vehicle defects discovered during these mandatory vehicle inspections? What safety conclusions do you draw from the results of these inspections?

19. Has your State or organization collected data related to crashes, injuries, or fatalities attributable to improperly maintained or inspected passenger-carrying CMVs? If so, please provide summary information or links to detailed data associated with these areas.

20. Has the occurrence of passenger-carrying CMV-involved crashes, injuries, or fatalities before and after the implementation of a mandatory inspection requirement been evaluated? If so, please provide summary information or links to detailed data associated with these areas.

21. After a State inspection requirement was instituted, what changes were observed over time in the number of safety violations discovered during inspections, if any.

22. Do programs that inspect only a sample of vehicles have significantly different outcomes than those where all vehicles are inspected, please provide examples of how they differ?

Inspection Facilities and Locations

23. Where does your State conduct mandatory passenger-carrying CMV

[1] The ANPRM and the ANPRM withdrawal are available in the docket for this request for comments.

[2] The questions reprinted here are identical to those in the ANPRM with the exception of two locations where the term ''bus'' is replaced with the more accurate term ''passenger-carrying CMV'' and removal of question 40, which the Agency now deems irrelevant.

inspections (*e.g.,* State owned/leased facility, third party facility, carrier's place of business, or other type of facility)?

24. Where should mandatory passenger-carrying CMV inspections be performed?

25. If mandatory passenger-carrying CMV inspections are conducted at the carrier's place of business, what accommodations must be made to ensure appropriate access (*e.g.,* pits, lifts, etc.) to conduct full inspections of motorcoaches and other large passenger vehicles?

26. How does facility location or accessibility for mandatory inspections impact inspections or compliance?

27. What delays may the State experience in completing mandatory inspections (*e.g.* lack of sufficient number of inspection facilities)?

Costs

28. What is the cost per mandatory vehicle inspection to the carrier?

29. Do inspection fees differ based on the type of vehicle being inspected?

30. Do vehicle inspection fees differ based on location of the inspections?

31. How much does it cost the State to establish and run inspection programs on an annual basis?

32. If a vehicle does not pass an inspection, is there an additional cost for the second inspection?

33. If fees are collected by the State, does the State dedicate the revenue to the administration of the program?

Uniformity of Mandatory Vehicle Inspection Programs

34. What qualifications should be applicable to individuals authorized to perform mandatory passenger-carrying CMV inspections?

35. Should minimum training elements be required for passenger-carrying CMV inspections? If so, how much training should be required and who should administer the training?

36. What should be the minimum vehicle components inspected under a mandatory passenger-carrying vehicle CMV inspection program?

37. How does the existence of different vehicle inspection requirements among the States affect carrier business practices?

38. How might business practices change under a uniform mandatory passenger-carrying vehicle CMV inspection program?

Current Federal Standards

39. How effective are existing Federal standards for the inspection of passenger-carrying CMVs in (1) mitigating the risks associated with improperly maintained vehicles and (2) ensuring the safe and proper operating condition of the vehicles?

Federal Authority

41. How should FMCSA incentivize the States to establish mandatory passenger-carrying CMV inspection programs?

Robin Hutcheson,

Deputy Administrator.

[FR Doc. 2022–09657 Filed 5–9–22; 8:45 am]

BILLING CODE 4910–EX–P

Notices

Federal Register
Vol. 87, No. 90
Tuesday, May 10, 2022

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

May 4, 2022.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by June 9, 2022 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Food Security Status and Well-Being of Nutrition Assistance Program (NAP) Participants in Puerto Rico.

OMB Control Number: 0584–NEW.

Summary of Collection: Following Hurricane Maria, Congress appropriated additional disaster relief funds provided by section 309 of Public Law 115–72 that were distributed through the Nutrition Assistance Program (NAP) to program participants in Puerto Rico. Under H.R. 2157, section 105, funds were appropriated for the Secretary of Agriculture to conduct an independent study, including a survey of NAP participants, to examine the food security, health status, and well-being of NAP participants and low-income residents in Puerto Rico.

Need and Use of the Information: FNS is conducting this study to establish baseline estimates of household food security status in Puerto Rico. FNS has identified five objectives for this study:

Produce descriptive statistics on key sociodemographic and economic variables, including household food security, in a representative sample of Puerto Rico households.

Produce descriptive statistics on key sociodemographic and economic variables, including household food insecurity, in multiple representative subsamples in Puerto Rico stratified according to the following classifications: NAP participants and low-income nonparticipants, adults aged 60 and older, disability status, employment status, and educational level.

Produce descriptive statistics for each subsample in Puerto Rico on key social, geospatial, and other policy-relevant elements of health and well-being associated with household food security.

Characterize the social context of food insecurity through in-depth interviews with individuals within the NAP participant and low-income nonparticipant subgroups. Each interview will ask the individual to consider the household or family, community and Federal food assistance, and disaster relief contexts.

Develop a detailed concept/problem map of the systemic factors that shape the implementation of the NAP program, particularly as a disaster relief tool. The concept mapping process will include data collection from key informants with knowledge of one or more of the stages of the Puerto Rican food and nutrition system: Production, processing, distribution, acquisition, preparation, consumption, digestion, transport, and metabolism.

Description of Respondents: Individuals/Households, State, Local, or Tribal government, Businesses or other for-Profits/Not-for-Profit Institutions.

Number of Respondents: 12,504.

Frequency of Responses: On Occasion.

Total Burden Hours: 4,994.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–09954 Filed 5–9–22; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

[Docket No. RUS–21–ELECTRIC–0017]

Notice of Request for Extension of a Currently Approved Information Collection

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice; comment requested.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the above-named agency to request Office of Management and Budget's (OMB) approval for an extension of a currently approved information collection in support of RUS Extensions of Payments of Principal and Interest.

DATES: Comments on this notice must be received by July 11, 2022.

FOR FURTHER INFORMATION CONTACT: Susan Woolard, Management Analyst, Rural Development Innovation Center—Regulations Management Division, USDA, 1400 Independence Avenue SW, South Building, Washington, DC 20250–1522. Telephone: (202) 720–9631. Email *susan.woolard@usda.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR part 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to

comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an existing information collection that the Agency is submitting to OMB for extension.

Comments

Comments are invited on: (a) Whether this collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) The accuracy of the Agency's estimate of the burden of the collection of information including the validity of the methodology and assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on those who respond, including through the use of appropriate automated, electronic, mechanical or other technological collection techniques, or other forms of information technology.

Comments may be sent by the Federal eRulemaking Portal: Go to *http://www.regulations.gov* and, in the lower ''Search Regulations and Federal Actions'' box, select ''RUS'' from the agency drop-down menu, then click on ''Submit.'' In the Docket ID column, select RUS–21–ELECTRIC–0017 to submit or view public comments and to view supporting and related materials available electronically. Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.

Title: 7 CFR part 1721, Extensions of Payments of Principal and Interest.

OMB Control Number: 0572–0123.

Type of Request: Extension of a currently approved collection.

Abstract: The Agency allows borrowers of loans made by RUS, under certain circumstances, to request extensions for the payment of principal and interest. The information collected under this package provides the information necessary for the Agency to make determinations of eligibility under section 12(a) of the Rural Electrification Act and section 236 of the Disaster Relief Act of 1970 (Pub. L. 91–606).

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 7.625 hours per response.

Respondents: Businesses, not-for-profit institutions and others.

Estimated Number of Respondents: 3.

Total Annual Responses: 8.

Estimated Number of Responses per Respondent: 2.67.

Estimated Total Annual Burden on Respondents: 61 hours.

Copies of this information collection can be obtained from Susan Woolard, Management Analyst, Innovation Center—Regulations Management Division, at (202) 720–9631. Email: *susan.woolard@usda.gov.*

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Christopher A. Mclean,

Acting Administrator, Rural Utilities Service.

[FR Doc. 2022–09978 Filed 5–9–22; 8:45 am]

BILLING CODE 3410–15–P

COMMISSION ON CIVIL RIGHTS

Sunshine Act Meeting Notice

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of Commission public business meeting.

DATES: Friday, May 13, 2022, 12:00 p.m. EST.

ADDRESSES: Meeting to take place by telephone and is open to the public: 877–222–5769; Conference ID code #333206.

FOR FURTHER INFORMATION CONTACT: Angelia Rorison: 202–376–8371; *publicaffairs@usccr.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Government in Sunshine Act (5 U.S.C. 552b), the Commission on Civil Rights is holding a meeting to discuss the Commission's business for the month. This business meeting is open to the public. Computer assisted real-time transcription (CART) will be provided. The web link to access CART (in English) on Friday, May 13, 2022, is *https://www.streamtext.net/player?event=USCCR.* Please note that CART is text-only translation that occurs in real time during the meeting and is not an exact transcript.

Meeting Agenda

I. Approval of Agenda
II. Business Meeting
  A. Presentations by State Advisory Committee Chairs on Released Reports and Memorandums
  B. Discussion and Vote on Advisory Committee Appointments
  C. Management and Operations
  • Staff Director's Report
III. Adjourn Meeting

Dated: May 6, 2022.

Angelia Rorison,

USCCR Media and Communications Director.

[FR Doc. 2022–10098 Filed 5–6–22; 4:15 pm]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Tennessee Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA) that a meeting of the Tennessee Advisory Committee to the Commission will hold a virtual debrief via Webex at 12:00 p.m. (CST) on Wednesday, June 8, 2022, web briefing on Voting and Civil Rights in Tennessee.

DATES: The meeting will be held on: Wednesday, June 8, 2022, 12:00 p.m. CST.

ADDRESSES:

Join from the meeting link: https://civilrights.webex.com/civilrights/j.php?MTID=m5be8c98e3252540f148315fc5dd26b4a

800–360–9505 USA Toll Free; Access Code: 2764 031 5006 #

FOR FURTHER INFORMATION CONTACT: Victoria Moreno at *vmoreno@usccr.gov* or by phone at 434–515–0204.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the WebEx link above. If joining only via phone, callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the call-in number found through registering at the web link provided above for the meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the respective meeting. Written comments may be emailed to Victoria Moreno at *vmoreno@usccr.gov.* All written comments received will be available to the public.

Persons who desire additional information may contact the Regional

Programs Unit at (202) 809–9618. Records and documents discussed during the meeting will be available for public viewing as they become available at the *www.facadatabase.gov.* Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Regional Programs Unit at the above phone number or email address.

Agenda

Wednesday, June 8, 2022; 12:00 p.m. (CST)

1. Welcome & Roll Call
2. Panel Debrief
3. Public Comment
4. Next Steps
5. Adjourn

Dated: May 4, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–09970 Filed 5–9–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the California Advisory Committee; Update

AGENCY: Commission on Civil Rights.

ACTION: Notice; revision to meeting type, update time and agenda.

SUMMARY: The Commission on Civil Rights published a notice in the **Federal Register** on Wednesday, April 6, 2022, concerning a business meeting of the California Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Brooke Peery, *bpeery@usccr.gov.*

Update: In the **Federal Register** on Wednesday, April 6, 2022, in FR Document Number 2022–07265, on page 19853, first and second columns, change the June 15, 2022, Business Meeting into a web Briefing.

Date: Wednesday, June 15, 2022, from 1:30 p.m. to 4:00 p.m. Pacific Time.

Webex Registration Link:

Agenda

I. Welcome & Opening Remarks

II. Panelist Testimony

III. Committee Q&A

IV. Public Comment

V. Adjournment

Dated: May 5, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–09974 Filed 5–9–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Virginia Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Virginia Advisory Committee (Committee) will hold a web meeting via WebEx on Tuesday, May 17, 2022, at 3:00 p.m. Eastern Time. The purpose of the meeting is to hear testimony from the Virginia Attorney General on police oversight and accountability in the state.

DATES: The meeting will be held on: Tuesday, May 17, 2022, at 3:00 p.m. Eastern Time.

ADDRESSES:

Online Registration: https://tinyurl.com/y8mva76e

Join by Phone: 1–800–360–9505 USA Toll Free; Access code: 2763 389 1656

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at *mwojnaroski@usccr.gov* or 1–202–618–4158.

SUPPLEMENTARY INFORMATION: Members of the public may listen to this discussion through the above call-in number (audio only) or online registration link (audio/visual). An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Individual who is deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Melissa Wojnaroski at *mwojnaroski@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Virginia Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call

II. Testimony on Police Oversight and Accountability: Attorney General of Virginia

III. Committee Q&A

IV. Public Comments

V. Adjournment

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given fewer than 15 calendar days prior to the meeting because of the exceptional circumstances of the speaking availability of the Attorney General.

Dated: May 4, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–09969 Filed 5–9–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Briefing of the California Advisory Committee; Update

AGENCY: Commission on Civil Rights.

ACTION: Notice; revision to meeting type, update time and agenda.

SUMMARY: The Commission on Civil Rights published a notice in the **Federal Register** on Wednesday, April 6, 2022, concerning a web briefing of the California Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Brooke Peery, *bpeery@usccr.gov.*

Update: In the **Federal Register** on Wednesday, April 6, 2022, in FR Document Number 2022–07262, on page 19852, first and second columns, change the May 16, 2022, web Briefing into a Business Meeting.

Date: Monday, May 16, 2022, from 1:30 p.m. to 3:00 p.m. Pacific Time.

Webex Registration Link: https://tinyurl.com/mrfyk6xn.

Agenda

I. Welcome & Roll Call

II. Approval of Minutes

III. Committee Discussion

IV. Public Comment

V. Adjournment

Dated: May 5, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–09975 Filed 5–9–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

RIN 0694–XC089

Request for Public Comments on Supply Chain Issues To Support the U.S.-EU Trade and Technology Council Secure Supply Chains Working Group

AGENCY: Bureau of Industry and Security, U.S. Department of Commerce.

ACTION: Extension of comment period.

SUMMARY: On April 6, 2022, the Bureau of Industry and Security (BIS) published the notice *Request for Public Comments on Supply Chain Issues To Support the U.S.-EU Trade and Technology Council Secure Supply Chains Working Group.* Today's notice extends the deadline for written comments to June 23, 2022. This extension is being made to allow for commenters to take into account any developments or announcements that may occur as a result of the United States-EU TTC second leaders' meeting scheduled for May 15–16, 2022 in France.

DATES: The comment period for the notice published April 6, 2022 at 87 FR 19854, is extended until June 23, 2022.

ADDRESSES: *Submissions:* You may submit comments, identified by docket number BIS–2021–0046 or RIN 0694–XC089, through the *Federal eRulemaking Portal: https://www.regulations.gov.* To submit comments via *https://www.regulations.gov,* enter the docket number BIS–2021–0046 on the home page and click ''Search.'' The site will provide a search results page listing all documents associated with this docket. Find a reference to this notice and click the button entitled ''Comment.'' For further information on using *https://www.regulations.gov,* please consult the resources provided on the website by clicking on ''FAQ.'' For further information regarding required comment formatting, please see the Solicited Written Comments and Requirements for Written Comments sections in the April 6 notice.

FOR FURTHER INFORMATION CONTACT: Kevin Coyne, U.S.-EU Trade and Technology Council Secure Supply Chains Working Group, Bureau of Industry and Security, at 202–482–4933, *ttc_secure_supply_chains@doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

On April 6, 2022, the Bureau of Industry and Security (BIS) published the notice *Request for Public Comments on Supply Chain Issues To Support the U.S.-EU Trade and Technology Council Secure Supply Chains Working Group.* (87 FR 19854). The April 6 notice specified that BIS requests public comments regarding how to advance supply chain resilience and security in key sectors: Semiconductors; solar photovoltaics; [1] critical minerals and materials including rare earth magnets,[2] lithium-ion batteries,[3] and material inputs to semiconductors; [4] and pharmaceuticals [5] to inform the work of the United States-European Union (EU) Trade and Technology Council (TTC) Secure Supply Chains Working Group. The Working Group is tasked with increasing transparency of supply and demand, mapping respective existing sectoral capabilities, exchanging information on policy measures and research and development priorities, and cooperating on strategies to promote supply chain resilience, security and diversification.

Extension of Comment Period Deadline

The April 6 notice included a comment period deadline of May 23, 2022. The Department of Commerce has determined at this time that it is warranted to extend the comment period by one month to allow for commenters to take into account any developments or announcements that may occur as a result of the United States-EU TTC second leaders' meeting scheduled for May 15–16, 2022 in France. Today's notice specifies that comments may be submitted at any time but must be received by June 23, 2022, to be considered.

Solicited Written Comments

BIS welcomes public comments on how best to achieve the four primary tasks of the Secure Supply Chains Working Group described above. While BIS invites input from all interested parties, it is particularly interested in obtaining information from foreign and domestic entities that actively participate in semiconductors, solar photovoltaics, critical minerals and materials, and pharmaceuticals supply chains. Interested parties are invited to submit written comments, data, analyses, or information pertinent to this request to BIS no later than June 23, 2022. See the April 6 notice for additional details on the U.S.-EU TTC and the request for public comments.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2022–10033 Filed 5–9–22; 8:45 am]

BILLING CODE 3510–33–P

[1] Solar photovoltaics include materials and production tools for the manufacturing of solar components.

[2] Critical minerals include neodymium and dysprosium.

[3] Critical minerals include lithium, cobalt, class 1 nickel, manganese, and graphite.

[4] Critical minerals include gallium and germanium.

[5] Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs.

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 03–4A008]

Export Trade Certificate of Review

ACTION: Notice of application for an amended Export Trade Certificate of Review for California Pistachio Export Council, LLC, application no. 03–4A008.

SUMMARY: The Secretary of Commerce, through the Office of Trade and Economic Analysis (OTEA) of the International Trade Administration, has received an application for an amended Export Trade Certificate of Review (Certificate). This notice summarizes the proposed application and seeks public comments on whether the Certificate should be issued.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, OTEA, International Trade Administration, (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) (the Act) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. The regulations implementing Title III are found at 15 CFR part 325. OTEA is issuing this notice pursuant to 15 CFR 325.6(a), which requires the Secretary of Commerce to publish a summary of the application in the **Federal Register**, identifying the applicant and each member and summarizing the proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination whether a Certificate should be issued. If the comments include any privileged or confidential business information, it must be clearly marked and a nonconfidential version of the comments (identified as such) should be included. Any comments not marked as privileged or confidential business information will be deemed to be nonconfidential.

Written comments should be sent to *ETCA@trade.gov.* An original and two (2) copies should also be submitted no later than 20 days after the date of this notice to: Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce, Room 21028, Washington, DC 20230.

Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). However, nonconfidential versions of the comments will be made available to the applicant if necessary for determining whether or not to issue the Certificate. Comments should refer to this application as ''Export Trade Certificate of Review, application number 03–4A008.'' A summary of the application follows.

Summary of the Application

Applicant: California Pistachio Export Council, LLC, 512 C St. NE, Washington, DC 20002.

Contact: Robert Schramm, Principal at Schramm, Williams & Associates, Inc.

Application No.: 03–4A008.

Date Deemed Submitted: April 27, 2022.

Proposed Amendment:

1. California Pistachio Export Council, LLC seeks to amend its Certificate as follows: Add the following entity as a Member of the Certificate within the meaning of section 325.2(l) of the Regulations (15 CFR 325.2(l)):

a. Meridian Nut Growers, LLC

2. The following entities have been removed as Members of the Certificate:

a. Arizona Nut Company, LLC
b. ARO Pistachios, Inc.
c. Horizon Growers Cooperative, Inc.
d. Nichols Pistachio

The proposed amendment would result in the following Members under the Certificate:

1. Keenan Farms, Inc.
2. Meridian Nut Growers, LLC
3. Monarch Nut Company
4. Primex Farms, LLC
5. Setton Pistachio of Terra Bella, Inc.
6. Zymex Industries, Inc.

Dated: May 4, 2022.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 2022–09937 Filed 5–9–22; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–822]

Welded Line Pipe From the Republic of Turkey: Rescission of the Antidumping Duty Administrative Review; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding this administrative review with respect to Cimtas Boru Imalatlari ve Ticaret, Ltd. Sti. (Cimtas). The period of review (POR) is December 1, 2019, through November 30, 2020.

DATES: Applicable May 10, 2022.

FOR FURTHER INFORMATION CONTACT: Alice Maldonado, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4682.

SUPPLEMENTARY INFORMATION:

Background

On January 4, 2022, Commerce published its preliminary intent to rescind this administrative review with respect to Cimtas in the **Federal Register**.[1] Although we invited parties to comment on the *Preliminary Results,*[2] no interested party submitted comments. Accordingly, no decision memorandum accompanies this **Federal Register** notice.

Scope of the Order

The products covered by the order are circular welded carbon and alloy steel (other than stainless steel) pipe of a kind used for oil or gas pipelines (welded line pipe), not more than 24 inches in nominal outside diameter, regardless of wall thickness, length, surface finish, end finish, or stenciling. Welded line pipe is normally produced to the American Petroleum Institute (API) specification 5L, but can be produced to comparable foreign specifications, to proprietary grades, or can be non-graded material. All pipe meeting the physical description set forth above, including multiple-stenciled pipe with an API or comparable foreign specification line pipe stencil is covered by the scope of this order.

The welded line pipe that is subject to the order is currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 7305.11.1030, 7305.11.5000, 7305.12.1030, 7305.12.5000, 7305.19.1030, 7305.19.5000, 7306.19.1010, 7306.19.1050, 7306.19.5110, and 7306.19.5150. The subject merchandise may also enter in HTSUS 7305.11.1060 and 7305.12.1060. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Rescission of Administrative Review

In the *Preliminary Results,* Commerce determined that the sole respondent in this administrative review, Cimtas, had no reviewable shipments, sales, or entries of subject merchandise during the POR.[3] Also, we stated that Cimtas' 2018–2019 POR entries will remain suspended until the completion of this review and will be liquidated based on the final results for Cimtas in this review. We received no comments from interested parties with respect to this record information or the preliminary rescission of the administrative review for Cimtas. Therefore, we are rescinding this administrative review with respect to Cimtas.[4]

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on and liquidate any of Cimtas' suspended entries from this POR and the 2018–2019 POR at the cash deposit rate in effect at the time of entry.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a

[1] *See Welded Line Pipe from the Republic of Turkey: Partial Rescission and Preliminary Intent to Rescind the Antidumping Duty Administrative Review; 2019–2020,* 87 FR 218 (January 4, 2022) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM) at 3–5. In the *Preliminary Results,* we also rescinded this review with respect to 18 companies. *Id.* at 3.

[2] *Id.,* 87 FR at 219.

[3] *See Preliminary Results* PDM at 3–5.

[4] *See* 19 CFR 351.213(d)(3).

statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

As Commerce has proceeded to a final rescission of this administrative review, no cash deposit rates will change. Accordingly, the current cash deposit requirements shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: May 4, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–09984 Filed 5–9–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice of Performance Evaluation of the Waquoit Bay National Estuarine Research Reserve and Public Meeting; Request for Comments

AGENCY: Office for Coastal Management, National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of public meeting and opportunity to comment.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA), Office for Coastal Management, will hold a public meeting to solicit comments on the performance evaluation of the Waquoit Bay National Estuarine Research Reserve. NOAA also will provide an opportunity for written comments on the performance evaluation.

DATES: Comments due: July 1, 2022. A public meeting will be held on Thursday, June 23, 2022, at 6 p.m. at Waquoit Bay National Estuarine Research Reserve Visitor Center, 131 Waquoit Hwy. (Rt. 28), Waquoit (E Falmouth), MA 02536.

ADDRESSES: You may submit written comments by emailing Ralph Cantral, Evaluator, NOAA Office for Coastal Management, at *Ralph.Cantral@noaa.gov.*

Timely comments received by the Office for Coastal Management are considered part of the public record and may be publicly accessible. Any personal information (*e.g.,* name, address) submitted voluntarily by the sender in the body of the email and any attachments to the email may also be publicly accessible. NOAA will accept anonymous comments.

You may also provide public comments during the public meeting, which is being held on Thursday, June 23, 2022, at 6 p.m. at Waquoit Bay National Estuarine Research Reserve Visitor Center, 131 Waquoit Hwy. (Rt. 28), Waquoit (E Falmouth), MA 02536.

Copies of the previous reserve evaluation findings, reserve management plan, and reserve site profile may be viewed and downloaded on the internet at *https://coast.noaa.gov/czm/evaluations.* A copy of the evaluation notification letter and most recent progress report may be obtained upon request by contacting Ralph Cantral at *ralph.cantral@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Ralph Cantral, *Ralph.Cantral@noaa.gov,* (843) 474–1357.

SUPPLEMENTARY INFORMATION: Section 312 of the Coastal Zone Management Act (CZMA) requires NOAA to conduct periodic evaluations of federally-approved national estuarine research reserves. The evaluation process includes holding one or more public meetings, consideration of written public comments, and consultations with interested federal, state, and local agencies and members of the public. During the evaluation, NOAA will consider the extent to which the Commonwealth of Massachusetts has met the national objectives, adhered to the management plan approved by the Secretary of Commerce, and adhered to the terms of financial assistance under the CZMA. When the evaluation is completed, NOAA's Office for Coastal Management will place a notice in the **Federal Register** announcing the availability of the final evaluation findings.

Keelin Kuipers,

Deputy Director, Office for Coastal Management National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2022–09935 Filed 5–9–22; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC011]

Marine Mammals; File No. 21585

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application for permit amendment.

SUMMARY: Notice is hereby given that Oregon State University, Marine Mammal Institute, 2030 Southeast Marine Science Drive, Newport, OR 97365 (Responsible Party: Lisa Ballance, Ph.D.) has applied for an amendment to Scientific Research Permit No. 21585–01.

DATES: Written, telefaxed, or email comments must be received on or before June 9, 2022.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 21585 from the list of available applications. These documents are also available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 21585 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request

via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Shasta McClenahan, Ph.D., or Amy Hapeman, (301)427–8401.

SUPPLEMENTARY INFORMATION: The subject amendment to Permit No. 21585–02 is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

Permit No. 21585, issued on December 20, 2018 (84 FR 4441; February 15, 2019), authorizes the Permit Holder to conduct research on 67 species of marine mammals including the following endangered or threatened species, stocks, or distinct population segment (DPS)of cetaceans: Beluga (*Delphinapterus leucas;* Cook Inlet DPS), blue (*Balaenoptera musculus*), bowhead (*Balaena mysticetes*), false killer (*Pseudorca crassidens;* Main Hawaiian Islands Insular DPS), fin (*Balaenoptera physalus*), gray (*Eschrichtius robustus;* Western North Pacific DPS), humpback (*Megaptera novaeangliae;* Arabian Sea, Cape Verde Islands/Northwest Africa, Central America, Mexico, and Western North Pacific DPSs), killer (*Orcinus orca;* Southern Resident DPS), North Pacific right (*Eubalaena japonica*), sei (*Balaenoptera. borealis*), Southern right (*E. australis*), and sperm (*Physeter macrocephalus*) whales. Authorized research may occur during vessel and manned aerial surveys including observation, photography, passive acoustic recording, echosounders for prey mapping, and collection of sloughed skin. The permit also authorizes biopsy sampling and deep-implant tagging of some species. The Permit Holder requests to increase the annual number of takes for the currently permitted vessel surveys and biopsy sampling to assess the distribution and abundance of cetaceans in the Northern California Current in California and Oregon. In addition, the Permit Holder is requesting to add biopsy sampling as a procedure for 26 species currently authorized only for Level B harassment during surveys. See the take table for specific take number changes requested by species. No changes to the currently permitted objectives, methods, or number of deep-implant tagging take numbers are proposed. The permit expires on December 31, 2023.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: May 4, 2022.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–10028 Filed 5–9–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB134]

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to the Port Everglades Harbor Deepening and Widening Project, Florida

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application for letter of authorization; request for comments and information.

SUMMARY: NMFS has received a request from the U.S. Army Corps of Engineers (USACE), Jacksonville District, for authorization to take, by Level B harassment only, small numbers of marine mammals incidental to the Port Everglades Harbor Deepening and Widening Project (Project), in Broward County, Florida, for a period of five years from August 2024 through August 2029. Pursuant to regulations implementing the Marine Mammal Protection Act (MMPA), NMFS is announcing receipt of USACE's request for the development and implementation of regulations governing the incidental taking of marine mammals. NMFS invites the public to provide information, suggestions, and comments on USACE's application and request.

DATES: Comments and information must be received no later than June 9, 2022.

ADDRESSES: Comments on the application should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910 and electronic comments should be sent to *ITP.Harlacher@noaa.gov.*

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted online at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Jenna Harlacher, Office of Protected Resources, NMFS, (301) 427–8401. An electronic copy of USACE's application may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An incidental take authorization shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an

immitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term ''take'' means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On September 3, 2020, NMFS received an application from the USACE requesting authorization for take of marine mammals incidental to confined blasting associated with the Port Everglades Harbor Deepening and Widening Project, Broward County, Florida. We provided comments on the application and the USACE submitted a revised version on April 3, 2021. We deemed the application adequate and complete on April 29, 2021. The requested regulations under which we would issue the requested LOA would be valid for five years, August 2024 and August 2029. The USACE plans to conduct confined underwater blasting to deepen and widen the Port Everglades harbor and entrance channel. Blasting may incidentally expose marine mammals to elevated levels of noise, thereby resulting in incidental take, by Level B harassment only. Therefore, the USACE requests authorization to incidentally take marine mammals.

Specified Activities

The purpose of the proposed project is to provide for increased navigational safety, efficiency, and improved economic conditions for ships calling at Port Everglades. The existing federal channel project depth of 42 feet at Port Everglades does not provide an adequate, safe depth for large tankers and container ships currently visiting the harbor. Furthermore, the next generation of container ships and oil tankers requires significantly more channel depth to operate efficiently and a wider and deeper entrance channel will greatly improve the safety of navigation. To achieve the proposed deepening and widening of Port Everglades, pretreatment of rock areas may be required using confined underwater blasting where dredging or other rock removal methods are unsuccessful due to the hardness and massiveness of the rock. The USACE anticipates a maximum of 280 confined, stemmed blasts would occur over the life of the LOA, if issued, at a rate of one blast per day. Blasting operations may take place six days a week with a maximum of one blast occurring per day. Confined underwater blasting operations will be prohibited between November 15 and March 15 in order to avoid take of the West Indian Manatee (*Trichecus manatus*). Blasting would occur in six designated areas: The outer entrance channel, inner entrance channel, main turning basin, widener, south access channel, and turning notch. The USACE's application contains mitigation and monitoring measures designed to reduce impacts to marine mammals. The application also contains proposed marine mammal and acoustic monitoring and reporting plans.

Information Solicited

Interested persons may submit information, suggestions, and comments concerning USACE's request (see **ADDRESSES**). NMFS will consider all information, suggestions, and comments related to the request during the development of proposed regulations governing the incidental taking of marine mammals by USACE, if appropriate.

Dated: May 4, 2022.

Kim Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–09934 Filed 5–9–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Notice of Intent To Prepare an Environmental Impact Statement for the NEXT Renewable Fuels Oregon Project, Columbia County, Oregon

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent.

SUMMARY: The U.S. Army Corps of Engineers, Portland District (Corps), has received an application for a Department of the Army (DA) permit (Corps number NWP–2020–383) from NEXT Renewable Fuels Oregon, LLC to construct a facility to produce renewable fuels. The Corps, as the lead agency under the National Environmental Policy Act (NEPA), has determined the proposed project may significantly affect the quality of the human environment and will prepare an environmental impact statement (EIS). The Corps' action will be to issue, issue with modifications, or deny a DA permit for the proposed project. The EIS will assess the potential social, economic, and environmental impacts of the proposed project.

ADDRESSES: Written comments regarding the proposed EIS scope should be submitted to: U.S. Army Corps of Engineers, Portland District, Attn: Ms. Kate Mott, P.O. Box 2946, Portland, Oregon 97208–2946. Individuals who would like to provide comments electronically should submit comments by email to: *nexteis@usace.army.mil*.

FOR FURTHER INFORMATION CONTACT: For information about this project or to be included on the mailing list for future updates and meeting announcements, contact Ms. Kate Mott at the Corps by telephone at (503) 808–4041, by email at *nexteis@usace.army.mil,* or by mail at the mailing address provided above.

SUPPLEMENTARY INFORMATION: The Corps intends to prepare an EIS for the proposed NEXT Renewable Fuels Oregon project. The proposed project requires authorization from the Corps under Section 404 of the Clean Water Act (33 U.S.C. 1344) for the discharge of dredged or fill material into waters of the United States. As part of the DA permit application process, the Corps issued a public notice on November 5, 2021. The purpose of the public notice was to initiate an early public scoping process to solicit comments and information from the public to identify relevant issues and concerns associated with the proposed project. All comments received to date, including those provided for review during the public notice comment period, will be considered by the Corps during preparation of the EIS.

1. *Proposed Action.* The project requiring an EIS involves the construction of the proposed NEXT Renewable Fuels Oregon facility. The purpose of the project is to produce renewable fuels for markets on the west

coast of the United States to meet the demand for fuels that are mandated by the Renewable Fuel Standard Program or other state mandates that require low-carbon fuels. The project would permanently fill 117.64 acres of wetlands and 1.79 acres of other waterways (ditches and slough) to construct a renewable fuels facility and ancillary components. The project would temporarily fill 32.03 acres of wetlands and 0.02 acres of waterways for project construction and a staging area.

The proposed project facility would be capable of producing 50,000 barrels per day of renewable diesel and other renewable fuel products. The production process would produce renewable fuels from a range of feedstocks such as various vegetable oils, used cooking oil, animal tallow, and inedible corn oil. The proposed facility and ancillary components constructed in wetlands/waterways would include: Main access road; natural gas pipeline; rail spur, ladder tracks, and rail spur access road; four new pipelines to connect with pipelines to an existing wharf; ten large product and feedstock tanks (125,000 to 225,000 barrels each); eleven smaller feedstock and process tanks (10,000 to 50,000 barrels each); pre-treatment plant; hydrogen facility; Ecofining™ units; storm and process water system; office/administration buildings/laboratory; and site landscaping and fencing.

The facility would be constructed by grading and filling the site. The overall final grade would be approximately 3 ft. above the existing grade. Fill material would consist of soil and aggregate imported from a local source. Facility components would be supported with pile foundations by installing approximately 15,200, 16-inch steel piles that are 90 ft. long (each) driven by a vibratory hammer. Facility components would also be supported with ground improvement foundations by wet soil mixing known as the Deep Mixing Method to construct concrete piles. Typical construction methods would be utilized for the stripping, grading, road construction, installation of underground utilities, stormwater, and processed water systems.

The project would rely on transportation by water, railroad and road to receive materials used in production (feedstock oils, tallows, bleaching earth) and to ship renewable fuels produced from the facility. The project would require unloading up to 118 barges per year (approximately 10 per month) to receive feedstock materials and require loading up to 58 ocean going vessels per year (approximately 5 per month) to transport renewable diesel produced from the facility to market. The project would require loading and unloading up to 208 trains per year (approximately 17 per month) to receive materials used in production (feedstock and bleaching earth) and to transport renewable diesel produced from the facility to market. The project would also require loading up to 720 trucks per year (approximately 60 per month) to transport renewable diesel produced from the facility to market.

The project includes a proposed compensatory mitigation site. The compensatory mitigation would enhance 471.08 acres of wetlands that are currently used for agriculture and silviculture.

2. *Location.* The project site is located at the Port Westward Industrial Park near Clatskanie, Columbia County, Oregon. The site is in Section 22, Township 8 North, Range 4 West at Latitude and Longitude: 46.167233°, −123.16195°.

3. *Alternatives.* The EIS will address an array of alternatives. Alternatives may include, but are not limited to, no action, alternative sites, and alternative facility designs. Mitigation measures could include, but are not limited to, avoidance and minimization, enhancement, restoration or establishment of wetlands.

4. *Scoping Process.* The scoping period will continue for 30 days from the date of this Notice of Intent. During the scoping period, the Corps invites federal, state, and local agencies, Native American Tribes, other interested parties, and the general public to participate in the scoping process. The purpose of the scoping process is to provide information to the public, serve as a mechanism to solicit agency and public input on alternatives, identify significant issues to be analyzed in the EIS, and ensure full and open participation in scoping for the draft EIS. Scoping comments may be submitted by conventional mail or email. All comments must include the Corps number NWP–2020–383. In order to be accepted, email comments must originate from the author's email account. All comments received will become part of the administrative record and are subject to public release under the Freedom of Information Act including any personally identifiable information such as names, phone numbers, and addresses. Additional information on the project and scoping process are available on the Corps' website listed below.

5. *Scoping Meetings.* The Corps will conduct virtual public scoping meetings during the 30-day scoping period in which agencies, organizations, and members of the general public are invited to present comments or suggestions with regard to the range of actions, alternatives, and potential impacts to be considered in the EIS. The specific dates and times of the meetings will be published in press releases, special public notices and on the Corps' project website (*https://www.nwp.usace.army.mil/Missions/Regulatory/*). At the Corps' website under Regulatory Pages, select Environmental Impact Statements.

5. *Availability of the Draft EIS.* The draft EIS is estimated to be available for public review and comment in early 2023. At that time, a 45-day public review period will be provided for public review and comment on the draft EIS.

Approved by:

Frances E. Coffey,

Director, Programs.

[FR Doc. 2022–10035 Filed 5–9–22; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2022–SCC–0028]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; NCES System Clearance for Cognitive, Pilot, and Field Test Studies 2022–2025

AGENCY: Institute of Educational Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of a currently approved information collection.

DATES: Interested persons are invited to submit comments on or before June 9, 2022.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2022–SCC–0028. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the

docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W201, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Carrie Clarady, 202–245–6347.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: NCES System Clearance for Cognitive, Pilot, and Field Test Studies 2022–2025.

OMB Control Number: 1850–0803.

Type of Review: An extension of a currently approved information collection.

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 600,000.

Total Estimated Number of Annual Burden Hours: 240,000.

Abstract: This is a request for a 3-year renewal of the generic clearance to allow the National Center for Education Statistics (NCES) to continue to develop, test, and improve its survey and assessment instruments and methodologies. The procedures utilized to this effect include but are not limited to experiments with levels of incentives for various types of survey operations, focus groups, cognitive laboratory activities, pilot testing, exploratory interviews, experiments with questionnaire design, and usability testing of electronic data collection instruments.

Dated: May 5, 2022.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–09985 Filed 5–9–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2022–SCC–0029]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Transition and Postsecondary Programs for Students With Intellectual Disabilities (TPSID) Evaluation Protocol

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before June 9, 2022.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Shedita Alston, 202–453–7090.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Transition and Postsecondary Programs for Students with Intellectual Disabilities (TPSID) Evaluation Protocol.

OMB Control Number: 1840–0825.

Type of Review: A revision of a currently approved collection.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 40.

Total Estimated Number of Annual Burden Hours: 792.

Abstract: In October 2020, the Institute for Community Inclusion (ICI), UMass Boston received a five-year cooperative agreement from the Office of Postsecondary Education to serve as the National Coordinating Center (NCC) for colleges and universities implementing inclusive higher education programs for students with intellectual disabilities, including 22 newly-funded model demonstration projects aimed at creating inclusive comprehensive transition and postsecondary programs for students with intellectual disabilities known as Transition and Postsecondary Programs for Students with Intellectual Disabilities (TPSIDs).

To reduce respondent burden, the NCC has streamlined and simplified the

previously approved evaluation system for the TPSID programs. The NCC will enhance the collection and analyses of longitudinal follow-up data from the new 22 TPSID model programs via an already developed and previously OMB approved evaluation system for the TPSID programs. The revised data collection system is part of an evaluation effort. The system will collect program data at the institutions from TPSID program staff via an online, secure data management system.

Dated: May 5, 2022.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–09986 Filed 5–9–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Native American-Serving Nontribal Institutions Program

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2022 for the Native American-Serving Nontribal Institutions (NASNTI) Program, Assistance Listing Number 84.031X. This notice relates to the approved information collection under OMB control number 1840–0816.

DATES:

Applications Available: May 10, 2022.

Deadline for Transmittal of Applications: July 11, 2022.

Deadline for Intergovernmental Review: September 7, 2022.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 27, 2021 (86 FR 73264) and available at *www.federalregister.gov/d/2021-27979.* Please note that these Common Instructions supersede the version published on February 13, 2019, and, in part, describe the transition from the requirement to register in *SAM.gov* a Data Universal Numbering System (DUNS) number to the implementation of the Unique Entity Identifier (UEI). More information on the phase-out of DUNS numbers is available at *https://www2.ed.gov/about/offices/list/ofo/docs/unique-entity-identifier-transition-fact-sheet.pdf.*

FOR FURTHER INFORMATION CONTACT: Don Crews, U.S. Department of Education, 400 Maryland Avenue SW, Room 2B110, Washington, DC 20202–4260. Telephone: (202) 453–7920. Email: *Don.Crews@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The NASNTI Program provides grants to eligible institutions of higher education (IHEs) to enable them to improve and expand their capacity to serve Native Americans and low-income individuals. Institutions may use the grants to plan, develop, undertake, and carry out activities to improve and expand their capacity to serve Native American and low-income students.

Background: Students' sense of belonging impacts postsecondary retention.[1] Creating that sense of belonging begins with ensuring the institution's ability to serve students well. Research shows that implementing intrusive advising practices[2] and other proactive strategies to directly support underserved students can lead to successful outcomes. Such proactive practices may be increasingly important as institutions reengage postsecondary students following enrollment decreases due to COVID–19.

Proactive practices alone may not be sufficient to retain students who suffer from financial hardship, however. Data have shown that higher education opportunity and outcomes are highly inequitable across family income groups.[3] Therefore, implementing or expanding supports that provide students with financial literacy, paid internship placement, and other services that help to alleviate financial stressors further support student retention.

Through this grant program, the Department encourages Native American-serving nontribal institutions to develop, create, or enhance programs that foster students' sense of belonging and to implement services that will help students complete their degree programs. Through the competitive preference priorities for this grant competition, the Department invites applicants to submit proposals to provide high-quality learning, improve student engagement, and reduce the cost of obtaining a college degree for Native American and low-income students. Although the most effective strategy to reduce the cost of attending college may vary across IHEs, we encourage applicants to consider strategies that reduce a student's need to incur debt to earn a degree, for example, by reducing the time to degree completion.

Priorities: This notice contains two competitive preference priorities. The priorities are from the Secretary's Supplemental Priorities and Definitions for Discretionary Grants Programs, published in the **Federal Register** on December 10, 2021 (86 FR 70612) (Supplemental Priorities).

Competitive Preference Priorities: For FY 2022 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i) we award up to an additional 5 points to an application for each priority, depending on how well the application meets the priorities. Applicants may respond to one or both priorities, for a total of up to 10 additional points.

These priorities are:

Competitive Preference Priority 1: Meeting Student Social, Emotional, and Academic Needs (up to 5 points).

Projects that are designed to improve students' social, emotional, academic, and career development, with a focus on underserved students (as defined in this notice), by creating a positive, inclusive, and identity-safe climate at IHEs through one or more of the following activities:

(a) Fostering a sense of belonging and inclusion for underserved students.

(b) Implementing evidence-based practices for advancing student success for underserved students.

(c) Providing evidence-based professional development opportunities designed to build asset-based mindsets for faculty and staff on campus and that are inclusive with regard to race, ethnicity, culture, language, and disability status.

[1] Davis, G.M., Hanzsek-Brill, M.B., Petzold, M.C., and Robinson, D.H., ''Students' Sense of Belonging: The Development of a Predictive Retention Model.'' *Journal of the Scholarship of Teaching and Learning,* vol. 19, no. 1, pp. 117–27 (Feb. 2019).

[2] Museus, S.D., Ravello, J.N., ''Characteristics of Academic Advising That Contribute to Racial and Ethnic Minority Student Success at Predominantly White Institutions.'' *NACADA Journal,* vol. 41, no. 1, pp. 13–25 (2021). *https://files.eric.ed.gov/fulltext/EJ1300278.pdf.*

[3] ''Indicators of Higher Education Equity in the United States: 2016 Historical Trend Report,'' The Pell Institute and PennAHEAD (Jan. 2016). *https://firstgen.naspa.org/report/indicators-of-higher-education-equity-in-the-united-states-2016-historical-trend-report.*

Competitive Preference Priority 2: Increasing Postsecondary Education Access, Affordability, Completion, and Post-Enrollment Success (up to 5 points).

Projects that are designed to increase postsecondary access, affordability, completion, and success for underserved students by addressing one or more of the following priority areas:

(a) Increasing postsecondary education access and reducing the cost of college by creating clearer pathways for students between institutions and making transfer of course credits more seamless and transparent.

(b) Increasing the number and proportion of underserved students who enroll in and complete postsecondary education programs, which may include strategies related to college preparation, awareness, application, selection, advising, counseling, and enrollment.

(c) Reducing the net price or debt-to-earnings ratio for underserved students who enroll in or complete college, other postsecondary education, or career and technical education programs.

(d) Supporting the development and implementation of student success programs that integrate multiple comprehensive and evidence-based services or initiatives, such as academic advising, structured/guided pathways, career services, credit-bearing academic undergraduate courses focused on career, and programs to meet basic needs, such as housing, childcare and transportation, student financial aid, and access to technological devices.

Note: Applicants must include in the one-page abstract submitted with the application a statement indicating that they are addressing one or both competitive preference priorities. If the applicant has addressed one or both competitive preference priorities, this information also must be listed on the NASNTI Program Profile form in the application booklet.

Definitions: The definitions below are from 34 CFR 77.1, 20 U.S.C. 1059f, and the Supplemental Priorities.

Demonstrates a rationale means a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes.

Department means the U.S. Department of Education.

Fiscal Year means the Federal fiscal year—a period beginning on October 1 and ending on the following September 30.

Grantee means the legal entity to which a grant is awarded and that is accountable to the Federal Government for the use of the funds provided. The grantee is the entire legal entity even if only a particular component of the entity is designated in the grant award notice (GAN). For example, a GAN may name as the grantee one school or campus of a university. In this case, the granting agency usually intends, or actually intends, that the named component assume primary or sole responsibility for administering the grant-assisted project or program. Nevertheless, the naming of a component of a legal entity as the grantee in a grant award document shall not be construed as relieving the whole legal entity from accountability to the Federal Government for the use of the funds provided. (This definition is not intended to affect the eligibility provision of grant programs in which eligibility is limited to organizations that may be only components of a legal entity.) The term ''grantee'' does not include any secondary recipients, such as subgrantees and contractors, that may receive funds from a grantee pursuant to a subgrant or contract.

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

Note: In developing logic models, applicants may want to use resources such as the Regional Educational Laboratory Program's (REL Pacific) Education Logic Model Application, available at *https://ies.ed.gov/ncee/edlabs/regions/pacific/elm.asp.* Other sources include: *https://ies.ed.gov/ncee/edlabs/regions/pacific/pdf/REL_2014025.pdf, https://ies.ed.gov/ncee/edlabs/regions/pacific/pdf/REL_2014007.pdf,* and *https://ies.ed.gov/ncee/edlabs/regions/northeast/pdf/REL_2015057.pdf.*

Native American means an individual who is of a tribe, people, or culture that is indigenous to the United States.

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program.

Underserved student means a student in postsecondary education or career and technical education, and adult learners, as appropriate, in one or both of the following subgroups:

(a) A student who is living in poverty.

(b) A student who is a member of a federally recognized Indian Tribe.[4]

Program Authority: 20 U.S.C. 1059f (title III, part A of the Higher Education Act of 1965, as amended (HEA)).

Note: In 2008, the HEA was amended by the Higher Education Opportunity Act of 2008 (HEOA), Public Law 110–315. Please note that the regulations in 34 CFR part 607 have not been updated to reflect these statutory changes.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in the Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations for this program in 34 CFR part 607. (e) The Supplemental Priorities.

II. Award Information

Type of Award: Discretionary grants. Five-year Individual Development Grants and Cooperative Arrangement Development Grants will be awarded in FY 2022.

Note: A cooperative arrangement is an arrangement to carry out allowable grant activities between an institution eligible to receive a grant under this part and another eligible or ineligible IHE, under which the resources of the cooperating institutions are combined and shared to better achieve the purposes of this part and avoid costly duplication of effort.

Estimated Available Funds: $3,200,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of

[4] The NASNTI Program serves Native American and low-income students. For the subgroup of ''underserved students'' described in paragraph (b) of this definition, for the purpose of this program, we refer to those students who are Native American, as defined in 20 U.S.C. 1059f.

unfunded applications from this competition.

Individual Development Grants:

Estimated Range of Awards: $250,000–$350,000 per year.

Estimated Average Size of Awards: $300,000 per year.

Maximum Award: We will not make an award exceeding $350,000 for a single budget period of 12 months.

Estimated Number of Awards: 6.

Cooperative Arrangement Development Grants:

Estimated Range of Awards: $400,000–$550,000 per year.

Estimated Average Size of Awards: $475,000 per year.

Maximum Award: We will not make an award exceeding $550,000 for a single budget period of 12 months.

Estimated Number of Awards: 2.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* This program is authorized by title III, part A, of the HEA. At the time of submission of their applications, applicants must certify their total undergraduate headcount enrollment and that not less than 10 percent of the IHE's enrollment is Native American. An official for the applicant must execute and submit an assurance form, which is included in the application materials for this competition.

To qualify as an eligible institution under the NASNTI Program, an institution must—

(i) Be accredited or preaccredited by a nationally recognized accrediting agency or association that the Secretary has determined to be a reliable authority as to the quality of education or training offered;

(ii) Be legally authorized by the State in which it is located to be a junior or community college or to provide an educational program for which it awards a bachelor's degree;

(iii) Be designated as an ''eligible institution,'' by demonstrating that it: (1) Has an enrollment of needy students as described in 34 CFR 607.3; and (2) has low average education and general expenditures per full-time equivalent (FTE) undergraduate student as described in 34 CFR 607.4.

Note: The notice announcing the FY 2022 process for designation of eligible institutions, and inviting applications for waiver of eligibility requirements, was published in the **Federal Register** on December 16, 2021 (86 FR 71470). The Department reopened the process for applications in a notice published in the **Federal Register** on February 7, 2022 (87 FR 6855). Only institutions that the Department determines are eligible, or which are granted a waiver under the process described in that notice, may apply for a grant in this program.

An eligible IHE that submits applications for an Individual Development Grant and a Cooperative Arrangement Development Grant in this competition may be awarded both in the same fiscal year. A grantee with an Individual Development Grant or a Cooperative Arrangement Development Grant may be a partner in one or more Cooperative Arrangement Development Grants. The lead institution in a Cooperative Arrangement Development Grant must be an eligible institution. Partners are not required to be eligible institutions. Tribally Controlled Colleges and Universities, as authorized by title III of the HEA, may participate in more than one Cooperative Arrangement Development Grant as a partner.

Relationship Between the Title III, Part A Programs and the Developing Hispanic-Serving Institutions (DHSI) Program

A grantee under the DHSI program, which is authorized under title V of the HEA, may not receive a grant under any HEA, title III, part A program. The title III, part A programs are: Strengthening Institutions Program; the Tribally Controlled Colleges and Universities Program; the Alaska Native and Native Hawaiian-Serving Institutions Program; the Asian American and Native American Pacific Islander-Serving Institutions Program; and the NASNTI Program. Furthermore, a current DHSI program grantee may not give up its HSI grant to receive a grant under any title III, part A program as described in 34 CFR 607.2(g)(1).

An eligible HSI that is not a current grantee under the DHSI program may apply for a FY 2022 grant under all title III, part A programs for which it is eligible, as well as receive consideration for a grant under the DHSI program. However, a successful applicant may receive only one grant as described in 34 CFR 607.2(g)(1).

2. a. *Cost Sharing or Matching:* This competition does not require cost sharing or matching unless the grantee uses a portion of its grant for establishing or improving an endowment fund. If a grantee uses a portion of its grant for endowment fund purposes, it must match those grant funds with non-Federal funds (20 U.S.C. 1057(d)(1)–(2)).

b. *Supplement-Not-Supplant:* This program involves supplement-not-supplant funding requirements. Grant funds must be used so that they supplement and, to the extent practical, increase the funds that would otherwise be available for the activities to be carried out under the grant and in no case supplant those funds (34 CFR 607.30(b)).

c. *Indirect Cost Rate Information:* A grantee may not use an indirect cost rate to determine allowable cost under its grant (34 CFR 607.30(c)).

d. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 27, 2021 (86 FR 73264) and available at *www.federalregister.gov/d/2021-27979,* which contain requirements and information on how to submit an application. Please note that these Common Instructions supersede the version published on February 13, 2019, and, in part, describe the transition from the requirement to register in *SAM.gov* a DUNS number to the implementation of the UEI. More information on the phase-out of DUNS numbers is available at *https://www2.ed.gov/about/offices/list/ofo/docs/unique-entity-identifier-transition-fact-sheet.pdf.*

2. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

3. *Funding Restrictions:* We specify unallowable costs in 34 CFR 607.10(c). We reference additional regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1)

limit the application narrative to no more than 55 pages for Individual Development Grants and no more than 75 pages for Cooperative Arrangement Development Grants and (2) use the standards below. If you are addressing one or both competitive preference priorities, we recommend that you limit your response to no more than an additional 10 pages total, four additional pages for Competitive Preference Priority 1 and six additional pages for Competitive Preference Priority 2. Please include a separate heading when responding to one or both competitive preference priorities.

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger, and no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract and the bibliography. However, the recommended page limit does apply to all of the application narrative.

Note: The Budget Information-Non-Construction Programs Form (ED 524) Sections A–C are not the same as the narrative response to the Budget section of the selection criteria.

V. Application Review Information

1. *Selection Criteria:* The following selection criteria for this competition are from 34 CFR 75.210. Applicants should address each of the following selection criteria separately for each proposed activity. The selection criteria are worth a total of 100 points; the maximum score for each criterion is noted in parentheses.

(a) *Need for project.* (Up to 15 points) The Secretary considers the need for the proposed project. In determining the need for the proposed project, the Secretary considers:

(1) The magnitude of the need for the services to be provided or the activities to be carried out by the proposed project. (5 points)

(2) The extent to which the proposed project will focus on serving or otherwise addressing the needs of disadvantaged individuals. (5 points)

(3) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses. (5 points)

(b) *Quality of the project design.* (Up to 25 points) The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers:

(1) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable. (10 points)

(2) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs. (5 points)

(3) The extent to which the proposed project demonstrates a rationale (as defined in this notice). (10 points)

(c) *Quality of project services.* (Up to 10 points) The Secretary considers the quality of the services to be provided by the proposed project.

(1) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. (4 points)

(2) In addition, the Secretary considers:

(i) The extent to which the services to be provided by the proposed project are appropriate to the needs of the intended recipients or beneficiaries of those services. (4 points)

(ii) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice. (2 points)

(d) *Quality of project personnel.* (Up to 20 points) The Secretary considers the quality of the personnel who will carry out the proposed project.

(1) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. (9 points)

(2) In addition, the Secretary considers:

(i) The qualifications, including relevant training and experience, of the project director or principal investigator. (3 points)

(ii) The qualifications, including relevant training and experience, of key project personnel. (8 points)

(e) *Adequacy of resources.* (Up to 5 points) The Secretary considers the adequacy of resources for the proposed project. In determining the adequacy of resources for the proposed project, the Secretary considers:

(1) The extent to which the budget is adequate to support the proposed project. (3 points)

(2) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project. (2 points)

(f) *Quality of the management plan.* (Up to 15 points) The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers:

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks. (8 points)

(2) The adequacy of procedures for ensuring feedback and continuous improvement in the operation of the proposed project. (2 points)

(3) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project. (5 points)

(g) *Quality of the project evaluation.* (Up to 10 points) The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers:

(1) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project. (5 points)

(2) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible. (5 points)

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also

consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

A panel of three non-Federal reviewers will review and score each application in accordance with the selection criteria. A rank order funding slate will be made from this review. Awards will be made in rank order according to the average score received from the peer review and from the competitive preference priority, if addressed by the applicant.

In tie-breaking situations for development grants, under 34 CFR 607.23(b), we award one additional point to an application from an IHE that has an endowment fund of which the current market value, per FTE enrolled student, is less than the average current market value of the endowment funds, per FTE enrolled student, at comparable type institutions that offer similar instruction. We award one additional point to an application from an IHE that has expenditures for library materials per FTE enrolled student that are less than the average expenditure for library materials per FTE enrolled student at similar type institutions. We also add one additional point to an application from an IHE that proposes to carry out one or more of the following activities:

(1) Faculty development.

(2) Funds and administrative management.

(3) Development and improvement of academic programs.

(4) Acquisition of equipment for use in strengthening

management and academic programs.

(5) Joint use of facilities.

(6) Student services.

For the purpose of these funding considerations, we use 2019–2020 data.

If a tie remains after applying the tie-breaker mechanism above, priority will be given to applicants that have the lowest endowment values per FTE enrolled student.

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this program the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must

submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

5. *Performance Measures:* The Secretary has established the following key performance measures for assessing the effectiveness of NASNTI:

(a) The percentage of first-time, full-time degree-seeking undergraduate students at 4-year NASNTIs who were in their first year of postsecondary enrollment in the previous year and are enrolled in the current year at the same NASNTI;

(b) The percentage of first-time, full-time degree-seeking undergraduate students at 2-year NASNTIs who were in their first year of postsecondary enrollment in the previous year and are enrolled in the current year at the same NASNTI;

(c) The percentage of first-time, full-time degree-seeking undergraduate students enrolled at 4-year NASNTIs who graduate within 6 years of enrollment; and

(d) The percentage of first-time, full-time degree-seeking undergraduate students enrolled at 2-year NASNTIs who graduate within 3 years of enrollment.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Michelle Asha Cooper,

Acting Assistant Secretary for the Office of Postsecondary Education.

[FR Doc. 2022–10001 Filed 5–9–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG22–109–000.

Applicants: Cutlass Solar LLC.

Description: Cutlass Solar LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 5/3/22.

Accession Number: 20220503–5209.

Comment Date: 5 p.m. ET 5/24/22.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: ER20–681–006; EL22–28–000.

Applicants: Tri-State Generation and Transmission Association, Inc., Tri-State Generation and Transmission Association, Inc.

Description: Response to March 25, 2022 Deficiency Letter of Tri-State Generation and Transmission Association, Inc.

Filed Date: 4/29/22.

Accession Number: 20220429–5715.

Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: EL22–55–000.

Applicants: Southern California Edison Company.

Description: Petition for Declaratory Order of [Southern California Edison Company].

Filed Date: 4/28/22.

Accession Number: 20220428–5520.

Comment Date: 5 p.m. ET 5/30/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2474–026; ER10–2475–027; ER10–2605–016; ER10–2611–024; ER10–2984–056; ER10–3246–020; ER11–2044–038; ER11–3876–027; ER12–162–032; ER12–1626–013; ER13–520–012; ER13–521–012; ER13–1266–038; ER13–1267–012; ER13–1268–012; ER13–1269–012; ER13–1270–012; ER13–1271–012; ER13–1272–012; ER13–1273–012; ER13–1441–012; ER13–1442–012; ER15–2211–035; ER16–438–008; ER16–1258–006; ER18–1419–005; ER21–2280–002.

Applicants: Independence Wind Energy LLC, Walnut Ridge Wind, LLC, Grande Prairie Wind, LLC, Marshall Wind Energy LLC, MidAmerican Energy Services, LLC, Solar Star California XX, LLC, Solar Star California XIX, LLC, Vulcan/BN Geothermal Power Company, Salton Sea Power L.L.C., Salton Sea Power Generation Company, Fish Lake Power LLC, Elmore Company, Del Ranch Company, CE Leathers Company, CalEnergy, LLC, Pinyon Pines Wind II, LLC, Pinyon Pines Wind I, LLC, Topaz Solar Farms LLC, Bishop Hill Energy II LLC, Cordova Energy Company LLC, MidAmerican Energy Company, PacifiCorp, Merrill Lynch Commodities, Inc., Saranac Power Partners, L.P., Yuma Cogeneration Associates, Nevada Power Company, Sierra Pacific Power Company.

Description: Notice of Non-Material Change in Status of Sierra Pacific Power Company, et al.

Filed Date: 5/2/22.

Accession Number: 20220502–5397.

Comment Date: 5 p.m. ET 5/23/22.

Docket Numbers: ER11–47–015; ER12–1540–013; ER12–1541–013; ER12–1542–013; ER12–1544–013; ER14–594–017; ER14–867–003; ER14–868–004; ER16–323–012; ER17–1930–007; ER17–1931–007; ER17–1932–007; ER19–606–005; ER19–1941–003; ER20–649–003; ER21–136–004.

Applicants: Flat Ridge 3 Wind Energy, LLC, AEP Energy Partners, Inc., Flat Ridge 2 Wind Energy LLC, AEP Generation Resources Inc.,

Southwestern Electric Power Company, AEP Texas Inc., Public Service Company of Oklahoma, Ohio Valley Electric Corporation, AEP Retail Energy Partners, LLC, AEP Energy, Inc., Ohio Power Company, Wheeling Power Company, Kingsport Power Company, Kentucky Power Company, Indiana Michigan Power Company, Appalachian Power Company.

Description: Notice of Change in Status of Appalachian Power Company, et al.

Filed Date: 4/29/22.

Accession Number: 20220429–5711.

Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: ER17–256–014; ER17–242–013; ER17–243–013; ER22–245–001; ER17–652–013.

Applicants: Lightstone Marketing LLC, Waterford Power, LLC, Lawrenceburg Power, LLC, Gavin Power, LLC, Darby Power, LLC.

Description: Notice of Non-Material Change in Status of Darby Power, LLC, et. al.

Filed Date: 5/2/22.

Accession Number: 20220502–5398.

Comment Date: 5 p.m. ET 5/23/22.

Docket Numbers: ER17–1742–005; ER13–2490–009; ER17–311–005; ER19–53–002; ER19–2595–004; ER19–2670–004; ER19–2671–004; ER19–2672–004; ER20–1073–003; ER20–2455–001; ER20–2510–003; ER20–2512–003; ER20–2515–003; ER20–2595–001; ER20–2663–003; ER21–2406–002; ER21–2407–002; ER21–2408–002; ER21–2409–002; ER21–2638–002; ER22–734–001.

Applicants: SR Arlington, LLC, SR Perry, LLC, SR Snipesville II, LLC, SR Lumpkin, LLC, SR Georgia Portfolio II Lessee, LLC, Lancaster Solar LLC, SR Snipesville, LLC, SR Rattlesnake, LLC, SR Georgia Portfolio I MT, LLC, SR Baxley, LLC, Odom Solar LLC, SR Platte, LLC, SR Terrell, LLC, SR Arlington II MT, LLC, SR Arlington II, LLC, SR Meridian III, LLC, SR Hazlehurst III, LLC, SR Millington, LLC, SR South Loving LLC, Simon Solar, LLC, Hattiesburg Farm, LLC.

Description: Notice of Change in Status of Hattiesburg Farm, LLC, et al.

Filed Date: 4/29/22.

Accession Number: 20220429–5712.

Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: ER20–1830–001.

Applicants: Duquesne Light Company, PJM Interconnection, L.L.C.

Description: Compliance filing: Duquesne Light Company submits tariff filing per 35: Duquesne Order 864 Supplemental Compliance Filing in ER20–1830 to be effective 1/27/2020.

Filed Date: 5/4/22.

Accession Number: 20220504–5135.

Comment Date: 5 p.m. ET 5/25/22.

Docket Numbers: ER22–1429–001.

Applicants: Appalachian Power Company.

Description: Tariff Amendment: RE 34—AEP East Transmission Agreement—Errata to be effective 12/31/9998.

Filed Date: 5/3/22.

Accession Number: 20220503–5193.

Comment Date: 5 p.m. ET 5/24/22.

Docket Numbers: ER22–1787–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: § 205(d) Rate Filing: Initial Filing of Rate Schedule FERC No. 342 and Request for Expedited Action to be effective 5/31/2022.

Filed Date: 5/3/22.

Accession Number: 20220503–5087.

Comment Date: 5 p.m. ET 5/24/22.

Docket Numbers: ER22–1790–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original NSA, Service Agreement No. 6450; Queue No. AD2–116 to be effective 4/5/2022.

Filed Date: 5/4/22.

Accession Number: 20220504–5031.

Comment Date: 5 p.m. ET 5/25/22.

Docket Numbers: ER22–1791–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original NSA, SA No. 6433; Queue No. AE2–060 to be effective 4/7/2022.

Filed Date: 5/4/22.

Accession Number: 20220504–5050.

Comment Date: 5 p.m. ET 5/25/22.

Docket Numbers: ER22–1792–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Modify Transmission Owner Selection Criteria and Scoring Process to be effective 7/4/2022.

Filed Date: 5/4/22.

Accession Number: 20220504–5052.

Comment Date: 5 p.m. ET 5/25/22.

Docket Numbers: ER22–1793–000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii: PowerSouth NITSA Amendment (Add Union Grove DP) to be effective 4/4/2022.

Filed Date: 5/4/22.

Accession Number: 20220504–5093.

Comment Date: 5 p.m. ET 5/25/22.

Docket Numbers: ER22–1794–000.

Applicants: Green USA, LLC.

Description: Baseline eTariff Filing: Application of Green USA for Market-Based Rate Authorization to be effective 5/6/2022.

Filed Date: 5/4/22.

Accession Number: 20220504–5104.

Comment Date: 5 p.m. ET 5/25/22.

Docket Numbers: ER22–1795–000.

Applicants: Duke Energy Florida, LLC.

Description: § 205(d) Rate Filing: DEF–FPL Settlement RS No. 362 to be effective 7/4/2022.

Filed Date: 5/4/22.

Accession Number: 20220504–5123.

Comment Date: 5 p.m. ET 5/25/22.

Docket Numbers: ER22–1796–000.

Applicants: Commonwealth Edison Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Commonwealth Edison Company submits tariff filing per 35.13(a)(2)(iii: Commonwealth Edison revisions to OATT, Attachment H–13 to be effective 4/29/2022.

Filed Date: 5/4/22.

Accession Number: 20220504–5130.

Comment Date: 5 p.m. ET 5/25/22.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES22–46–000.

Applicants: Southern Indiana Gas & Electric Company, Inc.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Southern Indiana Gas and Electric Company.

Filed Date: 5/4/22.

Accession Number: 20220504–5131.

Comment Date: 5 p.m. ET 5/25/22.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 4, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–09995 Filed 5–9–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 5124–022]

Washington Electric Cooperative, Inc.; Notice of Meeting

a. *Project Name and Number:* North Branch No. 3 Hydroelectric Project No. 5124–022.

b. *Applicant:* Washington Electric Cooperative, Inc. (WEC).

c. *Date and Time of Meeting:* May 20, 2022 from 10:00 a.m. to 11:00 a.m. EST.

d. *FERC Contact:* Michael Tust, (202) 502–6522, *michael.tust@ferc.gov.*

e. *Purpose of Meeting:* Commission staff will hold a teleconference with staff from WEC and the Vermont State Historic Preservation Office to discuss the Draft Programmatic Agreement and a schedule for finalizing and signing a Final Programmatic Agreement.

f. All local, state, and federal agencies, Native American tribes, and other interested parties are invited to attend the meeting. Please call or email Michael Tust at (202) 502–6522 or *michael.tust@ferc.gov* by May 18, 2022 at 4:30 p.m. EST, to RSVP and to receive specific instructions on how to participate.

Dated: May 4, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–09997 Filed 5–9–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 10615–058]

Tower Kleber Limited Partnership; Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 10615–058.

c. *Date filed:* April 28, 2022.

d. *Applicant:* Tower Kleber Limited Partnership.

e. *Name of Project:* Tower and Kleber Hydroelectric Project.

f. *Location:* On the Upper Black River in the Forest and Waverly Townships of Cheboygan County, Michigan. The project does not occupy any federal lands.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Nelson Turcotte, Tower Kleber Limited Partnership, 764 Lexington Crescent Road, Thunder Bay, Ontario, Canada P7B 7B8; (807) 633–3362.

i. *FERC Contact:* Lee Emery (202) 502–8379, or email at *lee.emery@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. Deadline for filing additional study requests and requests for cooperating agency status: June 27, 2022.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–10615–058.

m. The application is not ready for environmental analysis at this time.

n. The Tower and Kleber Hydroelectric Project consists of two developments. The Tower Development includes the following existing facilities: (1) An 83-acre reservoir with a gross storage capacity of 440 acre feet at a normal maximum water surface elevation of 722.1 feet National Geodetic Vertical Datum of 1929 (NGVD29); (2) a spillway with a Tainter gate; (3) a spillway with a vertical lift gate; (4) an uncontrolled spillway; (5) a concrete gravity non-overflow dam; (6) an earthen embankment with a concrete core wall; (7) a powerhouse with an integral concrete intake; (8) two 280-kilowatt (kW) turbine/generator units; (9) a 2.4-kilovolt (kV) transmission line; (10) a 2.4-kV to 12.5-kV step up transformer; and (11) appurtenant facilities. The Kleber Development includes the following existing facilities: (1) A 267-acre reservoir with a gross storage capacity of 3,000 acre feet at a normal maximum water surface elevation of 701.1 feet NGVD29; (2) an earthen embankment; (3) a spillway with a Tainter gate; (4) an emergency spillway, (5) an integral concrete intake; (6) two penstocks; (7) a powerhouse; (8) two 600-kW turbine/generator units; (9) a 2.4-kV transmission line; (10) a 2.4-kV to 12.5-kV step up transformer; and (11) appurtenant facilities. Both developments are operated in a run-of-river mode. The project has a total rated capacity of 1.760 megawatts.

o. A copy of the application may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC Online Support.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. Procedural schedule and final amendments: The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Issue Deficiency Letter (if necessary)—July 2022

Request Additional Information (if necessary)—July 2022

Issue Scoping Document 1 for comments—November 2022
Issue Scoping Document 2—(if necessary) January 2023
Issue Notice of Ready for Environmental Analysis—February 2023

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: May 4, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–10000 Filed 5–9–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP22–354–000]

Texas Gas Transmission, LLC.; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on April 29, 2022, Texas Gas Transmission, LLC (Texas Gas), 9 Greenway Plaza, Suite 2800, Houston, Texas 77046 filed in the above referenced docket, a prior notice pursuant to sections 157.205 and 157.208 of the Federal Energy Regulatory Commission's regulations under the Natural Gas Act, requesting authorization to replace, in the existing right-of-way a total of approximately 2.95 miles of existing parallel pipelines, Bastrop Eunice, 36–1, BAE 30–1, and BAE 26–1. In addition, the installation of a new 36-inch mainline block valve on the existing BAE 36–1 and minor work at six existing valve/metering facilities along the BAE system all located in Evangeline Parish, Louisiana (Pine Prairie Pipeline Replacement Project or Project).

Texas Gas proposes to replace the pipelines due to population increase and to maintain pipeline safety standards under the DOT design and integrity requirements. Texas proposes to replace the pipelines under authorities granted by its blanket certificate issued in Docket No. CP82–407–000.[1] Texas says that the replacements is necessary to ensure compliance with pipeline safety regulation and to keep communities near the facilities safe. The proposed replacement will have no impact on Texas existing customers or affect its existing storage operations. The estimated potential replacement cost for the Project is approximately $19,100,000, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions concerning this application should be directed to Michael E. McMahon, Senior Vice President and General Counsel, Texas Gas Transmission, LLC (Texas Gas), 9 Greenway Plaza, Suite 2800, Houston, Texas 77046; by phone: (713) 479–3480; or email: *Mike.McMahon@bwpipelines.com*.

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[2] within 90 days of this Notice the Commission staff will either: Complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: You can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on July 5, 2022. How to file protests, motions to intervene, and comments is explained below.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[3] any person [4] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[5] and must be submitted by the protest deadline, which is July 5, 2022. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [6] and the regulations under the NGA [7] by the intervention deadline for the project, which is July 5, 2022. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding

[1] *Texas Gas Transmission Corp.,* 20 FERC ¶ 62,417 (1982).

[2] 18 CFR (Code of Federal Regulations) § 157.9.

[3] 18 CFR 157.205.

[4] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[5] 18 CFR 157.205(e).

[6] 18 CFR 385.214.

[7] 18 CFR 157.10.

the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before July 5, 2022. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP22–354–000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select General'' and then select ''Protest'', ''Intervention'', or ''Comment on a Filing''; or [8]

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP22–354–000.

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: Michael E. McMahon, Senior Vice President and General Counsel, Texas Gas Transmission, LLC (Texas Gas), 9 Greenway Plaza, Suite 2800, Houston, Texas 77046; by phone: (713) 479–3480; or email: *Mike.McMahon@bwpipelines.com* . Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

[8] Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

Dated: May 4, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–09998 Filed 5–9–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RD22–1–000 and IC22–7–000]

Commission Information Collection Activities (FERC–725K); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comments on the requested renewal and revision of FERC–725K (Mandatory Reliability Standard for the SERC Region), which will be submitted to the Office of Management and Budget (OMB) for review.

The Commission published a 60-day notice in the **Federal Register** on March 4, 2022 (87 FR 12440), and received no comments on the 60-day notice.

DATES: Comments on the collection of information are due June 9, 2022.

ADDRESSES: Send written comments on FERC 725K to OMB through *www.reginfo.gov/public/do/PRAMain,* Attention: Federal Energy Regulatory Commission Desk Officer. Please identify the OMB Control Number 1902–0260 (Mandatory Reliability Standard for the SERC Region) in the subject line. Your comments should be sent within 30 days of publication of this notice in the **Federal Register**.

Please submit copies of your comments (identified by Docket No. IC22–7–000 and the form) to the Commission as noted below. Electronic filing through *http://www.ferc.gov,* is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery.

○ *Mail via U.S. Postal Service only, addressed to:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

○ *Hand (including courier) delivery to:* Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Please reference the specific collection number(s) and/or title(s) in your comments.

Instructions: OMB submissions must be formatted and filed in accordance with submission guidelines at: *www.reginfo.gov/public/do/PRAMain.* Using the search function under the ''Currently Under Review field,'' select Federal Energy Regulatory Commission; click ''submit'' and select ''comment'' to the right of the subject collection. FERC submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov.* For user assistance contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov* and telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION: [1]

Title: FERC–725K, Mandatory Reliability Standard for the SERC Region.

OMB Control No.: 1902–0260.

Type of Request: Request for comment on the revised information collection requirements resulting from Docket No. RD22–1–000 [2] and the three-year extension of FERC–725K.

Abstract: Section 215 of the Federal Power Act (FPA) [3] requires a Commission-certified Electric Reliability Organization (ERO) to develop mandatory and enforceable Reliability Standards, which are subject to Commission review and approval. Once approved, the Reliability Standards may be enforced by NERC, subject to Commission oversight, or by the Commission independently.

Reliability Standards that NERC proposes to the Commission may include Reliability Standards that are proposed by a Regional Entity to be effective in that region. In Order No. 672, the Commission noted that:

> As a general matter, we will accept the following two types of regional differences, provided they are otherwise just, reasonable, not unduly discriminatory or preferential and in the public interest, as required under the statute: (1) A regional difference that is more stringent than the continent-wide Reliability Standard, including a regional difference that addresses matters that the continent-wide Reliability Standard does not; and (2) a regional Reliability Standard that is necessitated by a physical difference in the Bulk-Power System.

When NERC reviews a regional Reliability Standard that would be applicable on an interconnection-wide basis and that has been proposed by a Regional Entity organized on an interconnection-wide basis, NERC must rebuttably presume that the regional Reliability Standard is just, reasonable, not unduly discriminatory or preferential, and in the public interest.[4] In turn, the Commission must give ''due weight'' to the technical expertise of NERC and of a Regional Entity organized on an interconnection-wide basis.[5] As stated in the NERC Petition, in 2008, SERC commenced work on Reliability Standard PRC–006–SERC–01. NERC also began work on revising PRC–006–0 at a continent-wide level. The SERC standard has been developed to be consistent with the NERC UFLS standard. PRC–006–SERC–02 was developed due to periodic review of the standard and PRC–006–1 clearly defines the roles and responsibilities of parties to whom the standard applies.

On February 18, 2022 FERC issued the Delegated Letter Order in Docket No. RD22–1–000 approving the NERC petition's request (Joint Petition of the North American Electric Reliability Corporation and SERC Reliability Corporation for Approval of Proposed Regional Reliability Standard PRC–006–SERC–03), which modifies the information collection of FERC–725K. The collection follows the NERC Petition request in Docket No. RD22–1–000 which proposes to update the reliability standard for the SERC region from PRC–006–SERC–02 to PRC–006–SERC–03. As stated in the NERC Petition submitted on December 14, 2021, the updated reliability standard provides additional flexibility for planning coordinators to adjust island boundaries to perform more accurate studies; address the transition of the Florida Reliability Coordinating Council (FRCC) registered entities to SERC following the dissolution of the FRCC on July 1, 2019; and to clarify technical requirements within the UFLS settings that are unique to the Florida peninsula. When FRCC was dissolved and the registered entities located in the Florida peninsula would eventually became subject to SERC's regional Reliability Standard PRC–006–SERC–02.

The PRC–006–1 standard identifies the Planning Coordinator (PC) as the entity responsible for developing underfrequency load shedding (UFLS) schemes within their PC area. The regional standard (PRC–006–SERC–03) adds specificity not contained in the NERC standard for a UFLS scheme in the SERC Region. The added specificity that PRC–006–SERC–03 provides effectively mitigates the consequences of an underfrequency event.

The purpose of regional Reliability Standard PRC–006–SERC–03 is to establish consistent and coordinated requirements for the design, implementation, and analysis of automatic UFLS programs among all SERC applicable entities. The regional Reliability Standard PRC–006–SERC–03 incorporates revisions to: (i) Provide more flexibility for Planning Coordinators to adjust island boundaries in order to perform more accurate and complete studies; (ii) address the transition of Florida Reliability Coordinating Council (''FRCC'') registered entities to SERC following the dissolution of FRCC as a regional entity on July 1, 2019; [6] (iii) clarify a technical term used in the regional Reliability Standard; and (iv) align requirement language with the current continent-wide NERC Reliability Standard, PRC–006–5.

Currently effective regional Reliability Standard PRC–006–SERC–02 was approved by the Commission on October 16, 2017 [7] and became effective for registered entities in the SERC region on January 1, 2018. Following the addition of FRCC's registered entities to SERC in 2019, SERC initiated a project to review PRC–006–SERC–02. SERC's Dynamics Working Group identified the need to revise the regional Reliability Standard to account for UFLS settings that are unique to the Florida peninsula. As part of this project, SERC also

[1] Due to expiration dates in 2019 for many of the Commission's financial forms, the renewal work for several of the forms was in process or pending at OMB during the 2019 Forms Refresh rulemaking effort in Docket No. RM19–12–000. The simultaneous OMB processes required the assignment of alternate temporary information collection numbers (*e.g.,* 60A) at the NOPR and/or final rule stages. Accordingly, FERC Form No. 60A represents the additional burden associated with the final rule in RM19–12–000. *Revisions to the Filing Process for Comm'n Forms,* Order No. 859, 167 FERC ¶ 61,241 (2019).

[2] Delegated Letter Order approving Joint Petition requesting to update the regional Reliability Standard PRC–006–SERC–03 under RD22–1 (dated 12/14/2021) filed by the North American Electric Reliability Corporation (*https://elibrary.ferc.gov/eLibrary/filelist?accession_num=20220218-3010*).

[3] 16 U.S.C. 824*o*.

[4] 16 U.S.C. 824o(d)(3).

[5] *Id.* § 824o(d)(2).

[6] Letter Order Approving the Joint Petition Requesting Certain Approvals in connection with the Dissolution of FRCC, 167 FERC ¶ 61,095, (2019).

[7] North American Electric Reliability Corporation (NERC), Docket No. RD17–9–000 (Oct. 16, 2017) (delegated letter order).

identified other opportunities to enhance the regional standard. SERC proposed to modify its UFLS Standard, PRC–006–SERC–02. Requirements R1 and R7 of the currently effective standard are removed in the updated regional Reliability PRC–006–SERC–03, but the numbering for the remaining Requirements is unchanged in the interest of administrative convenience.[8]

SERC proposed to remove Requirement R1, which says:

Each Planning Coordinator shall include its SERC subregion as an identified island in the criteria (required by the NERC PRC standard on UFLS) for selecting portions of the BPS that may form islands.[9]

SERC proposed the retirement of Requirement R7, which sets specific data requirements for Planning Coordinators (PCs) to provide SERC. SERC no longer plans to maintain a database of this information; therefore, it proposed to retire R7, that removes the requirement for SERC to maintain a UFLS database. SERC notes that this requirement is no longer needed because the continent-wide UFLS standard requires PCs to maintain a UFLS database.

Type of Respondents: Entities registered with the North American Electric Reliability Corporation within the SERC region.

Estimate of Annual Burden:[10] Our estimate below regarding the number of respondents is based on the NERC compliance registry as of January 7, 2022. According to the NERC compliance registry, there are 28 planning coordinators (PC) and 175 generator owners (GO) within the SERC Region. The individual burden estimates are based on the time needed for planning coordinators and generator operators to meet the requirements of both the regional SERC requirement and the national reliability requirements. The estimates include the costs to document and store data, run studies, assess UFLS design, and analyze results from design, development, and updating of the UFLS programs to be compliant with the SERC and NERC standards. Additionally, generator owners must provide a detailed set of data and documentation to SERC within 30 days of a request to facilitate post event analysis of frequency disturbances. These burden estimates are consistent with estimates for similar tasks in other Commission-approved Reliability Standards.

There are two burden tables below, the first showing the reduction in burden following RD22–1–000, and the second showing the estimated burden of the collection. The Commission estimates the annual reporting burden and cost for the Reliability Standard PRC–006–SERC–3 as:

FERC–725K—MODIFICATIONS DUE TO DLO IN DOCKET NO. RD22–1

[Reduction in burden]

Reliability standard and associated requirement	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response	Total annual burden & total annual cost	Cost per respondent ($)
	(1)	(2)	(1) * (2) =(3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
PRC–006–SERC–3						
PCs: Provide Documentation and Data to SERC.	28	1	.....	16 hrs.; $1,392	448 hrs.; $38,976	$1,392
Total Reduction due to RD22–1	.....	.....	.....	.....	448 hrs.; $38,976	.....

FERC–725K—MANDATORY RELIABILITY STANDARD FOR THE SERC REGION

[Renewal]

	Number of respondents[11]	Annual number of responses per respondent	Total number of responses	Average burden & cost per response[12]	Total annual burden hours & total annual cost	Cost per respondent ($)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
PCs: Design and Document Automatic UFLS Program.	28	1	28	8 hrs.; $696.00	224 hrs.; $19,488.00	$696.00
GOs: Provide Documentation and Data to SERC.	175	1	175	16 hrs.; $1,392.00	2800 hrs.; $243,600.00 ...	1,392.00
GOs: Record Retention	175	1	175	4 hrs.; $348.00	700 hrs.; $60,900	348.00
Total	.....	.....	.....	.....	3,724 hrs. $323,988[13]	.....

[11] Between previous information collection there is an increase in the number of PCs and GOs which largely reflect entities from the former FRCC and SPP regions now applicable PRC–006–SERC–03.

[12] The estimated hourly cost (salary plus benefits) provided in this section is based on the salary figures and benefits of the average 2021 FERC FTE costs ($180,703 per year, or $87.00 per hour), which we estimate is comparable for salary plus benefits costs of a utilities staff.

[13] The total hours reflect the total hours required for the collection following the reduction in burden from RD22–1–000.

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use

[8] NERC petition identified on page 8.

[9] NERC petition identified on page 9.

[10] ''Burden'' is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, reference 5 Code of Federal Regulations 1320.3.

of automated collection techniques or other forms of information technology.

Dated: May 4, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–09999 Filed 5–9–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL –9817–01–OA]

Public Meeting of the Science Advisory Board Drinking Water Committee (DWC) Augmented for the Contaminant Candidate List 5 Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces one public meeting of the Science Advisory Board Drinking Water Committee (DWC) Augmented for the Contaminant Candidate List 5 (CCL 5) Review. The purpose of the meeting is for the Committee to discuss their draft report reviewing EPA's *Draft Fifth Drinking Water Contaminant Candidate List (CCL 5)* (86 FR 37948) and three associated support documents: *Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5)—Contaminant Information Sheets; Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5)—Chemical Contaminants;* and *Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5)—Microbial Contaminants.*

DATES: The public meeting for the Science Advisory Board DWC Augmented for the CCL 5 Review to review its draft document will be held on June 6, 2022, from 12:30 p.m.—5:00 p.m. (Eastern Time).

ADDRESSES: The meeting will be conducted virtually. Please refer to the SAB website at *https://sab.epa.gov* for information on how to attend the meeting.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wants further information concerning this notice may contact Carolyn Kilgore, Designated Federal Officer (DFO), via telephone (202) 564–0230, or email at *Kilgore.Carolyn@epa.gov.* General information about the SAB, as well as any updates concerning the meetings announced in this notice can be found on the SAB website at *https://sab.epa.gov.*

SUPPLEMENTARY INFORMATION:

Background: The SAB was established pursuant to the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA), codified at 42 U.S.C. 4365, to provide independent scientific and technical advice to the EPA Administrator on the scientific and technical basis for agency positions and regulations. The SAB is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies. Pursuant to FACA and EPA policy, notice is hereby given that the Science Advisory Board DWC Augmented for the CCL 5 5 Review will hold a public meeting to discuss their draft report reviewing EPA's Draft Fifth Drinking Water Contaminant Candidate List and associated support documents.

Availability of Meeting Materials: All meeting materials, including the agenda will be available on the SAB web page at *https://sab.epa.gov.*

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office. Federal advisory committees and panels, including scientific advisory committees, provide independent advice to the EPA. Members of the public can submit relevant comments pertaining to the committee's charge or meeting materials. Input from the public to the SAB will have the most impact if it provides specific scientific or technical information or analysis for the SAB to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should follow the instruction below to submit comments.

Oral Statements: In general, individuals or groups requesting an oral presentation at a meeting conducted by telephone will be limited to three minutes. Each person making an oral statement should consider providing written comments as well as their oral statement so that the points presented orally can be expanded upon in writing. Persons interested in providing oral statements should contact the DFO, in writing (preferably via email) at the contact information noted above by May 31, 2022, to be placed on the list of registered speakers.

Written Statements: Written statements will be accepted throughout the advisory process; however, for timely consideration by SAB members, statements should be submitted to the DFO by May 24, 2022, for consideration at the June 6, 2022, meeting. Written statements should be supplied to the DFO at the contact information above via email. Submitters are requested to provide a signed and unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its websites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the SAB website. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, please contact the DFO, at the contact information noted above, preferably at least ten days prior to the meeting, to give the EPA as much time as possible to process your request.

Thomas H. Brennan,

Director, Science Advisory Board Staff Office.

[FR Doc. 2022–09945 Filed 5–9–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–0879; FRL–9801–01–OCSPP]

Environmental Modeling Public Meeting; Notice of Virtual Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA will hold a virtual Environmental Modeling Public Meeting (EMPM) on Tuesday, June 23, 2022, with participation by phone and webcast only. The EMPM provides a public forum for EPA and its stakeholders to discuss current issues related to modeling pesticide fate, transport, exposure, and ecotoxicity for pesticide risk assessments in a regulatory context. This Notice announces the meeting and provides information on its theme which is a focus on the Endangered Species Act and practical solutions to avoid, minimize or offset potential effects to Federally Listed endangered and threatened species and designated critical habitats from pesticides.

DATES: *Meeting:* This virtual meeting will be held on June 23, 2022, from 9:00 a.m. to approximately 4:30 p.m. EDT.

Requests to participate: Requests to attend the meeting must be submitted on or before June 16, 2022. Requests to present with an accompanying abstract must be submitted on or before May 26, 2022.

ADDRESSES: This is a virtual meeting. To register to attend and/or to present at this virtual meeting, please send an email to *OPP_EMPM@epa.gov.* You must register *via* email to receive the webcast meeting link and audio teleconference information for participation. Registrants will be added to the ''empmlist'' LYRIS list server (*https://lists.epa.gov/read/all_forums/*). Meeting updates and participation information will be distributed through ''empmlist''.

FOR FURTHER INFORMATION CONTACT: The 2022 EMPM Co-chairs, William Gardner, telephone number: (202) 566–1642 and Patricia Engel, telephone number: (202) 566–1690; email address: *OPP_EMPM@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are a pesticide registrant, a potential pesticide registrant, or a user of a pesticide under the Toxic Substances Control Act (TSCA), the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Agriculture, Forestry, Fishing and Hunting NAICS code 11.
- Utilities NAICS code 22.
- Professional, Scientific and Technical NAICS code 54.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2009–0879, is available at *http://www.regulations.gov.* It contains materials for all previous EMPMs. EPA will similarly include materials for this EMPM after the meeting.

Please note that due to the public health emergency, the Environmental Protection Agency Docket Center (EPA/DC) and Public Reading Room are now available in-person, *by appointment only,* at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets* and *https://www.epa.gov/dockets/epa-docket-center-and-reading-room-open-public-appointment-only.* Our EPA/DC staff will also continue to provide customer service via email, phone, and webform.

II. Background

The purpose of the EMPM is for presentation and discussion of current issues related to modeling pesticide fate, transport, and exposure for risk assessment in a regulatory context.

III. Theme for the Meeting

The 2022 EMPM will provide a forum for presentations on the incorporation of analyses into environmental exposure and ecological risk assessments, meant to comply with the Endangered Species Act, with a focus on practical solutions to avoid, minimize or offset potential effects to Federally Listed endangered and threatened species and designated critical habitats. Potential topics: Approaches to avoid and minimize effects to listed species that inhabit pesticide use sites, label mitigations to avoid jeopardy and adverse modifications to listed species and their critical habitat; evaluation of mitigation effectiveness; and chemical specific case studies. EPA may also provide updates on ongoing topics.

(Authority: 7 U.S.C. 136 *et seq.*)

Dated: April 29, 2022.

Jan Matuszko,

Acting Director, Environmental Fate and Effects Division, Office of Pesticide Programs.

[FR Doc. 2022–09947 Filed 5–9–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1159; FR ID 85775]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before July 11, 2022. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–1159.

Title: Part 25—Satellite Communications; and Part 27—

Miscellaneous Wireless Communication Services: 2.3 GHz Band.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for profit entities.

Number of Respondents and Responses: 155 respondents and 5,761 responses.

Estimated Time per Response: 0.5–40 hours.

Frequency of Response: Recordkeeping requirement, Third Party Disclosure, and On occasion and Quarterly reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is 47 U.S.C. 154, 301, 302(a), 303, 309, 332, 336, and 337 unless otherwise noted.

Total Annual Burden: 24,065 hours.

Annual Cost Burden: $370,250.

Needs and Uses: The information filed by Wireless Communications Service (WCS) licensees in support of their construction notifications will be used to determine whether licensees have complied with the Commission's performance benchmarks. Further, the information collected by licensees in support of their coordination obligations will help avoid harmful interference to Satellite Digital Audio Radio Service (SDARS), Aeronautical Mobile Telemetry (AMT) and Deep Space Network (DSN) operations in other spectrum bands.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2022–09941 Filed 5–9–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0975; FR ID 85420]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it can further reduce the information collection burden for small business concerns with fewer than 25 employees.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before June 9, 2022.

ADDRESSES: Comments should be sent to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–0975.

Title: Sections 68.105 and 1.4000, Promotion of Competitive Networks in Local Telecommunications Markets Multiple Tenant Environments (MTEs).

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions, and State, local, or Tribal governments.

Number of Respondents and Responses: 5,022 respondents; 217,658 responses.

Estimated Time per Response: 0.5 hour–10 hours.

Frequency of Response: On occasion reporting requirement and third-party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151 and the Telecommunications Act of 1996, Public Law 104–104.

Total Annual Burden: 144,217 hours.

Total Annual Cost: No cost.

Needs and Uses: This information facilitates efficient interaction between premises owners and local exchange carriers (LECs) regarding the placement of the demarcation point, which marks the end of wiring under control of the LEC and the beginning of wiring under the control of the premises owner or subscriber. The demarcation point is a critical point of interconnection where competitive LECs can gain access to the inside wiring of the building to provide service to customers in the building. This collection also helps ensure that fixed wireless antennas covered by the OTARD rule comply with the Commission's limits on radiofrequency exposure and provides the Commission with information on the state of the

market. In short, this collection helps foster competition in local telecommunications markets by ensuring that competing telecommunications providers can provide services to customers in multiple tenant environments.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2022–09940 Filed 5–9–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Report of Institution-to-Aggregate Granular Data on Assets and Liabilities on an Immediate Counterparty Basis (FR 2510; OMB No. 7100–0376).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Report title: Report of Institution-to-Aggregate Granular Data on Assets and Liabilities on an Immediate Counterparty Basis.

Agency form number: FR 2510.

OMB control number: 7100–0376.

Frequency: Quarterly.

Respondents: Any bank holding company (BHC) that is organized under the laws of the United States or any U.S. state and that is identified as a global systemically important bank (G–SIB) holding company under the Board's Regulation Q.

Estimated number of respondents: 8.

Estimated average hours per response: 568.

Estimated annual burden hours: 18,176.

General description of report: The FR 2510 collects granular exposure data on the assets, liabilities, and off-balance sheet holdings of G–SIBs, providing breakdowns by country, instrument, currency, maturity, sector, and other factors, and also collects country exposure data on an immediate counterparty basis and detailed information on firms' derivatives exposures. The information collected by the FR 2510 supports the Board's supervision of U.S. G–SIBs by allowing for a more complete balance sheet analysis of these firms and allows the Board to more closely monitor the systemic impacts of such firms' activities and investments.

Legal authorization and confidentiality: The FR 2510 is authorized by section 5 of the Bank Holding Company Act (BHC Act). Section 5 of the BHC Act authorizes the Board to require a bank holding company and any subsidiary of such company to submit reports under oath to keep the Board informed as to its financial condition, systems for monitoring and controlling financial and operating risks, and transactions with depository institution subsidiaries of the bank holding company.[1] The FR 2510 is mandatory for U.S. G–SIBs.

The information collected in the FR 2510 is collected as part of the Board's supervisory process and is therefore considered confidential pursuant to exemption 8 of the Freedom of Information Act (FOIA), which protects information contained in ''examination, operating, or condition reports'' obtained in the bank supervisory process. In addition, individual respondents may request that information be kept confidential pursuant to exemption 4 of the FOIA, which protects nonpublic commercial or financial information, which is both customarily and actually treated as private by the respondent. Determinations of confidentiality based on exemption 4 of the FOIA would be made on a case-by-case basis.

Current actions: On October 18, 2021, the Board published a notice in the **Federal Register** (86 FR 57672) requesting public comment for 60 days on the extension, without revision, of the Report of Institution-to-Aggregate Granular Data on Assets and Liabilities on an Immediate Counterparty Basis. The comment period for this notice expired on December 17, 2021. The Board received one comment.

Detailed Discussion of Public Comments

First, the commenter identified certain reporting differences between the Country Exposure Report (FFIEC 009; OMB No. 7100–0035) and the FR 2510 and argued that reporting of similar items between the two reports should be more aligned in order to minimize reporting burden. Specifically, the commenter highlighted the difference in remaining maturity on debt securities held for trading between the FFIEC 009 and the FR 2510. On the FFIEC 009, only a single bucket containing maturities of one year or less is required, whereas the FR 2510 requires four maturity buckets across the entire term structure. While the Board acknowledges the additional burden in reporting all maturity buckets in the FR 2510, this was part of the original design of the report and was meant to ''provide significantly more detail regarding the balance sheet and derivatives exposures of U.S. G–SIBs.'' [2] This original design was part of an internationally agreed upon process to facilitate the aggregation and analysis of consistent and comparable data from G–SIBs globally. In addition, the FR 2510 collects a more fulsome set of remaining maturity information to better understand the credit market and liquidity profiles of U.S. G–SIBs, which may have systemic implications at the individual institution level or the aggregate level. The FFIEC 009, on the other hand, collects overall country risk exposures for banks of all sizes and such detail is not needed for smaller institutions.

[1] 12 U.S.C. 1844(c)(1)(A).

[2] 83 FR 42680 (August 27, 2018).

The commenter also noted that the FR 2510 instructions allow respondents to use either the final contractual maturity or the next repricing date, where applicable, for reporting the remaining maturity of debt securities. In contrast, the FFIEC 009 instructions do not offer firms this option and require the use of final contractual maturity. The Board recognizes that on the FR 2510, firms are allowed to report next repricing date; however, firms are not required to do so. FR 2510 respondents are free to report remaining maturity of debt securities data on the same basis as the FFIEC 009. Also, the option to use final contractual maturity or next repricing date is comparable to how remaining maturity of debt securities is reported on the Consolidated Financial Statements for Holding Companies (FR Y–9C; OMB No. 7100–0128), specifically on the Securities Schedule HC–B, line items M2 and M2(a)–M2(c).

Additionally, the commenter identified an inconsistency between the FR 2510 and the FFIEC 009 with respect to the sector utilized for the reporting of central bank exposures. On the FR 2510, claims on central banks are reported in the ''Unallocated'' sector, which is designated for positions for which the sector of the counterparty is unknown or the sector information does not need to be reported. However, the reporting instructions to the FFIEC 009 require respondents to include central banks in the ''Public'' sector, which includes government departments and agencies. While the Board acknowledges that this difference can cause issues with comparability and can be burdensome for the reporting institutions, this distinction was intentional, as to avoid lumping claims on central banks together with claims banks have on governments such as sovereign bond and municipal security holdings.

Second, the commenter highlighted a concern with the inconsistency of reporting debt securities on the FR 2510 and the FR Y–9C. The FR 2510 requires debt securities to be broken out into the following three categories: Asset-backed securities (ABS), Other secured debt securities, and unsecured debt securities. This segmentation is not the same as found on the FR Y–9C, which requires respondents to break down debt securities into the following six groupings: U.S. Treasury securities, U.S. government agency and sponsored agency obligations, Securities issued by states and political subdivisions in the U.S., Mortgage-back securities (MBS), Asset-backed securities and structured financial products, and Other debt securities. The commenter pointed out that this discrepancy requires firms to look through and track features of securities that are not captured on other reports in great detail, creating significant burden. The commenter requested that the FR 2510 be modified to adopt the debt securities classification from the FR Y–9C. While the Board acknowledges the burden entailed in having two different classifications for the same debt securities, the internationally-agreed template for G–SIBs includes a different and less detailed breakdown than that which U.S. regulators have specified in various regulatory reports including the FR Y–9C, which is aggregated around several classes of securities that are idiosyncratic to and proportionately more important in U.S. debt markets.

Finally, the commenter raised several process issues regarding rounding differences between the data reported on the FR 2510 and the FFIEC 009, synchronizing proposed future changes to these reports, and providing adequate lead time for any proposed revisions to the FR 2510.[3] With respect to the rounding differences, the Federal Reserve regularly reviews and updates operational controls associated with Reporting Central outside of the clearance process and will review this recommendation accordingly. To the degree that there are future proposed changes to the FR 2510 or the FFIEC 009, which apply to both reports, the Board will strive to make these changes on similar timelines and provide adequate lead time for such changes. The Board does not plan at this time to propose changes to the FR 2510 that are consistent with the current FFIEC 009 proposal.[4] Those proposed changes to the FFIEC 009 are not applicable to the FR 2510.

The Board believes that the differences in reporting between the FR 2510, the FFIEC 009, and the FR Y–9C are warranted for the reasons described above. Therefore, the Board will not adopt any revisions to the FR 2510 as part of the extension of this collection.

Board of Governors of the Federal Reserve System, May 4, 2022.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–09979 Filed 5–9–22; 8:45 am]

BILLING CODE 6210–01–P

[3] Specifically, the commenter asked for a delayed effective date of any changes made to the FR 2510. This comment is not applicable to the current extension of the FR 2510, as no revisions were proposed or are being adopted.

[4] See 87 FR 3170 (January 20, 2022).

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than May 25, 2022.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Suresh Alla, individually, and as general partner of Thornwood Holdings LP, both of Bettendorf, Iowa;* to join the Alla Family Control Group, a group acting in concert, to acquire voting shares of AmBank Holdings, Inc., and thereby indirectly acquire voting shares of American Bank and Trust N.A., both of Davenport, Iowa.

Board of Governors of the Federal Reserve System, May 5, 2022.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–10027 Filed 5–9–22; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH); Meeting

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting of the Advisory Board on Radiation and Worker Health (ABRWH). This meeting is open to the public, but without a public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcome to listen to the meeting by joining the teleconference (information below). The audio conference line has 150 ports for callers.

DATES: The meeting will be held on June 15, 2022, from 11:00 a.m. to 1:00 p.m., EDT. Written comments must be received on or before June 8, 2022.

ADDRESSES: You may submit comments by mail to:

Sherri Diana, National Institute for Occupational Safety and Health (NIOSH), CDC, 1090 Tusculum Avenue, Mailstop C–34, Cincinnati, Ohio 45226.

Meeting Information: Audio Conference Call via FTS Conferencing. The USA toll-free dial-in number is 1–866–659–0537; the passcode is 9933701.

FOR FURTHER INFORMATION CONTACT: Rashaun Roberts, Ph.D., Designated Federal Officer, NIOSH, CDC, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226, Telephone (513) 533–6800; Email: *ocas@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines, which have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC.

The Advisory Board's charter was issued on August 3, 2001, was renewed at appropriate intervals, was rechartered on March 22, 2022, and will terminate on March 22, 2024.

Purpose: This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters to be Considered: The agenda will include discussions on the following: Work Group and Subcommittee Reports; Update on the Status of SEC Petitions; and plans for the August 2022 Advisory Board Meeting. Agenda items are subject to change as priorities dictate.

For additional information, please contact Toll Free 1–800–232–4636.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–09948 Filed 5–9–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2022–0065]

Advisory Committee on Immunization Practices (ACIP)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. Time will be available for public comment.

DATES: The meeting will be held on May 19, 2022, from 11:00 a.m. to 4:00 p.m., EDT (times subject to change). The meeting will be webcast live via the World Wide Web. Written comments must be received on or before May 19, 2022.

ADDRESSES: You may submit comments identified by Docket No. CDC–2022–0065 by either of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H24–8, Atlanta, Georgia 30329–4027, Attn: May 19, 2022, ACIP Meeting.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the *https://www.regulations.gov* suitability policy will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, Mailstop H24–8, Atlanta, Georgia 30329–4027, Telephone: (404) 639–8367; Email: *ACIP@cdc.gov.*

SUPPLEMENTARY INFORMATION: In accordance with 41 CFR 102–3.150(b), less than 15 calendar days' notice is being given for this meeting due to the exceptional circumstances of the

COVID–19 pandemic and rapidly evolving COVID–19 vaccine development and regulatory processes. The Secretary of Health and Human Services has determined that COVID–19 is a Public Health Emergency. A notice of this ACIP meeting has also been posted on CDC's ACIP website at: *http://www.cdc.gov/vaccines/acip/index.html.* In addition, CDC has sent notice of this ACIP meeting by email to those who subscribe to receive email updates about ACIP.

Purpose: The committee is charged with advising the Director, CDC, on the use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the CDC Director and appear on CDC immunization schedules must be covered by applicable health plans.

Matters to be Considered: The agenda will include discussions on the use of COVID–19 vaccines. A recommendation vote(s) is scheduled. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda, visit *https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html.* The meeting will be webcast live via the World Wide Web; for more information on ACIP, visit the ACIP website: *https://www.cdc.gov/vaccines/acip/index.html.*

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: The docket will be opened to receive written comments on May 10, 2022. Written comments must be received on or before May 19, 2022.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes, including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the May 19, 2022, ACIP meeting must submit a request at *https://www.cdc.gov/vaccines/acip/meetings/index.html* no later than 11:59 p.m., EDT, May 17, 2022, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email on May 18, 2022. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may speak only once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–10130 Filed 5–6–22; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Council for the Elimination of Tuberculosis

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). This meeting is open to the public and limited to 1,000 audio and web conference lines. Members of the public are welcome to listen to the meeting by accessing the telephone number and web access provided in the addresses section below. Time will be available for public comment (registration required to provide oral comment).

DATES: The meeting will be held on June 21, 2022, from 10:00 a.m. to 4:30 p.m., EDT, and June 22, 2022, from 10:00 a.m. to 12:05 p.m., EDT. Written comments must be received on or before June 7, 2022. Registration to make oral comments must be submitted by June 16, 2022.

ADDRESSES: The telephone access number is 1–669–254–5252, Webinar ID: 160 137 0413, and the Passcode is 37403108. The web conference access is *https://cdc.zoomgov.com/j/1601370413?pwd=T0pucU1yNENQVUlRNUNVUVBKbHh2UT09,* and the Passcode is ^Sm35?s2. The number of available audio and web conference lines is 1,000.

FOR FURTHER INFORMATION CONTACT: Marah Condit, MS, Committee Management Lead, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, CDC, 1600 Clifton Road NE, Mailstop US8–6, Atlanta, GA 30329–4027, Telephone:(404)639–3423; Email: *nchhstppolicy@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The Council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

Matters to be Considered: The agenda will include discussions on (1) NIH-funded clinical trials; (2) domestic pediatric tuberculosis; (3) immigration and tuberculosis; and (4) considerations for bringing new tuberculosis drugs to market. Agenda items are subject to change as priorities dictate.

Public Participation

Written Public Comment: Members of the public are welcome to submit written comments in advance of the meeting. Written comments must be submitted by emailing *nchhstppolicy@cdc.gov* with subject line ''June ACET Public Comment Registration'' by June 7, 2022.

Oral Public Comment: Individuals who would like to make an oral comment during the public comment period must register by emailing *nchhst ppolicy@cdc.gov* with subject line ''June ACET Public Comment Registration'' by June 16, 2022. The public comment period is on June 22, 2022, at 11:55 a.m., EDT.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–09949 Filed 5–9–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2022–0062]

Advisory Committee on Immunization Practices (ACIP)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. Time will be available for public comment.

DATES: The meeting will be held on June 22, 2022, from 10:00 a.m. to 5:00 p.m., EDT, and June 23, 2022, from 10:00 a.m. to 2:00 p.m., EDT (times subject to change). The meeting will be webcast live via the World Wide Web. Written comments must be received on or before June 23, 2022.

ADDRESSES: You may submit comments identified by Docket No. CDC–2022–0062 by either of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H24–8, Atlanta, Georgia 30329–4027, Attn: ACIP Meeting.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the *https://www.regulations.gov* suitability policy will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.* Do not submit comments by email; CDC does not accept comments by email. Written public comments submitted by 72 hours prior to the ACIP meeting will be provided to ACIP members before the meeting.

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, Mailstop H24–8, Atlanta, Georgia 30329–4027, Telephone: (404) 639–8367; Email: *ACIP@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The committee is charged with advising the Director, CDC, on the use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the CDC Director and appear on CDC immunization schedules must be covered by applicable health plans.

Matters to be considered: The agenda will include discussions on influenza vaccines; pneumococcal vaccine; human papillomavirus vaccine; measles, mumps, rubella (MMR) vaccine; respiratory syncytial virus vaccine; rotavirus vaccine; and Chikungunya vaccine. Recommendation votes on influenza vaccines, pneumococcal vaccine, and MMR vaccine are scheduled. No VFC votes are scheduled. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda, visit *https://www.cdc.gov/vaccines/acip/meetings/index.html.* The meeting will be webcast live via the World Wide Web; for more information on ACIP, visit the ACIP website: *https://www.cdc.gov/vaccines/acip/index.html.*

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: The docket will be opened to receive written comments on May 10, 2022. Written comments must be received on or before June 23, 2022.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes, including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the June 22–23,

2022, ACIP meeting must submit a request at *https://www.cdc.gov/vaccines/acip/meetings/index.html* no later than 11:59 p.m., EDT, June 13, 2022, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by June 15, 2022. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may speak only once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–09950 Filed 5–9–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—SIP22–005, Building Resilience Against Climate Effects (BRACE): Enhancing Practical Guidance To Support Climate and Health Adaptation Planning; Amended Notice of Closed Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—SIP22–005, Building Resilience Against Climate Effects (BRACE): Enhancing Practical Guidance to Support Climate and Health Adaptation Planning; May 4, 2022, 11 a.m.–6 p.m., EDT, in the original FRN.

The meeting was published in the **Federal Register** on March 1, 2022, Volume 87, Number 40, page 11444.

The meeting is being amended to change the meeting date and time and should read as follows:

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)— SIP22–005, Building Resilience Against Climate Effects (BRACE): Enhancing Practical Guidance to Support Climate and Health Adaptation Planning.

Date: May 19, 2022.

Time: 3 p.m.–6 p.m., EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

The meeting is closed to the public.

SUPPLEMENTARY INFORMATION: In accordance with 41 CFR 102–3.150(b), less than 15 calendar days' notice is being given for this amended closed meeting due to an unforeseen medical emergency and exceptional circumstances that led to an anomaly of programmatic matters and the necessity to resolve issues, reschedule, and convene as soon as possible.

FOR FURTHER INFORMATION CONTACT: Jaya Raman, Ph.D., Scientific Review Officer, CDC, 4770 Buford Highway, Mailstop F80, Atlanta, Georgia 30341, Telephone: (770) 488–6511, *kva5@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–10023 Filed 5–9–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS–10286 & CMS–10630]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *June 9, 2022.*

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information,

including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Notice of Research Exception under the Genetic Information Nondiscrimination Act; *Use:* Under the Genetic Information Nondiscrimination Act of 2008 (GINA), a plan or issuer may request (but not require) a genetic test in connection with certain research activities so long as such activities comply with specific requirements, including: (i) The research complies with 45 CFR part 46 or equivalent federal regulations and applicable State or local law or regulations for the protection of human subjects in research; (ii) the request for the participant or beneficiary (or in the case of a minor child, the legal guardian of such beneficiary) is made in writing and clearly indicates that compliance with the request is voluntary and that non-compliance will have no effect on eligibility for benefits or premium or contribution amounts; and (iii) no genetic information collected or acquired will be used for underwriting purposes. The Secretary of Labor or the Secretary of Health and Human Services is required to be notified if a group health plan or health insurance issuer intends to claim the research exception permitted under Title I of GINA. Nonfederal governmental group health plans and issuers solely in the individual health insurance market or Medigap market will be required to file with the Centers for Medicare & Medicaid Services (CMS). The Notice of Research Exception under the Genetic Information Nondiscrimination Act is a model notice that can be completed by group health plans and health insurance issuers and filed with either the Department of Labor or CMS to comply with the notification requirement. *Form Number:* CMS–10286, OMB control number: 0938–1077; *Frequency:* On Occasion; *Affected Public:* Private Sector; State, Local or Tribal governments; *Number of Respondents:* 2; *Total Annual Responses:* 2; *Total Annual Hours:* 1. (For policy questions regarding this collection contact Usree Bandyopadhyay at 410–786–6650)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* The PACE Organization (PO) Monitoring and Audit Process in 42 CFR part 460; *Use:* Sections 1894(e)(4) and 1934(e)(4) of the Act and the implementing regulations at 42 CFR 460.190 and 460.192 state that CMS, in conjunction with the State Administering Agency (SAA), must oversee a PACE organization's continued compliance with the requirements for a PACE organization.

The data collected with the data request tools included in this package allow CMS to conduct a comprehensive review of PACE organizations' compliance in accordance with specific federal regulatory requirements. The information gathered during this audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM), as well as the SAA, to assess POs' compliance with PACE program requirements. If outliers or other data anomalies are detected, other offices within CMS will work in collaboration with MOEG for follow-up and resolution. Additionally, POs will receive the audit results, and will be required to implement corrective action to correct any identified deficiencies. *Form Number:* CMS–10630 (OMB control number: 0938–1327); *Frequency:* Annually; *Affected Public:* Private Sector, State, Local, or Tribal Governments and Business or other for-profit institutions; *Number of Respondents:* 40; *Total Annual Responses:* 40; *Total Annual Hours:* 31,200. (For policy questions regarding this collection contact Kathleen Flannery at 410–786–6722.)

Dated: May 5, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–10026 Filed 5–9–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0939]

Determination That GLUCOTROL (Glipizide) Tablets, 2.5 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that GLUCOTROL (glipizide) tablets, 2.5 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for glipizide tablets, 2.5 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Dan Ritterbeck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993–0002, 301–796–4673, *Daniel.Ritterbeck@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) Has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

GLUCOTROL (glipizide) tablets, 2.5 mg, are the subject of NDA 017783, held by Pfizer Inc., and initially approved on May 8, 1984. GLUCOTROL is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

GLUCOTROL (glipizide) tablets, 2.5 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated August 24, 2021 (Docket No. FDA–2021–P–0939), under 21 CFR 10.30, requesting that the Agency determine whether GLUCOTROL (glipizide) tablets, 2.5 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that GLUCOTROL (glipizide) tablets, 2.5 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that GLUCOTROL (glipizide) tablets, 2.5 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of GLUCOTROL (glipizide) tablets, 2.5 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list GLUCOTROL (glipizide) tablets, 2.5 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to GLUCOTROL (glipizide) tablets, 2.5 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09944 Filed 5–9–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–N–1721; FDA–2005–N–0101; FDA–2021–N–0386; FDA–2012–N–0294; and FDA–2018–N–3404]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections approved recently by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Investigational New Drug Regulations	0910–0014	3/31/2025
Prescription Drug User Fee Program	0910–0297	3/31/2025
Medical Device Reporting	0910–0437	3/31/2025
Food Additives; Food Contact Substances Notification System	0910–0495	3/31/2025
Generic Drug User Fee Program	0910–0727	3/31/2025

Dated: May 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–10017 Filed 5–9–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0168]

Benefit-Risk Considerations for Product Quality Assessments; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Benefit-Risk Considerations for Product Quality Assessments.'' This guidance describes the benefit-risk principles applied by FDA when conducting product quality-related assessments of chemistry, manufacturing, and controls (CMC) information submitted for FDA assessment as part of original new drug applications (NDAs), original biologics license applications (BLAs), or supplements to such applications, in addition to other information (*e.g.,* inspectional findings) available to FDA during its assessment. This guidance discusses how FDA assesses risks, sources of uncertainty, and possible mitigation strategies for a product quality-related issue and how those considerations inform FDA's understanding of the potential effect on a product. This guidance also discusses how unresolved product quality issues may be addressed in the context of regulatory decision making. The guidance notes that product quality assessments are also done for abbreviated new drug applications (ANDAs), and it discusses how, in certain rare circumstances, unresolved product quality issues may be addressed when there is an urgent clinical need for

an ANDA (*e.g.,* a public health emergency or a pervasive drug shortage).

DATES: Submit either electronic or written comments on the draft guidance by July 11, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0168 for ''Benefit-Risk Considerations for Product Quality Assessments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Natalia Comella, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6648, Silver Spring, MD 20993–0002, 301–796–6226.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Benefit-Risk Considerations for Product Quality Assessments.'' This guidance describes the benefit-risk principles applied by FDA when conducting product quality-related assessments of CMC information submitted for FDA assessment as part of original NDAs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), original BLAs under section 351 of the Public Health Service Act (42 U.S.C. 262), or supplements to such applications, in addition to other information (*e.g.,* inspectional findings) available to FDA during its assessment. This guidance discusses how FDA assesses risks, sources of uncertainty, and possible mitigation strategies for a product quality-related issue and how those considerations inform FDA's understanding of the potential effect on a product. The outcome of the product quality assessment results in a determination as to whether an applicant has developed a drug product, manufacturing process, and control strategy that will consistently result in a product of acceptable quality when manufactured at the facilities named in the application.

When a regulatory decision regarding the approval of an NDA or BLA is made, FDA considers the overall benefit(s) and risks identified for the product. This can include any residual risk related to unresolved product quality issues if they directly affect the assessment. This guidance also discusses how unresolved product quality issues may be addressed in the context of regulatory decision making. The guidance notes that product quality assessments are also done for ANDAs, and it discusses how, in certain rare circumstances, unresolved product quality issues may be addressed when there is an urgent clinical need for an ANDA (*e.g.,* a public health emergency or a pervasive drug shortage).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Benefit-Risk Considerations for Product Quality Assessments.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if

it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR parts 601 and 610 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov.*

Dated: May 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–10030 Filed 5–9–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0173]

Practices To Prevent Unsafe Contamination of Animal Feed From Drug Carryover; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry #272 entitled ''Practices to Prevent Unsafe Contamination of Animal Feed from Drug Carryover.'' We are issuing this draft guidance to describe practices that medicated feed manufacturers can use to prevent unsafe contamination from drug carryover into a non-medicated animal feed or an animal feed containing a different approved new animal drug. Unsafe contamination of animal feed from drug carryover can pose a risk to human and animal health. When finalized, this guidance will replace Compliance Policy Guides (CPGs) Sec. 680.500 and 680.600.

DATES: Submit either electronic or written comments on the draft guidance by August 8, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0173 for ''Practices to Prevent Unsafe Contamination of Animal Feed from Drug Carryover.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kevin Klommhaus, Center for

Veterinary Medicine (HFV–236), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 515–318–8075.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #272 entitled ''Practices to Prevent Unsafe Contamination of Animal Feed from Drug Carryover.'' This draft guidance contains much of the information found in the CPGs Sec. 680.500 ''Unsafe Contamination of Animal Feed from Drug Carryover'' and 680.600 ''Sequencing as a Means to Prevent Unsafe Drug Contamination in the Production, Storage, and Distribution of Feeds'' but includes updates and additional information. We intend to withdraw the CPGs after this guidance is finalized. Drug carryover generally occurs when a drug used in the manufacture of a batch of medicated feed, for which the drug is approved, gets inadvertently included in a subsequent batch of: (1) A non-medicated feed, (2) a different medicated feed for which the drug is not approved (*e.g.,* medicated feed for another species), or (3) a medicated feed that contains the same drug that can result in a higher drug level than is stated on the labeling. This carryover can occur for multiple reasons, including the use of the same equipment to manufacture both medicated and non-medicated feed, inadequate cleanout practices for manufacturing and distribution equipment between sequential batches, or human error.

We understand that an absolute avoidance of all batch-to-batch drug carryover may not be possible. However, measures can be implemented to avoid unsafe contamination of animal feed from drug carryover. In this draft guidance, unsafe contamination of an animal feed refers to a degree of contamination, by a drug approved for a medicated feed use, that poses an unacceptable risk to human or animal health. Human health may be at risk if humans consume a product derived from animals that have consumed animal feed contaminated from drug carryover and there is drug residue in the edible tissues of that animal (*e.g.,* milk, meat, or eggs). Unsafe contamination from drug carryover in animal feed can impact animal health when an animal consumes the contaminated feed, *e.g.,* horses consuming feed contaminated with the drug monensin. Horses are sensitive to ionophore drugs like monensin, and ingestion can result in severe illness or death.

Our regulation ''Current Good Manufacturing Practice for Medicated Feeds,'' 21 CFR part 225, contains requirements for equipment cleanout procedures to avoid unsafe contamination of feeds with drugs (see 21 CFR 225.65 and 225.165). In this guidance, we provide information on some ways to comply with these requirements to help prevent unsafe contamination of animal feed from drug carryover.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on some practices that can be used in feed mills manufacturing medicated feed to prevent unsafe contamination of animal feed from drug carryover. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: May 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09939 Filed 5–9–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group Developmental Brain Disorders Study Section

Date: June 8–9, 2022.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pat Manos, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, (301) 408–9866, *manospa@csr.nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group Nanotechnology Study Section.

Date: June 9–10, 2022.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Joseph Thomas Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9694, *petersonjt@csr.nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group Integrative Myocardial Physiology/Pathophysiology B Study Section.

Date: June 14–15, 2022.

Time: 9:00 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Kirk E Dineley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 806E, Bethesda, MD 20892, (301) 867–5309, *dineleyke@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group Maximizing Investigators' Research Award C Study Section.

Date: June 14–15, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Jimok Kim, Ph.D., Scientific Review Officer, Center for

Scientific Review, 6107 Rockledge Drive, Bethesda, MD 20892, (301) 402–8559, *jimok.kim@nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group Macromolecular Structure and Function B Study Section.

Date: June 14–15, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Alexei A Yeliseev, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–443–0552, *yeliseeva@mail.nih.gov.*

Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 4, 2022.

David W Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09965 Filed 5–9–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID Resource Related Research Projects (R24 Clinical Trial Not Allowed).

Date: June 7, 2022.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G42, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Sandip Bhattacharyya, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G42, Rockville, MD 20852, (240) 292–0189, *sandip.bhattacharyya@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 4, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09988 Filed 5–9–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Clinical and Basic Science Study Section.

Date: June 23–24, 2022.

Time: 10:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Heart, Lung, and Blood Institute, RKL1, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rajiv Kumar, Ph.D., Chief, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6705 Rockledge Drive, Bethesda, MD 20892, (301) 827–4612, *rajiv.kumar@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 4, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09963 Filed 5–9–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; Clinical Trials Review Study Section.

Date: June 23–24, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda MD 20817 (Virtual Meeting).

Contact Person: Keary A. Cope, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 209–A, Bethesda, MD 20892–7924, (301) 827–7912, *copeka@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 4, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09962 Filed 5–9–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel HEAL Initiative: Harm Reduction Policies, Practices, and Modes of Delivery for Persons with Substance Use Disorders: Coordination Center.

Date: June 1, 2022.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sindhu Kizhakke Madathil, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021 Bethesda, MD 20892, (301) 827–5702, *sindhu.kizhakkemadathil@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel HEAL Initiative: Harm Reduction Policies, Practices, and Modes of Delivery for Persons with Substance Use Disorders: Coordination Center.

Date: June 16, 2022.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Contact Person: Sindhu Kizhakke Madathil, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892 (301) 827–5702, *sindhu.kizhakkemadathil@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel NIDA Training SEP.

Date: June 9, 2022.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sindhu Kizhakke Madathil, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–5702, *sindhu.kizhakkemadathil@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel NIDA Training SEP.

Date: June 17, 2022.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sindhu Kizhakke Madathil, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–5702, *sindhu.kizhakkemadathil@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel HEAL Initiative: HEAL Data2Action Innovation Projects and Centers.

Date: June 21, 2022,

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Trinh T. Tran, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–5843, *trinh.tran@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel HEAL Initiative: HEAL Data2Action Innovation Projects and Centers.

Date: June 23, 2022.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Trinh T. Tran, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–5843, *trinh.tran@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: May 4, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09987 Filed 5–9–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Patient-Oriented Research Study Section.

Date: June 30–July 1, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Stephanie Johnson Webb, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–V, Bethesda, MD 20892, (301) 827–7992, *stephanie.webb@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 4, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09964 Filed 5–9–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIDCR.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Dental and Craniofacial Research, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIDCR.

Date: June 2–3, 2022.

Time: June 2, 2022, 10:00 a.m. to 6:05 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 6701 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Time: June 3, 2022, 10:00 a.m. to 2:15 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 6701 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lynn M. King, Ph.D., Director, Division of Extramural Activities, National Institute of Dental and Craniofacial Research, 6701 Democracy Boulevard, Bethesda, MD 20892, (301) 594–5006, *lynn.king@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: May 5, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–10034 Filed 5–9–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs & Border Protection

Document Imaging System (DIS) Pilot for Used Self-Propelled Vehicles Export Document Submission

AGENCY: U.S. Customs and Border Protection, DHS.

ACTION: General notice.

SUMMARY: This document announces that U.S. Customs and Border Protection (CBP) plans to conduct a pilot to promote paperless processing of export documentation for used self-propelled vehicles (USPVs). Generally, USPVs include any vehicle that can be driven on land but not rail. The CBP regulations require a person attempting to export a USPV to present original vehicle ownership documentation to CBP at the port of exportation. In an effort to expedite and modernize the document submission and review process, CBP will be operating a voluntary pilot in which participants will submit the required vehicle ownership documentation to CBP electronically via the Document Imaging System (DIS). This voluntary pilot will evaluate the feasibility of using the DIS for the purpose of obtaining and reviewing vehicle ownership documentation for USPVs. This notice includes a description of the pilot, the eligibility requirements for participation, and invites public comment on any aspect of the pilot.

DATES: This voluntary pilot will begin no earlier than June 9, 2022 and will run for approximately two years. The pilot will apply to the export of all USPVs regardless of the mode of transportation. Implementation of the pilot for each mode of transportation and/or port participation will be staggered and will be announced to the public through the Cargo Systems Messaging Service (CSMS).[1] The CSMS message will include the start date for accepting ownership documentation via the DIS. Comments concerning this notice and all aspects of the announced pilot may be submitted at any time during the pilot period.

ADDRESSES: Interested parties should contact their local CBP vehicle export processing office and express their interest and intent to participate in the DIS pilot. Written comments concerning the program, policy, and technical issues may be submitted at *UsedVehicleDISTEST@cbp.dhs.gov.*

[1] Archived public CSMS messages can be accessed at: *https://www.cbp.gov/trade/automated/cargo-systems-messaging-service.*

FOR FURTHER INFORMATION CONTACT: Stephan Keating, Cargo and Conveyance Security (CCS), Office of Field Operations (OFO), U.S. Customs and Border Protection, at 202–344–2847 or via email at *Stephan.D.Keating@cbp.dhs.gov* and David Garcia, Cargo and Conveyance Security (CCS), OFO, CBP at *David.USCS.Garcia@cbp.dhs.gov* and 202–344–3277.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose of the Pilot

A. Current Requirements for Export of Used Self-Propelled Vehicles

In 1984, Congress enacted the Motor Vehicle Theft Enforcement Act, Public Law 98–547, 98 Stat. 2754 codified at 19 U.S.C. 1627a (1984 Act), which makes it unlawful to import or export, or attempt to import or export, any stolen self-propelled vehicle, vessel, or aircraft. Pursuant to the 1984 Act, the Department of Homeland Security is authorized to promulgate regulations for the export of used self-propelled vehicles. The 1984 Act allows CBP to share relevant information with such Federal, State, local, and foreign law enforcement or governmental authorities, and with such organizations engaged in theft prevention activities, as may be designated by the Secretary.

In 1992, Congress imposed additional requirements on the export of used vehicles, with the enactment of the Anti Car Theft Act, Public Law 102–519, 106 Stat. 3400, codified at 19 U.S.C. 1646b—1646c (1992 Act). The 1992 Act requires all persons or entities exporting used automobiles, by air or vessel, including automobiles exported for personal use, to provide CBP with certain information including the Vehicle Identification Number (VIN) and proof of ownership of the vehicle at least 72 hours prior to exportation. The 1992 Act authorizes the Commissioner of CBP to establish risk-based targeting criteria for automobiles being exported, and to check the VIN of targeted automobiles against the information in the National Crime Information Center (NCIC) to determine whether the vehicle has been reported stolen. *See* 19 U.S.C. 1646c.

The implementing regulations for the above statutes are set forth in part 192 of title 19 of the Code of Federal Regulations (19 CFR part 192). Among other things, part 192 includes regulations pertaining to procedures for the lawful exportation of USPVs. In general, a self-propelled vehicle is any vehicle that can be driven on land but not on rail. Specifically, 19 CFR 192.1 defines *self-propelled vehicle* as any automobile, truck, tractor, bus, motorcycle, motor home, self-propelled

agricultural machinery, self-propelled construction equipment, self-propelled special use equipment, and any other self-propelled vehicle used or designed for running on land but not on rail. Section 192.1 defines *used* as any self-propelled vehicle the equitable or legal title to which has been transferred by a manufacturer, distributor, or dealer to an ultimate purchaser. Finally, section 192.1 defines *export* as the transportation of merchandise out of the U.S. for the purpose of being entered into the commerce of a foreign country.

19 CFR 192.2 requires that in the case of a vehicle being exported by vessel or aircraft, both the required documentation describing the vehicle and the vehicle must be presented to CBP at least 72 hours prior to export, and in the case of a vehicle being exported at a land border crossing (by rail, highway, or under its own power), the required documentation must be submitted at least 72 hours prior to export, and the vehicle must be presented at the time of export. The required documentation includes the VIN or, if the vehicle does not have a VIN, the product information number (PIN). Section 192.2(b) specifies the type of documents that must be submitted in different circumstances. Exportation of a vehicle is permitted only upon compliance with these requirements unless, as per section 192.2(a), the vehicle was entered into the United States under an in-bond procedure, or under a carnet or Temporary Importation Bond (TIB). Such vehicles are exempt from these requirements.

B. Authorization for the Pilot

The test described in this notice is authorized pursuant to 19 CFR 101.9(a), which grants the Commissioner of CBP the authority to impose requirements different from those specified in CBP regulations for purposes of conducting a test program or procedure designed to evaluate the effectiveness of new technology or operational procedures regarding the processing of passengers, vessels, or merchandise.

C. Purpose of Pilot

CBP is implementing this voluntary Document Imaging System (DIS) pilot in order to expedite and modernize the document submission and review process for the export of used self-propelled vehicles.

During Fiscal Years 2018–2020, there was an annual average of 1.4 million, used self-propelled vehicles exported from the United States. Under the current regulatory export procedures, the person who is attempting to export a used self-propelled vehicle must present to CBP both the vehicle and specified paper documents. This paper process is a drain on limited CBP staffing resources at ports with significant traffic because it requires CBP to devote numerous hours to review vehicle export paperwork.

The pilot will allow CBP to test the mechanisms through which the required documentation may be submitted electronically, as a preliminary step towards moving to a more automated and efficient export reporting system for export of used self-propelled vehicles. Having the required documentation available electronically will enable CBP to institute better risk-based targeting of exports. This will be accomplished by making electronic document and information submission the primary means for meeting export reporting requirements and reserving field inspection of vehicles and examination of original ownership documentation only for cases where targeting and risk assessment have identified a need for additional scrutiny. The receipt of the electronic ownership documentation will also improve CBP's ability to target and identify high-risk vehicle exports pre-departure while facilitating the process for legitimate exportation through a more streamlined and efficient port procedure. Considering the high volume of vehicle exports, it is expected that the electronic submission of the required documentation will have a significant impact on the speed and efficiency of vehicle export processing. The pilot will allow CBP to assess the effectiveness of these procedures and will allow the agency to test the functionality of the systems required for electronic submission. The results of the pilot will help CBP determine whether to eventually require through rulemaking the electronic submission of vehicle ownership documentation using the DIS.

II. Description of Pilot

In this voluntary pilot, participants will submit the required ownership documentation as set forth in 19 CFR part 192 through the DIS in ACE, using either the Electronic Data Interchange (EDI) via an Approved Broker Interface (ABI), or via email (at *docs@cbp.dhs.gov*). Participants will be required to submit the documentation in accordance with existing regulatory timeframes depending on the mode of export.[2] Participation in the pilot will not alter the requirements for presentation of the vehicle to CBP. *See* 19 CFR 192.2(c), (d).

Under the pilot, the electronically submitted documents will be linked to the Electronic Export Information (EEI)[3] filing in the Automated Export System (AES) via the Internal Transaction Number (ITN) generated at the time of the EEI submission. Participants will be required to transmit a valid ITN number to CBP with the DIS submission. Participants will have to submit EEI prior to submitting the vehicle documents to DIS. CBP will request original documentation and conduct a physical examination of the vehicle when necessitated by the results of targeting and risk assessment.

The sections below describe the pilot, including specific instructions on how to participate in the pilot (section D), in more detail.

A. Procedures for the Export of Used Self-Propelled Vehicles Under the Pilot

As discussed in section I.A., 19 CFR 192.2 requires a person attempting to export a used self-propelled vehicle to present the vehicle and certain required documents at the port of exportation. The documentary requirements vary by type of vehicle,[4] and the timeframes for presenting the documents and vehicle vary by manner of export.[5] The DIS pilot changes only the *manner* in which the required documents are submitted to CBP. For pilot participants, CBP will waive the requirement in 19 CFR 192.2 to present original physical copies of the documents and require the documents to be submitted electronically using the DIS (EDI or email) instead. However, CBP will retain the right to request original documents on an as-needed basis. All other requirements of 19 CFR part 192, including the requirement to present the vehicle, will remain unchanged.[6]

[2] For export by ocean or air, participants must submit the documents at least 72 hours prior to export, but only after the vehicle is delivered to the port in preparation for departure from the United States; for export by land or rail, participants must submit documentation 72 hours prior to arriving at the border for departure from the United States. 19 CFR 192.2(c).

[3] The Electronic Export Information (EEI) is required pursuant to the Census Foreign Trade Regulations (FTR). 15 CFR part 30, subpart E. 19 CFR part 192 also sets forth CBP's requirements pertaining to the Automated Export System (AES), implemented by FTR. The AES is the electronic system of record for collecting EEI from persons exporting goods from the United States to foreign countries. The EEI for all used self-propelled vehicles must be filed via AES regardless of value or country of destination 72 hours prior to export. 15 CFR 30.2(a)(1)(iv)(H), (b)(5).

[4] For example, U.S. titled vehicles, vehicles with title that evidences third-party ownership/claims, foreign titled vehicles, etc. *See* 19 CFR 192.2(b).

[5] *See* 19 CFR 192.2(c).

[6] The pilot does not change the specific documents required for any particular type of vehicle, nor does it change the timeframes by which the documentation must be submitted. The pilot

Continued

Pilot participants agree to provide via electronic means, and in accordance with timeframes that apply by mode of transportation, the documentation required under 19 CFR 192.2. Pilot participants agree to submit the documentation required for the export of used self-propelled vehicles via the DIS, using either the EDI via an approved ABI or by submitting the documents in PDF format to the email address *docs@cbp.dhs.gov.* Participants will receive an automated response in the format in which the required documents were submitted, EDI or email, confirming that the document submission was received.[7] The participants will be able to use the automated response together with the AES-generated ITN to show that they complied with CBP's reporting requirements. The documentation submitted via the DIS will be used by CBP to review and process vehicles pending export to ensure compliance with U.S. laws and regulations. CBP reserves the right to request original (paper) documentation at any time. Consequently, pilot participants must continue to have access to the documentation in its original form for the entire time from submission to clearance by CBP, in the same manner as required by 19 CFR part 192.

For vehicles to be transported by ocean or air, the required documents must be submitted at least 72 hours prior to export, and only after the vehicle is delivered to the port in preparation for departure from the United States. For vehicles to be transported by land or rail, the documents must be submitted 72 hours prior to the vehicle's arriving at the border for departure from the United States. These are the same timeframes that apply under the current regulations, and CBP anticipates that these timeframes will provide adequate time for CBP to perform proper risk assessment, while minimizing disruption to the flow of goods. Consistent with current standard operational procedures, the inspections could potentially take place at any time prior to departure from the United States.

Pilot participants agree to adhere to established operational security protocols that correspond to their local CBP vehicle export processing office. Pilot participants also agree to participate in any teleconferences or meetings called by CBP, to ensure that any challenges, or operational or technical issues regarding the pilot are properly communicated and addressed.

Participation in the pilot does not alter participants' obligations to comply with any other applicable statutory or regulatory requirements. Participants will continue to be subject to applicable penalties for non-compliance. In addition, submission of documentation using the DIS under the pilot does not exempt the participant from any CBP or other U.S. Government agency program requirements or any statutory sanctions in the event that a violation of U.S. export control laws occurs or prohibited articles are discovered with a vehicle presented for export from the United States.

B. Duration and Scope of Pilot

Participants must be individually approved by CBP in order to participate in the pilot, and the pilot may be limited to a single or small number of ports until any operational, training, or technical issues on the trade or government side are established and/or resolved. The start date for the pilot will be no earlier than June 9, 2022. Implementation of the pilot for each mode of transportation and/or participating port will be staggered and will be announced to the public through the CSMS. The CSMS message will include the start date for accepting ownership documentation via the DIS. The pilot will run for approximately two years from the start date.

C. Eligibility Requirements

Eligibility is limited to parties who are responsible for submitting the documentation required by 19 CFR 192.2 as part of the export transaction and who have access to the ITN for the AES commodity filing. In addition, participants must agree to submit the required documentation via the DIS, as described above.

D. Application Process and Acceptance

Parties interested in participating in this pilot should, as a preliminary matter, submit a request to receive *Export* updates via the CSMS. Requests may be made at *https://www.cbp.gov/trade/automated/cargo-systems-messaging-service.* The CSMS will be used to provide pilot participants with technical and operational updates and guidance throughout the pilot, and may be used to announce technical, non-substantive changes to the pilot. CBP will utilize the CSMS to announce the implementation of the pilot for each mode of transportation and/or participating port. Only once the pilot has been extended to their mode of transportation and participating port, will an interested party be able to participate in the pilot.

Once the pilot has been implemented for their mode of transportation and port, interested parties should then contact their local CBP vehicle export processing office and express their interest and intent to participate in the DIS pilot. Detailed instructions for participation in the pilot can be found in the DIS Instructional Guide for the Exportation of Used Self-Propelled Vehicles located on the CBP website, at *https://www.cbp.gov/trade/basic-import-export/export-docs/motor-vehicle.* There is no specific application for participation in the pilot. However, interested participants must communicate their interest and intent to the relevant port before taking any other action. The port will further direct potential pilot participants. Prospective participants will be asked to submit the first submission of ownership documents and contact their local CBP vehicle processing office to verify that their first transmission of ownership documents is successful, prior to being granted participation in the pilot. Once this review and verification is complete, participants will be permitted to participate fully in the pilot.

Participation in the pilot is open to all eligible parties that have been approved to participate, subject to the discretion of the Port Director at the port from which parties intend to export the USPVs.

E. Technical Specifications

Ownership documents must be submitted via the DIS, either using the EDI via an approved ABI or via email at *docs@cbp.dhs.gov,* in a PDF format up to 10MB. Detailed instructions for participation in the pilot can be found in a document named DIS Instructional Guide for the Exportation of Used Self-Propelled Vehicles located on the CBP website, at *https://www.cbp.gov/trade/basic-import-export/export-docs/motor-vehicle.*

F. Costs to Pilot Participants

Participants are responsible for all costs incurred as a result of their participation in the pilot.

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also does not change the requirement to present the vehicle to CBP, as set forth in 19 CFR 192.2(c) and (d). 19 CFR part 192 exempts certain categories of vehicles from the EEI filing requirement of the Census Foreign Trade Regulations (15 CFR part 30, subpart E). The EEI filing requirements remain unchanged under this pilot.

[7] This is different from the current process whereby CBP ports of export stamp the original documentation provided by the exporter and the exporter then uses the stamped documentation as evidence that CBP cleared the vehicle prior to departure from the United States.

G. Benefits to Pilot Participants

While the benefits to individual pilot participants may vary, advantages to joining in the pilot include:

- Reducing the costs associated with paper processing;
- Expediting review and release of USPVs by CBP;
- Providing input into CBP's efforts to establish, test and refine the interface between government and industry communication systems in order to enable paper-free processing of USPV export requirements;
- Facilitating corporate preparedness for possible future mandatory implementation of electronic submission of documentation using the DIS; and
- Facilitating the efficient processing of legitimate USPV exports across all modes of transportation.

H. Evaluation of the Pilot

While the pilot is ongoing, CBP will evaluate the effectiveness of using the DIS and will determine if any extensions or modifications are needed. Technical modifications will be announced using the CSMS. Any substantive changes to the pilot, including extensions, will be announced in the **Federal Register**.

The results of the pilot will help CBP analyze and evaluate the effectiveness of using the DIS or some other method to collect export documentation for USPVs. When sufficient analysis and evaluation have been conducted, CBP will decide whether to require electronic submission of ownership documentation using the DIS or some other method. Any changes to the regulations will be done through rulemaking.

I. Confidentiality

All data submitted and entered into ACE is subject to the Trade Secrets Act (18 U.S.C. 1905) and is considered confidential, except to the extent as otherwise provided by law. However, participation in this or any ACE pilot is not confidential and upon a written Freedom of Information Act (FOIA) request, the name(s) of an approved participant(s) will be disclosed by CBP in accordance with 5 U.S.C. 552.

III. Privacy

CBP will ensure that all Privacy Act requirements and applicable policies are adhered to during the implementation of this pilot.

IV. Paperwork Reduction Act

The Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3507(a)) requires that CBP consider the impact of paperwork and other information collection burdens imposed on the public. An agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB. The collection of information regarding Exportation of Self-Propelled Vehicles was previously reviewed and approved by OMB in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) under OMB Control Number 1651–0054. No new information is being collected under this pilot. Therefore, no new information collection or update to the existing information collection is required at this time.

V. Misconduct Under the Pilot

A pilot participant may be subject to civil and criminal penalties, administrative sanctions, liquidated damages, or discontinuance from participation in the pilot for any of the following:

(1) Failure to comply with the rules, procedures, or terms and conditions of this pilot;

(2) Failure to exercise reasonable care in the execution of participant obligations; or

(3) Failure to abide by the applicable laws and regulations that have not been waived.

An intentional violation of an obligation under the pilot will result in the immediate removal of the participant from the pilot, and the violator may be subject to penalties or seizure of the vehicle(s). Continuous technical violations will also result in the participant's being removed from the pilot. Additionally, CBP has the right to suspend or remove a pilot participant based on a determination that an unacceptable compliance risk exists, or where public health interests or safety so require.

If CBP finds that there is a basis to suspend or remove a participant from the pilot, the pilot participant will be provided a written notice informing the participant of immediate suspension or removal from the program. The pilot participant will be offered the opportunity to appeal the decision in writing. Any appeal must be addressed to the Outbound Enforcement and Policy Branch Chief and submitted via email to *cbpvehicleexports@cbp.dhs.gov* within 15 business days of notification of suspension or removal from the program. The appeal must address the facts or conduct charges contained in the notice and state how the participant has or will achieve compliance. CBP will notify the participant within 30 business days of receipt of an appeal whether the appeal is granted. The participant will not be permitted to participate in the pilot while an appeal is pending and may not become active in the pilot again until CBP approves the participant's reinstatement. If no timely appeal is received, the notice becomes the final decision of the Agency as of the date that the appeal period expires.

Pete Flores,

Executive Assistant Commissioner, Office of Field Operations, U.S. Customs and Border Protection.

[FR Doc. 2022–09966 Filed 5–9–22; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2022–0002; Internal Agency Docket No. FEMA–B–2232]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these

changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Colorado:						
Arapahoe	City of Aurora (21–08–0396P).	The Honorable Mike Coffman, Mayor, City of Aurora, 15151 East Alameda Parkway, Aurora, CO 80012.	Public Works Department, 15151 East Alameda Parkway, Aurora, CO 80012.	*https://msc.fema.gov/portal/advanceSearch.*	Jul. 29, 2022 ..	080002
Arapahoe	City of Greenwood Village (21–08–0598P).	The Honorable George Lantz, Mayor, City of Greenwood Village, 6060 South Quebec Street, Greenwood Village, CO 80111.	City Hall, 6060 South Quebec Street, Greenwood Village, CO 80111.	*https://msc.fema.gov/portal/advanceSearch.*	Jul. 15, 2022 ..	080195
Florida:						
Manatee ..	Unincorporated areas of Manatee County (21–04–3451P).	The Honorable Kevin Van Ostenbridge, Chairman, Manatee County Board of Commissioners, P.O. Box 1000, Bradenton, FL 34206.	Manatee County Building and Development Services Department, 1112 Manatee Avenue West, Bradenton, FL 34205.	*https://msc.fema.gov/portal/advanceSearch.*	Aug. 2, 2022 ..	120153
Monroe	City of Marathon (22–04–2591P).	The Honorable John Bartus, Mayor, City of Marathon, 9805 Overseas Highway, Marathon, FL 33050.	Planning Department, 9805 Overseas Highway, Marathon, FL 33050.	*https://msc.fema.gov/portal/advanceSearch.*	Aug. 8, 2022 ..	120681
Monroe	Unincorporated areas of Monroe County (22–04–1700P).	The Honorable David Rice, Mayor, Monroe County Board of Commissioners, 9400 Overseas Highway, Suite 210, Marathon, FL 33050.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	*https://msc.fema.gov/portal/advanceSearch.*	Aug. 4, 2022 ..	125129

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Palm Beach.	Unincorporated areas of Palm Beach County (21–04–3850P).	Ms. Verdenia C. Baker, Palm Beach County Administrator, 301 North Olive Avenue, West Palm Beach, FL 33401.	Palm Beach County Building Division, 2300 North Jog Road, West Palm Beach, FL 33411.	*https://msc.fema.gov/portal/advanceSearch*.	Jul. 13, 2022 ..	120192
Sumter	City of Wildwood (21–04–1742P).	The Honorable Ed Wolf, Mayor, City of Wildwood, 100 North Main Street, Wildwood, FL 34785.	City Hall, 100 North Main Street, Wildwood, FL 34785.	*https://msc.fema.gov/portal/advanceSearch*.	Jul. 25, 2022 ..	120299
Sumter	Unincorporated areas of Sumter County (21–04–1742P).	Mr. Bradley Arnold, Sumter County Administrator, 7375 Powell Road, Wildwood, FL 34785.	The Villages—Sumter County Service Center, 7375 Powell Road, Wildwood, FL 34785.	*https://msc.fema.gov/portal/advanceSearch*.	Jul. 25, 2022 ..	120296
Kentucky:						
Hardin	City of Elizabethtown (21–04–4539P).	The Honorable Jeffrey H. Gregory, Mayor, City of Elizabethtown, 200 West Dixie Avenue, Elizabethtown, KY 42701.	Stormwater Department, 200 West Dixie Avenue, Elizabethtown, KY 42701.	*https://msc.fema.gov/portal/advanceSearch*.	Aug. 10, 2022	210095
Hardin	Unincorporated areas of Hardin County (21–04–4539P).	Mr. Harry L. Berry, Hardin County Executive, 150 North Provident Way, Suite 314 Elizabethtown, KY 42701.	Hardin County Engineering and GIS Department, 150 North Provident Way, Suite 223, Elizabethtown, KY 42701.	*https://msc.fema.gov/portal/advanceSearch*.	Aug. 10, 2022	210094
Mississippi: Harrison.	City of Pass Christian (22–04–1912P).	The Honorable Jimmy Rafferty, Mayor, City of Pass Christian, 200 West Scenic Drive, Pass Christian, MS 39571.	City Hall, 200 West Scenic Drive, Pass Christian, MS 39571.	*https://msc.fema.gov/portal/advanceSearch*.	Aug. 8, 2022 ..	285261
North Carolina: Cumberland.	City of Fayetteville (21–04–3782P).	The Honorable Mitch Colvin, Mayor, City of Fayetteville, 433 Hay Street, Fayetteville, NC 28301.	Zoning Department, 433 Hay Street, Fayetteville, NC 28301.	*https://msc.fema.gov/portal/advanceSearch*.	Jul. 27, 2022 ..	370077
Oklahoma:						
Oklahoma	City of Oklahoma City (21–06–2787P).	The Honorable David Holt, Mayor, City of Oklahoma City, 200 North Walker Avenue, 3rd Floor, Oklahoma City, OK 73102.	Public Works Department, 420 West Main Street, Suite 700, Oklahoma City, OK 73102.	*https://msc.fema.gov/portal/advanceSearch*.	Jul. 21, 2022 ..	405378
Oklahoma	Unincorporated areas of Oklahoma County (21–06–2787P).	The Honorable Brian Maughan, Chairman, Oklahoma County Board of Commissioners, 320 Robert S. Kerr Avenue, Suite 201, Oklahoma City, OK 73102.	Oklahoma County Engineering and Planning Department, 320 Robert S. Kerr Avenue, Suite 201, Oklahoma City, OK 73102.	*https://msc.fema.gov/portal/advanceSearch*.	Jul. 21, 2022 ..	400466
Texas:						
Bastrop	City of Elgin (21–06–2966P).	The Honorable Ron Ramirez, Mayor, City of Elgin, P.O. Box 591, Elgin, TX 78621.	City Hall, 310 North Main Street, Elgin, TX 78621.	*https://msc.fema.gov/portal/advanceSearch*.	Jul. 22, 2022 ..	480023

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Bastrop	Unincorporated areas of Bastrop County (21–06–2966P).	The Honorable Paul Pape, Bastrop County Judge, 804 Pecan Street, Bastrop, TX 78602.	Bastrop County Development Services Department, 211 South Jackson Street, Bastrop, TX 78602.	*https://msc.fema.gov/portal/advanceSearch*.	Jul. 22, 2022 ..	481193
Bexar	City of San Antonio (21–06–2757P).	The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capital Improvements Department, Stormwater Division, 1901 South Alamo Street, San Antonio, TX 78204.	*https://msc.fema.gov/portal/advanceSearch*.	Jul. 11, 2022 ..	480045
Brazos	City of Bryan (21–06–2790P).	The Honorable Andrew Nelson, Mayor, City of Bryan, P.O. Box 1000, Bryan, TX 77805.	City Hall, 300 South Texas Avenue, Bryan, TX 77803.	*https://msc.fema.gov/portal/advanceSearch*.	Aug. 10, 2022	480082
Dallas	City of Sachse (21–06–2964P).	The Honorable Mike Felix, Mayor, City of Sachse, 3815 Sachse Road, Building B, Sachse, TX 75048.	Engineering Department, 3815 Sachse Road, Building B, Sachse, TX 75048.	*https://msc.fema.gov/portal/advanceSearch*.	Aug. 5, 2022 ..	480186
Harris	Unincorporated areas of Harris County (21–06–1709P).	The Honorable Lina Hidalgo, Harris County Judge, 1001 Preston Street, Suite 911, Houston, TX 77002.	Harris County Engineering Department, Permit Division, 10555 Northwest Freeway, Suite 120, Houston, TX 77002.	*https://msc.fema.gov/portal/advanceSearch*.	Jul. 18, 2022 ..	480287
Harris	Unincorporated areas of Harris County (21–06–3108P).	The Honorable Lina Hidalgo, Harris County Judge, 1001 Preston Street, Suite 911, Houston, TX 77002.	Harris County Engineering Department, Permit Division, 10555 Northwest Freeway, Suite 120, Houston, TX 77002.	*https://msc.fema.gov/portal/advanceSearch*.	Jul. 18, 2022 ..	480287
McLennan	City of Bellmead (22–06–0249P).	The Honorable Gary Moore, Mayor, City of Bellmead, 3015 Bellmead Drive, Bellmead, TX 76705.	City Hall, 3015 Bellmead Drive, Bellmead, TX 76705.	*https://msc.fema.gov/portal/advanceSearch*.	Aug. 3, 2022 ..	480457
McLennan	City of Waco (22–06–0249P).	The Honorable Dillon Meek, Mayor, City of Waco, P.O. Box 2570, Waco, TX 76702.	Public Works Department, 401 Franklin Avenue, Waco, TX 76701.	*https://msc.fema.gov/portal/advanceSearch*.	Aug. 3, 2022 ..	480461
McLennan	Unincorporated areas of McLennan County (22–06–0249P).	The Honorable Scott M. Felton, McLennan County Judge, P.O. Box 1728, Waco, TX 76703.	McLennan County Engineering and Mapping Department, 215 North 5th Street, Suite 130, Waco, TX 76701.	*https://msc.fema.gov/portal/advanceSearch*.	Aug. 3, 2022 ..	480456
Medina	City of Castroville (21–06–1723P).	The Honorable Darrin Schroeder, Mayor, City of Castroville, 1209 Fiorella Street, Castroville, TX 78009.	Public Works Department, 703 Paris Street, Castroville, TX 78009.	*https://msc.fema.gov/portal/advanceSearch*.	Aug. 5, 2022 ..	480932
Medina	Unincorporated areas of Medina County (21–06–1723P).	The Honorable Chris Schuchart, Medina County Judge, 1300 Avenue M, Room 250, Hondo, TX 78861.	Medina County Environmental Health Department, 709 Avenue Y, Hondo, TX 78861.	*https://msc.fema.gov/portal/advanceSearch*.	Aug. 5, 2022 ..	480472
Montgomery.	Unincorporated areas of Montgomery County (21–06–1709P).	The Honorable Mark J. Keough, Montgomery County Judge, 501 North Thompson Street, Suite 401, Conroe, TX 77301.	Montgomery County Engineering Department, 501 North Thompson Street, Suite 103, Conroe, TX 77301.	*https://msc.fema.gov/portal/advanceSearch*.	Jul. 18, 2022 ..	480483

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Tarrant	City of Grapevine (21–06–2959P).	The Honorable William D. Tate, Mayor, City of Grapevine, P.O. Box 95104, Grapevine, TX 76099.	City Hall, 200 South Main Street, Grapevine, TX 76051.	*https://msc.fema.gov/portal/advanceSearch*.	Aug. 8, 2022 ..	480598
Tarrant	Unincorporated areas of Tarrant County (21–06–2812P).	The Honorable B. Glen Whitley, Tarrant County Judge, 100 East Weatherford Street, Suite 501, Fort Worth, TX 76196.	Tarrant County Administration Building, 100 East Weatherford Street, Fort Worth, TX 76196.	*https://msc.fema.gov/portal/advanceSearch*.	Aug. 8, 2022 ..	480582
Webb	City of Laredo (21–06–1751P).	The Honorable Pete Saenz, Mayor, City of Laredo, 1110 Houston Street, 3rd Floor, Laredo, TX 78040.	Planning and Zoning Department, 1413 Houston Street, Laredo, TX 78040.	*https://msc.fema.gov/portal/advanceSearch*.	Jul. 7, 2022	480651
Wise	Unincorporated areas of Wise County (21–06–2812P).	The Honorable J.D. Clark, Wise County Judge, 101 North Trinity Street, Decatur, TX 76234.	Wise County Public Works Department, 2901 South FM 51, Building 200, Decatur, TX 76234.	*https://msc.fema.gov/portal/advanceSearch*.	Aug. 8, 2022 ..	481051
Utah:						
Wasatch ..	Town of Wallsburg (21–08–0901P).	The Honorable Celeni Richins, Mayor, Town of Wallsburg, 70 West Main Canyon Road, Wallsburg, UT 84082.	Town Hall, 70 West Main Canyon Road, Wallsburg, UT 84082.	*https://msc.fema.gov/portal/advanceSearch*.	Jul. 14, 2022 ..	490168
Wasatch ..	Unincorporated areas of Wasatch County (21–08–0901P).	Mr. Dustin Grabau, Wasatch County Manager, 25 North Main Street, Heber City, UT 84032.	Wasatch County Planning Department, 55 South 500 Street East, Heber City, UT 84032.	*https://msc.fema.gov/portal/advanceSearch*.	Jul. 14, 2022 ..	490164
Virginia: Prince William.	City of Manassas Park (21–03–1049P).	The Honorable Jeanette Rishell, Mayor, City of Manassas Park, 1 Park Center Court, Manassas Park, VA 20111.	City Hall, 1 Park Center Court, Manassas Park, VA 20111.	*https://msc.fema.gov/portal/advanceSearch*.	Aug. 5, 2022 ..	510123

[FR Doc. 2022–10003 Filed 5–9–22; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA–2006–26514]

Extension of Agency Information Collection Activity Under OMB Review: Rail Transportation Security

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0051, abstracted below to OMB for review and approval of an extension of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The collection involves the submission of contact information of security coordinators (SCs) and alternate SCs from certain freight rail and passenger rail entities; reporting of significant security concerns; documenting the transfer of custody and control of certain hazardous materials rail cars; and providing location and shipping information for certain hazardous materials rail cars.

DATES: Send your comments by June 9, 2022. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' and by using the find function.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Information Technology (IT), TSA–11, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598–6011; telephone (571) 227–2062; email *TSAPRA@tsa.dhs.gov.*

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on December 23, 2021, 86 FR 72990.

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be available at *http://www.reginfo.gov* upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Rail Transportation Security.

Type of Request: Extension of a currently approved collection.

OMB Control Number: 1652–0051.

Forms(s): NA.

Affected Public: Freight rail, passenger rail, and shippers/receivers of certain hazardous materials.

Abstract: TSA requires freight railroad carriers and certain facilities handling specified categories and quantities of hazardous materials be able to report location and shipping information to TSA upon request. *See* 49 CFR 1580.203. These regulated carriers and facilities must also implement chain of custody and control requirements to ensure a positive and secure exchange of the specified categories and quantities of hazardous materials listed in 49 CFR 1580.205, and make the reports available to TSA upon request. TSA further collects information from regulated parties on Security Coordinators and significant security concerns telephonically and electronically reporting.[1]

Number of Respondents: 1,760.

Estimated Annual Burden Hours: An estimated 112,600 hours annually.[2]

Dated: May 5, 2022.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Information Technology.

[FR Doc. 2022–09990 Filed 5–9–22; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2712–22; DHS Docket No. USCIS–2014–004]

RIN 1615–ZB79

Extension and Redesignation of South Sudan for Temporary Protected Status—Correction

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS).

ACTION: Notice; correction.

SUMMARY: U.S. Citizenship and Immigration Services (USCIS), a component of the Department of Homeland Security (DHS), is making a correction to the notice titled ''Extension and Redesignation of South Sudan for Temporary Protected Status'' that published in the **Federal Register** on March 3, 2022, at 87 FR 12190. USCIS is correcting a typographical error in the ''General Employment-Related Information for TPS Applicants and Their Employers'' section of the notice to correct the date from September 17, 2021 to May 2, 2022 as the eligibility date that should be showing on South Sudan TPS-based Employment Authorization Documents (EADs) in order to receive an automatic 180-day EAD extension through November 1, 2022.

FOR FURTHER INFORMATION CONTACT:

• You may contact Rená Cutlip-Mason, Chief, Humanitarian Affairs Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, U.S. Department of Homeland Security, by mail at 5900 Capital Gateway Drive, Camp Springs, MD 20746, or by phone at 800–375–5283.

• For further information on TPS, including guidance on the registration and re-registration process and additional information on eligibility, please visit the USCIS TPS web page at *http://www.uscis.gov/tps.* You can find specific information about this extension of South Sudan's TPS designation by selecting ''South Sudan'' from the menu on the left side of the TPS web page.

• If you have additional questions about TPS, please visit *uscis.gov/tools.* Our online virtual assistant, Emma, can answer many of your questions and point you to additional information on our website. If you are unable to find your answers there, you may also call our USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

• Applicants seeking information about the status of their individual cases may check Case Status Online, available on the USCIS website at *uscis.gov*, or visit the USCIS Contact Center at *uscis.gov/contactcenter.*

• Further information will also be available at local USCIS offices upon publication of this Notice.

SUPPLEMENTARY INFORMATION: On March 3, 2022, DHS published a notice in the **Federal Register** at 87 FR 12190. USCIS is making a correction to that published notice. The correction is as follows:

On page 12198, under the question ''Am I eligible to receive an automatic 180-day extension of my current EAD through November 1, 2022, using this **Federal Register** notice?'' USCIS is revising the second sentence to correct the referenced expiration date on the face of the card for TPS EADs issued under the prior TPS South Sudan extension. This date should reflect May 2, 2022, not September 17, 2021.

Applicable to automatic extension periods of current EADs for this population, DHS published a Temporary Final Rule on May 4, 2022 that temporarily increased the automatic 180-day extension under 8 CFR 274a.13(d) to up to 540 days for those TPS beneficiaries that file to renew their existing EAD.[1] Accordingly, for TPS beneficiaries who are covered under the South Sudan TPS Notice and file to renew their EAD with a May 2, 2022 expiration date on the face of the card during the filing period described under the South Sudan TPS Notice, the Temporary Final Rule permits an automatic extension of their EAD for up

[1] The requirements of this section also apply to certain over-the-road bus owner/operators and owner/operators of bus-only public transportation systems. The collection of information associated with bus operations is covered by OMB Control No. 1652–0066; Security Training Program for Surface Transportation Employees.

[2] Since the publication of the 60-day notice, TSA has updated the annual burden hours from 112,764 to 112,600 hours.

[1] *See* ''Temporary Increase of the Automatic Extension Period of Employment Authorization and Documentation for Certain Renewal Applicants'' (May 4, 2022, 87 FR 26614).

to 540 days after the expiration date on the face of the EAD.

Correction

In FR 2022–04573, on page 12198 in the **Federal Register** of March 3, 2022, in the second column, USCIS is correcting the second sentence as follows:

Regardless of your country of birth, provided that you currently have a South Sudan TPS-based EAD with an expiration date of May 2, 2022, on the face of the card, bearing the notation A–12 or C–19 under Category, this notice automatically extends your EAD through November 1, 2022.[2]

Samantha Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, U.S. Department of Homeland Security.

[FR Doc. 2022–10018 Filed 5–9–22; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2022–N009; FXES11130100000C4–223–FF01E00000]

Endangered and Threatened Wildlife and Plants; Initiation of 5-Year Status Reviews for 167 Species in Oregon, Washington, Idaho, Montana, California, Hawaii, Guam, and the Northern Mariana Islands

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of initiation of reviews; request for information.

SUMMARY: We, the U.S. Fish and Wildlife Service, are initiating 5-year status reviews for 167 species in Oregon, Washington, Idaho, Montana, California, Hawaii, Guam, and the Northern Mariana Islands under the Endangered Species Act of 1973. Two of these species also occur outside of U.S. jurisdiction in Canada and the South Pacific. A 5-year status review is based on the best scientific and commercial data available at the time of the review; therefore, we are requesting submission of any new information on these species that has become available since the last reviews.

DATES: To ensure consideration in our reviews, we are requesting submission of new information no later than July 11, 2022. However, we will continue to accept new information about any species at any time.

ADDRESSES: *Submitting Information on Species:*

- *Marbled murrelet:*
  - ➢ *U.S. mail:* State Supervisor, Attention: 5-Year Review, U.S. Fish and Wildlife Service, Washington Fish and Wildlife Office, 510 Desmond Dr. Southeast, Suite 102, Lacey, WA 98503; or
  - ➢ *Email: WFWO_LR@fws.gov.*
- *Howell's spectacular thelypody:*
  - ➢ *U.S. mail:* State Supervisor, Attention: 5-Year Review, U.S. Fish and Wildlife Service, Oregon Fish and Wildlife Office, 2600 SE 98th Ave., Suite 100, Portland, OR 97266; or
  - ➢ *Email: fw1ofwo@fws.gov.*
- *Snake River physa snail and Bruneau hot springsnail:*
  - ➢ *U.S. mail:* State Supervisor, Attention: 5-Year Review, U.S. Fish and Wildlife Service, Idaho Fish and Wildlife Office, 1387 S Vinnell Way, Suite 368, Boise, ID 83709; or
  - ➢ *Email: ifwo@fws.gov.*
- *Any of the 163 species occurring in Hawaii, Guam, and/or the Commonwealth of the Northern Mariana Islands:*
  - ➢ *U.S. mail:* Field Supervisor, Attention: 5-Year Review, U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office, 300 Ala Moana Blvd., Room 3–122, Honolulu, HI 96850; or
  - ➢ *Email: pifwo_admin@fws.gov.*

FOR FURTHER INFORMATION CONTACT: For general information, please contact Grant Canterbury at 503–231–6151. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

For information about the specific species, contact the following people:

- *Marbled murrelet:* Tom McDowell, Washington Fish and Wildlife Office, 360–753–9440.
- *Howell's spectacular thelypody:* Jennifer Siani, Oregon Fish and Wildlife Office, 503–231–6179.
- *Snake River physa snail and Bruneau hot springsnail:* Kathleen Hendricks, Idaho Fish and Wildlife Office, 208–378–5243.
- *Any of the 163 species occurring in Hawaii, Guam, and/or the Commonwealth of the Northern Mariana Islands:* Megan Laut, Pacific Islands Fish and Wildlife Office, 808–792–9400.

SUPPLEMENTARY INFORMATION:

Why do we conduct 5-year status reviews?

Under the Endangered Species Act of 1973, as amended (Act; 16 U.S.C. 1531, *et seq.*), we maintain lists of endangered and threatened wildlife and plant species (referred to as the List) in the Code of Federal Regulations (CFR) at 50 CFR 17.11 (for wildlife) and 17.12 (for plants). Section 4(c)(2) of the Act requires us to review each listed species' status at least once every 5 years. For additional information about 5-year status reviews, refer to our factsheet at *https://www.fws.gov/endangered/what-we-do/recovery-overview.html.*

What information do we consider in our review?

A 5-year status review considers all new information available at the time of the review. In conducting these reviews, we consider the best scientific and commercial data that have become available since the listing determination or most recent status reviews, such as:

A. Species biology, including but not limited to population trends, distribution, abundance, demographics, and genetics;

B. Habitat conditions, including but not limited to amount, distribution, and suitability;

C. Conservation measures that have been implemented that benefit the species;

D. Threat status and trends in relation to the five listing factors (as defined in section 4(a)(1) of the Act); and

E. Other new information, data, or corrections, including but not limited to taxonomic or nomenclatural changes, identification of erroneous information contained in the List, and improved analytical methods.

Any new information will be considered during the 5-year status review and will also be useful in evaluating the ongoing recovery programs for these species.

Which species are under review?

This notice announces our active review of 167 species, including 4 birds, 1 reptile, 50 snails, 9 insects, and 103 plants, as listed in the table below.

[2] Again, for applicants who filed a request to renew their existing EAD and their EAD has a facial expiration of May 2, 2022, the May 4th Temporary Final Rule automatically extends that EAD for up to 540 days through October 24, 2023.

Common name	Scientific name	Status	Known range of species occurrence	Final listing rule and publication date
ANIMALS				
Birds:				
Marbled murrelet [CA, OR, WA distinct population segment (DPS)].	*Brachyramphus marmoratus*	Threatened	California, Oregon, Washington	57 FR 45337, 10/1/1992.
Hawaiian goose (Nēnē)	*Branta sandvicensis*	Threatened	Hawaii	32 FR 4001, 3/11/1967; 84 FR 69918, 12/19/2019.
Oahu ‘elepaio	*Chasiempis ibidis*	Endangered	Hawaii	65 FR 20760, 4/18/2000.
Oahu creeper	*Paroreomyza maculata*	Endangered	Hawaii	35 FR 16047, 10/13/1970.
Reptiles:				
Slevin’s skink (gualik halumtanu, gholuuf).	*Emoia slevini*	Endangered	Guam, Commonwealth of the Northern Mariana Islands.	80 FR 59423, 10/1/2015.
Snails:				
Oahu tree snails	*Achatinella* spp. (includes all 41 species in genus)*.	Endangered	Hawaii	46 FR 3178, 1/13/1981.
Newcomb’s tree snail	*Newcombia cumingi*	Threatened	Hawaii	78 FR 32013, 5/28/2013.
Humped tree snail (akaleha’, denden).	*Partula gibba*	Endangered	Guam, Commonwealth of the Northern Mariana Islands.	80 FR 59423, 10/1/2015.
Langford’s tree snail (akaleha’, denden).	*Partula langfordi*	Endangered	Commonwealth of the Northern Mariana Islands.	80 FR 59423, 10/1/2015.
Guam tree snail (akaleha’, denden)	*Partula radiolata*	Endangered	Guam	80 FR 59423, 10/1/2015.
Lanai tree snail	*Partulina semicarinata*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Lanai tree snail	*Partulina variabilis*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Snake River physa snail	*Physa natricina*	Endangered	Idaho	57 FR 59244, 12/14/1992.
Bruneau hot springsnail	*Pyrgulopsis bruneauensis*	Endangered	Idaho	58 FR 5938, 1/25/1993.
Fragile tree snail	*Samoana fragilis*	Endangered	Guam, Commonwealth of the Northern Mariana Islands.	80 FR 59423, 10/1/2015.
Insects:				
Hawaiian picture-wing fly	*Drosophila aglaia*	Endangered	Hawaii	71 FR 26835, 5/9/2006.
Hawaiian picture-wing fly	*Drosophila hemipeza*	Endangered	Hawaii	71 FR 26835, 5/9/2006.
Hawaiian picture-wing fly	*Drosophila montgomeryi*	Endangered	Hawaii	71 FR 26835, 5/9/2006.
Hawaiian picture-wing fly	*Drosophila obatai*	Endangered	Hawaii	71 FR 26835, 5/9/2006.
Hawaiian picture-wing fly	*Drosophila substenoptera*	Endangered	Hawaii	71 FR 26835, 5/9/2006.
Hawaiian picture-wing fly	*Drosophila tarphytrichia*	Endangered	Hawaii	71 FR 26835, 5/9/2006.
Rota blue damselfly (dulalas Luta, dulalas Luuta).	*Ischnura luta*	Endangered	Commonwealth of the Northern Mariana Islands.	80 FR 59423, 10/1/2015.
Blackburn’s sphinx moth	*Manduca blackburni*	Endangered	Hawaii	65 FR 4770, 2/1/2000.
Mariana wandering butterfly (ababbang, libweibwogh).	*Vagrans egistina*	Endangered	Commonwealth of the Northern Mariana Islands.	80 FR 59423, 10/1/2015.
PLANTS				
Flowering Plants:				
No common name	*Abutilon sandwicense*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
Round-leaved chaff-flower	*Achyranthes splendens* var. *rotundata*	Endangered	Hawaii	51 FR 10518, 3/26/1986.
Ko ‘oko ‘olau	*Bidens amplectens*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Siboyas halumtanu, siboyan halom tano.	*Bulbophyllum guamense*	Threatened	Guam, Commonwealth of the Northern Mariana Islands.	80 FR 59423, 10/1/2015.
Ewa Plains ‘akoko	*Chamaesyce [=Euphorbia] skottsbergii* var. *skottsbergii.*	Endangered	Hawaii	47 FR 36846, 8/24/1982.
Haha	*Cyanea acuminata*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
Haha	*Cyanea calycina*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Haha	*Cyanea crispa*	Endangered	Hawaii	59 FR 14482, 3/28/1994.
Haha	*Cyanea grimesiana* ssp. *obatae*	Endangered	Hawaii	59 FR 32932, 6/27/1994.
Haha	*Cyanea humboldtiana*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
Haha	*Cyanea koolauensis*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
Haha	*Cyanea lanceolata*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Haha	*Cyanea longiflora*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
Haha	*Cyanea pinnatifida*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
Haha	*Cyanea purpurellifolia*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Haha	*Cyanea st.-johnii*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
No common name	*Cyanea superba*	Endangered	Hawaii	56 FR 46235, 9/11/1991.
Haha	*Cyanea truncata*	Endangered	Hawaii	59 FR 14482, 3/28/1994.
Fadang, faadang	*Cycas micronesica*	Threatened	Guam, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Independent Republic of Palau.	80 FR 59424, 10/1/2015.
Pu‘uka‘a	*Cyperus trachysanthos*	Endangered	Hawaii	61 FR 53108, 10/10/1996.
Ha’iwale	*Cyrtandra crenata*	Endangered	Hawaii	59 FR 14482, 3/28/1994.
Ha‘iwale	*Cyrtandra dentata*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
Ha‘iwale	*Cyrtandra gracilis*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Ha‘iwale	*Cyrtandra kaulantha*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Ha‘iwale	*Cyrtandra polyantha*	Endangered	Hawaii	59 FR 14482, 3/28/1994.
Ha‘iwale	*Cyrtandra sessilis*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Ha‘iwale	*Cyrtandra subumbellata*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
Ha‘iwale	*Cyrtandra viridiflora*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
Ha‘iwale	*Cyrtandra waiolani*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Oha	*Delissea subcordata*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
No common name	*Delissea undulata*	Endangered	Hawaii	61 FR 53124, 10/10/1996.
No common name	*Dendrobium guamense*	Threatened	Guam, Commonwealth of the Northern Mariana Islands.	80 FR 59424, 10/1/2015.
Na‘ena‘e	*Dubautia herbstobatae*	Endangered	Hawaii	56 FR 55770, 10/29/1991.

Common name	Scientific name	Status	Known range of species occurrence	Final listing rule and publication date
Fosberg's love grass	*Eragrostis fosbergii*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
No common name	*Eugenia bryanii*	Endangered	Guam	80 FR 59424, 10/1/2015.
Nioi	*Eugenia koolauensis*	Endangered	Hawaii	59 FR 14482, 3/28/1994.
ʻAkoko	*Euphorbia celastroides* var. *kaenana*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
ʻAkoko	*Euphorbia deppeana*	Endangered	Hawaii	59 FR 14482, 3/28/1994.
ʻAkoko	*Euphorbia herbstii*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
ʻAkoko	*Euphorbia kuwaleana*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
ʻAkoko	*Euphorbia rockii*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
Nanu	*Gardenia mannii*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
No common name	*Gouania vitifolia*	Endangered	Hawaii	59 FR 32932, 6/27/1994.
Pau dedu, pao doodu	*Hedyotis megalantha*	Endangered	Guam	80 FR 59424, 10/1/2015.
Ufa halumtanu, ufa halom tano	*Heritiera longipetiolata*	Endangered	Guam, Commonwealth of the Northern Mariana Islands.	80 FR 59424, 10/1/2015.
No common name	*Hesperomannia arbuscula*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
No common name	*Kadua degeneri*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
No common name	*Kadua parvula*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
Kohe malama malama o Kanaloa	*Kanaloa kahoolawensis*	Endangered	Hawaii	64 FR 48307, 9/3/1999.
Hulumoa	*Korthalsella degeneri*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Kamakahala	*Labordia cyrtandrae*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
ʻAnaunau	*Lepidium arbuscula*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
ʻAnaunau	*Lepidium orbiculare*	Endangered	Hawaii	81 FR 67786, 9/30/2016.
Nehe	*Lipochaeta lobata* var. *leptophylla*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
No common name	*Lobelia koolauensis*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
No common name	*Lobelia monostachya*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
No common name	*Lobelia oahuensis*	Endangered	Hawaii	59 FR 14482, 3/28/1994.
Nehe	*Melanthera tenuifolia*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
Alani	*Melicope christophersenii*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Alani	*Melicope hiiakae*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Alani	*Melicope lydgatei*	Endangered	Hawaii	59 FR 14482, 3/28/1994.
Alani	*Melicope makahae*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Alani	*Melicope saint-johnii*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
Kolea	*Myrsine juddii*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
No common name	*Neraudia angulata*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
Kulu ī	*Nototrichium humile*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
No common name	*Phyllanthus saffordii*	Endangered	Guam	80 FR 59424, 10/1/2015.
No common name	*Phyllostegia hirsuta*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
No common name	*Phyllostegia kaalaensis*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
No common name	*Phyllostegia mollis*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
No common name	*Platydesma cornuta* var. *cornuta*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
No common name	*Platydesma cornuta* var. *decurrens*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Hala pepe	*Pleomele forbesii*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Ohe ʻohe	*Polyscias gymnocarpa*	Endangered	Hawaii	59 FR 14482, 3/28/1994.
No common name	*Polyscias lydgatei*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Loulu	*Pritchardia kaalae*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
Kopiko	*Psychotria hexandra* ssp. *oahuensis*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Aplokating palaoan	*Psychotria malaspinae*	Endangered	Guam	80 FR 59424 10/1/2015.
Kaulu	*Pteralyxia macrocarpa*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
No common name	*Sanicula mariversa*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
Diamond Head schiedea	*Schiedea adamantis*	Endangered	Hawaii	49 FR 6099, 2/17/1984.
No common name	*Schiedea kaalae*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
Maʻoliʻoli	*Schiedea kealiae*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
No common name	*Schiedea nuttallii*	Endangered	Hawaii	61 FR 53108, 10/10/1996.
No common name	*Schiedea obovata*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
No common name	*Schiedea trinervis*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
No common name	*Silene perlmanii*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
Biringenas halumtanu, Birengenas halom tano.	*Solanum guamense*	Endangered	Guam, Commonwealth of the Northern Mariana Islands.	80 FR 59424, 10/1/2015.
No common name	*Stenogyne kanehoana*	Endangered	Hawaii	57 FR 20592, 5/13/1992.
No common name	*Tabernaemontana rotensis*	Threatened	Guam, Commonwealth of the Northern Mariana Islands.	80 FR 59424, 10/1/2015.
No common name	*Tetramolopium filiforme*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
No common name	*Tetramolopium lepidotum* ssp. *lepidotum*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
Howell's spectacular thelypody	*Thelypodium howellii* ssp. *spectabilis*	Threatened	Oregon	64 FR 28403, 5/26/1999.
No common name	*Tinospora homosepala*	Endangered	Guam	80 FR 59424, 10/1/2015.
No common name	*Trematolobelia singularis*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
No common name	*Tuberolabium guamense*	Threatened	Guam, Commonwealth of the Northern Mariana Islands.	80 FR 59424, 10/1/2015.
Opuhe	*Urera kaalae*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
Pamakani	*Viola chamissoniana* ssp. *chamissoniana.*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
No common name	*Viola oahuensis*	Endangered	Hawaii	61 FR 53089, 10/10/1996.
Aʻe	*Zanthoxylum oahuense*	Endangered	Hawaii	77 FR 57647, 9/18/2012.
Ferns and Allies:				
No common name	*Asplenium dielfalcatum*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
No common name	*Asplenium unisorum*	Endangered	Hawaii	59 FR 32932, 6/27/1994.
No common name	*Doryopteris takeuchii*	Endangered	Hawaii	77 FR 57647, 9/18/2012.

* Species within the listed genus *Achatinella* include *A. abbreviata, A. apexfulva, A. bellula, A. buddii, A. bulimoides, A. byronii, A. caesia, A. casta, A. cestus, A. concavospira, A. curta, A. decipiens, A. decora, A. dimorpha, A. elegans, A. fulgens, A. fuscobasis, A. juddii, A. juncea, A. lehuiensis, A. leucorrhaphe, A. lila, A. livida, A. lorata, A. mustelina, A. papyracea, A. phaeozona, A. pulcherrima, A. pupukanioe, A. rosea, A. sowerbyana, A. spaldingi, A. stewartii, A. swiftii, A. taeniolata, A. thaanumi, A. turgida, A. valida, A. viridans, A. vittata,* and *A. vulpina.*

Request for New Information

To ensure that a 5-year status review is complete and based on the best available scientific and commercial information, we request new information from all sources. See What Information Do We Consider in Our Review? for specific criteria. If you submit information, please support it with documentation such as maps, references, methods used to gather and analyze the data, and/or copies of any pertinent publications, reports, or letters by knowledgeable sources.

If you wish to provide information for any species listed in the table, please submit your comments and materials to the appropriate contact in **ADDRESSES**.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Completed and Active Reviews

A table including hyperlinks to the most recently completed 5-year status review for each listed species, as well as notices of 5-year status reviews that are currently in progress, is available at *https://ecos.fws.gov/ecp/report/species-five-year-review.*

Authority

This document is published under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Nanette Seto,

Acting Regional Director, U.S. Fish and Wildlife Service.

[FR Doc. 2022–09980 Filed 5–9–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–33859; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before April 30, 2022, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by May 25, 2022.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State>.'' If you have no access to email you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before April 30, 2022. Pursuant to Section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers:

ARIZONA

Maricopa County

Sutton Place, Osborn Rd. and 26th St., Phoenix, SG100007785

ARKANSAS

Pulaski County

Calvary Cemetery, Historic Section, SW corner of Charles Bussey Ave. (20th St.) and Woodrow St., Little Rock, SG100007766

MINNESOTA

Ramsey County

Amhoist Tower, 345 Saint Peter St., 59 4th St. West, Saint Paul, SG100007789

Rock County

Manfred, Frederick and Maryanna, House, 1341 141st St. (141st St. and US 75), Luverne, SG100007790

PENNSYLVANIA

Chester County

Lincoln University, 1570 Baltimore Pike, Lower Oxford Township, SG100007786

Passtown Elementary School (Educational Resources of Pennsylvania MPS), 890 West Lincoln Hwy., Valley Township, MP100007787

Philadelphia County

Reyburn Manufacturing Company Building, 3111 West Allegheny Ave., Philadelphia, SG100007771

E.A. Wright Bank Note Company Building, 2527–2537 North Broad St., Philadelphia, SG100007788

SOUTH CAROLINA

Allendale County

Allendale Training School (Equalization Schools in South Carolina, 1951–1960 MPS) (African-American Primary and Secondary School Buildings MPS), 4561 Allendale-Fairfax Hwy., Allendale, MP100007773

Clarendon County

Clarendon County Health Center and Office Building, 3 South Church St., Manning, SG100007767

Lancaster County

Ellen Dean Hotel, 113–141 North White St., Lancaster, SG100007778

UTAH

Sanpete County

Olsen House and Mortuary, 315 South 200 East, Ephraim, SG100007779

Washington County

Dixie Hillside ''D'', West Black Ridge, St. George vicinity, SG100007768

La Verkin Hydroelectric Power Plant (Electric Power Plants of Utah MPS), Off South State St., La Verkin, MP100007777

VIRGINIA

Henrico County

Chatsworth School, 1451 Chatsworth Rd., Henrico, SG100007781

Petersburg Independent City

Byrne Street USO Club, 464 Byrne St., Petersburg, SG100007780

Wythe County

Fulton, Andrew and Sarah, Farm, 531 Kohler Ave., Austinville vicinity, SG100007782

WISCONSIN

Douglas County

Gordon, Antoine and Sarah, House, 97 Cty. Rd. Y, Gordon, SG100007769

Additional documentation has been received for the following resources:

KENTUCKY

Fulton County

Fulton Downtown Historic District, Part of Carr, Commercial, Lake, Main, and Walnut Sts., Fulton, AD03000710

RHODE ISLAND

Providence County

Woonsocket Company Mill Complex (Additional Documentation), 100–115 Front St., Woonsocket, AD73000005

UTAH

Summit County

Shields, John, House (Additional Documentation) (Mining Boom Era Houses TR), 416 Park Ave., Park City, AD84003997

(Authority: Section 60.13 of 36 CFR part 60)

Dated: May 4, 2022.

Sherry A. Frear,

Chief, National Register of Historic Places/ National Historic Landmarks Program.

[FR Doc. 2022–09967 Filed 5–9–22; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–591]

Economic Impact of Section 232 and 301 Tariffs on U.S. Industries

ACTION: Notice of investigation and scheduling of a public hearing.

SUMMARY: As directed by an explanatory statement related that accompanied the Consolidated Appropriations Act, 2022, enacted on March 15, 2022, the U.S. International Trade Commission (Commission) instituted Investigation No. 332–591, *Economic Impact of Section 232 and 301 Tariffs on U.S. Industries.* In the explanatory statement, the House and Senate Committees on Appropriations (Committees) directed that the Commission conduct a retrospective investigation and provide a report on the impacts in the U.S. industries most affected by the Section 232 and 301 tariffs that were active as of March 15, 2022.

DATES:

July 6, 2022: Deadline for filing requests to appear at the public hearing.

July 8, 2022: Deadline for filing prehearing briefs and statements.

July 14, 2022: Deadline for filing electronic copies of oral hearing statements.

July 21, 2022: Public hearing.

August 12, 2022: Deadline for filing posthearing briefs and statements.

August 24, 2022: Deadline for filing all other written submissions.

March 15, 2023: Transmittal of Commission report to Committees.

ADDRESSES: All Commission offices are in the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC. Due to the COVID–19 pandemic, the Commission's building is currently closed to the public. Once the building reopens, persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

FOR FURTHER INFORMATION CONTACT: Project Leader Peter Herman (*Peter.Herman@usitc.gov* or 202–205–3186) or Deputy Project Leader Kelsi Van Veen (*Kelsi.VanVeen@usitc.gov* or 202–205–3086) for information specific to this investigation. For information on the legal aspects of this investigation, contact William Gearhart of the Commission's Office of the General Counsel (*William.Gearhart@usitc.gov* or 202–205–3091). The media should contact Jennifer Andberg, Office of External Relations (*Jennifer.Andberg@usitc.gov* or 202–205–1819).

The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* General information concerning the Commission may also be obtained by accessing its website (*https://www.usitc.gov*). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810.

SUPPLEMENTARY INFORMATION: As requested by the Committees, the Commission will include in its report detailed information on U.S. trade, production, and prices in the industries directly and most affected by active tariffs under section 232 of the Trade Expansion Act of 1962 (19 U.S.C. 1862) and section 301 of the Trade Act of 1974 (19 U.S.C. 2232). The Commission has instituted the investigation under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)) to facilitate the receipt of public comments and for the purpose of including the Commission's report in an existing series of reports.

The tariffs covered in the report will be the additional tariffs on U.S. imports imposed under section 232 of the Trade Expansion Act of 1962 (19 U.S.C. 1862) and imposed under section 301 of the Trade Act of 1974 (19 U.S.C. 2411 *et seq.*) that were in effect as of March 15, 2022—as reflected in the 2022 Harmonized Tariff Schedule of the United States, Revision 2, USITC Pub. 5293. Additional information on the section 232 actions can be found under HTS numbers 9903.80.01 through 9903.81.80 and 9903.85.01 through 9903.85.44. Additional information on the section 301 actions can be found under HTS numbers 9903.88.01, 9903.88.02, 9903.88.03, 9903.88.04, and 9903.88.15.

The Committees requested that the Commission transmit its report no later than 12 months following the enactment of the Consolidated Appropriations Act. The Commission's report will be made available to the public.

Public hearing: A public hearing in connection with this investigation will be held beginning at 9:30 a.m. Eastern Time on Thursday July 21, 2022. Information about the place and form of the hearing, including about how to participate in and/or view the hearing, will be posted on the Commission's website at (*https://usitc.gov/research_and_analysis/what_we_are_working_on.htm*). Once on that web page, scroll down to Investigation No. 332–591, *Economic Impact of Section 232 and 301 Tariffs on U.S. Industries,* and click on the link to ''Hearing Instructions.'' Interested parties should check the Commission's website periodically for updates.

Requests to appear at the public hearing should be filed with the Secretary to the Commission no later than 5:15 p.m., Wednesday, July 6, 2022, in accordance with the requirements in the ''Written Submissions'' section below. All prehearing briefs and statements should be filed not later than 5:15 p.m., Friday, July 8, 2022. To facilitate the hearing, including the preparation of an accurate written transcript of the hearing, oral testimony to be presented at the hearing must be submitted to the Commission electronically no later than noon on Thursday, July 14, 2022. All post-hearing briefs and statements should be filed no later than 5:15 p.m., Friday, August 12, 2022. Post-hearing briefs and statements should address matters raised at the hearing. For a description of the different types of written briefs and statements, see the ''Definitions'' section below.

In the event that, as of the close of business on July 6, 2022, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or nonparticipant should check the Commission website two paragraphs above for information concerning whether the hearing will be held.

Written submissions: In lieu of or in addition to participating in the hearing, interested parties are invited to file written submissions concerning this investigation. All written submissions should be addressed to the Secretary and should be received not later than

5:15 p.m., Wednesday, August 24, 2022. All written submissions must conform to the provisions of section 201.8 of the Commission's Rules of Practice and Procedure (19 CFR 201.8), as temporarily amended by 85 FR 15798 (March 19, 2020). Under that rule waiver, the Office of the Secretary will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding electronic filing should contact the Office of the Secretary, Docket Services Division (202–205–1802), or consult the Commission's Handbook on Filing Procedures.

Definitions of types of documents that may be filed; requirements: In addition to requests to appear at the hearing, this notice provides for the possible filing of four types of documents: prehearing briefs, oral hearing statements, post-hearing briefs, and other written submissions.

(1) Prehearing briefs refers to written materials relevant to the investigation and submitted in advance of the hearing, and includes written views on matters that are the subject of the investigation, supporting materials, and any other written materials that you consider will help the Commission in understanding your views. You should file a prehearing brief particularly if you plan to testify at the hearing on behalf of an industry group, company, or other organization, and wish to provide detailed views or information that will support or supplement your testimony.

(2) *Oral hearing statements (testimony)* refers to the actual oral statement that you intend to present at the public hearing. Do not include any confidential business information in that statement. If you plan to testify, you must file a copy of your oral statement by the date specified in this notice. This statement will allow Commissioners to understand your position in advance of the hearing and will also assist the court reporter in preparing an accurate transcript of the hearing (*e.g.,* names spelled correctly).

(3) *Post-hearing briefs* refers to submissions filed after the hearing by persons who appeared at the hearing. Such briefs: (a) Should be limited to matters that arose during the hearing, (b) should respond to any Commissioner and staff questions addressed to you at the hearing, (c) should clarify, amplify, or correct any statements you made at the hearing, and (d) may, at your option, address or rebut statements made by other participants in the hearing.

(4) *Other written submissions* refers to any other written submissions that interested persons wish to make, regardless of whether they appeared at the hearing, and may include new information or updates of information previously provided.

In accordance with the provisions of section 201.8 of the Commission's Rules of Practice and Procedure (19 CFR 201.8) the document must identify on its cover (1) the investigation number and title and the type of document filed (*i.e.,* prehearing brief, oral statement of (name), posthearing brief, or written submission), (2) the name and signature of the person filing it, (3) the name of the organization that the submission is filed on behalf of, and (4) whether it contains confidential business information (CBI). If it contains CBI, it must comply with the marking and other requirements set out below in this notice relating to CBI. Submitters of written documents (other than oral hearing statements) are encouraged to include a short summary of their position or interest at the beginning of the document, and a table of contents when the document addresses multiple issues.

Confidential business information: Any submissions that contain confidential business information must also conform to the requirements of section 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''non-confidential'' version, and that the confidential business information is clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties.

As requested by the Committees, the Commission will not include any confidential business information in its report. However, all information, including confidential business information, submitted in this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel for cybersecurity purposes. The Commission will not otherwise disclose any confidential business information in a way that would reveal the operations of the firm supplying the information.

Summaries of written submissions: Persons wishing to have a summary of their position included in the report should include a summary with their written submission on or before August 24, 2022, and should mark the summary as having been provided for that purpose. The summary should be clearly marked as ''summary for inclusion in the report'' at the top of the page. The summary may not exceed 500 words and should not include any confidential business information. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. The Commission will list the name of the organization furnishing the summary and will include a link to the Commission's Electronic Document Information System (EDIS) where the written submission can be found.

By order of the Commission.

Issued: May 5, 2022.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2022–10021 Filed 5–9–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1258]

Certain Smart Thermostat Systems, Smart HVAC Systems, Smart HVAC Control Systems, and Components Thereof; Notice of Request for Submissions on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that on April 4, 2022, the presiding administrative law judge (''ALJ'') issued a Final Initial Determination on Violation of Section 337. The ALJ also issued a Recommended Determination on remedy and bonding should a violation be found in the above-captioned investigation. The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation. This notice is soliciting comments from the public only.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Esq., Office of the General Counsel, U.S. International

Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–4716. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that, if the Commission finds a violation, it shall exclude the articles concerned from the United States:

unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1).

The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation, specifically: A limited exclusion order directed to certain smart thermostat systems, smart HVAC systems, smart HVAC control systems, and components thereof imported, sold for importation, and/or sold after importation by respondents: Ecobee, Ltd., ecobee Inc., and Google LLC (collectively, ''Respondents''). Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

The Commission is interested in further development of the record on the public interest in this investigation. Accordingly, members of the public are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the ALJ's Recommended Determination on Remedy and Bonding issued in this investigation on April 4, 2022. Comments should address whether issuance of the recommended remedial orders in this investigation, should the Commission find a violation, would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the recommended remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;

(iii) identify like or directly competitive articles that complainant, complainant's licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third-party suppliers have the capacity to replace the volume of articles potentially subject to the recommended orders within a commercially reasonable time; and

(v) explain how the recommended orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on May 20, 2022.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (''Inv. No. 337–TA–1258'') in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: May 5, 2022.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2022–10022 Filed 5–9–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

[F.C.S.C. Meeting and Hearing Notice No. 03–22]

Sunshine Act Meeting

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR part 503.25) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings as follows:

TIME AND DATE: Wednesday, May 18, 2022, at 2:00 p.m. EST.

PLACE: This meeting will be held by teleconference. There will be no physical meeting place.

STATUS: Open. Members of the public who wish to observe the meeting via teleconference should contact Patricia M. Hall, Foreign Claims Settlement Commission, Tele: (202) 616–6975, two business days in advance of the meeting. Individuals will be given call-in information upon notice of attendance to the Commission.

MATTERS TO BE CONSIDERED: 2:00 p.m.—Issuance of Proposed Decisions under the Guam World War II Loyalty Recognition Act, Title XVII, Public Law 114–328.

CONTACT PERSON FOR MORE INFORMATION: Requests for information, advance

notices of intention to observe an open meeting, and requests for teleconference dial-in information may be directed to: Patricia M. Hall, Foreign Claims Settlement Commission, 441 G St. NW, Room 6234, Washington, DC 20579. Telephone: (202) 616–6975.

Jeremy R. LaFrancois,

Chief Administrative Counsel.

[FR Doc. 2022–10125 Filed 5–6–22; 4:15 pm]

BILLING CODE 4410–BA–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Computer and Information Science and Engineering; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub., L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Computer and Information Science and Engineering (#1115).

Date and Time: May 16, 2022–11:00 a.m.–5:00 p.m. (Eastern); May 17, 2022–11:00 a.m.–4:30 p.m. (Eastern)

Place: NSF, 2415 Eisenhower Avenue, Alexandria, VA 22314 (Virtual).

Virtual meeting attendance only; to attend the virtual meeting, please send your request for the virtual meeting link to the following email: *cmessam@nsf.gov.*

Type of Meeting: Open.

Contact Persons: KaJuana Mayberry, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone: 703–292–8900; email: *kmayberry@nsf.gov*

Purpose of Meeting: To provide advice, recommendations and counsel on major goals and policies pertaining to Computer and Information Science and Engineering programs and activities.

Agenda

- NSF and CISE update
- NASEM report on responsible computing research
- NSF activities towards geography of innovation

Reason for Late Notice: Due to the unforeseen scheduling complications and the necessity to proceed with CISE updates and the NASEM reports to the committee.

Dated: May 5, 2022.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2022–09996 Filed 5–9–22; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–295, 50–304, 72–1037, 50–320, 50–409, 72–046, 50–305, 72–64, 030–39013, 11005620, and 11005897; NRC–2021–0232 and NRC–2022–0092]

In the Matter of Energy*Solutions,* LLC; Zion Nuclear Power Station, Units 1 and 2; Three Mile Island Nuclear Station, Unit 2; La Crosse Boiling Water Reactor; Kewaunee Power Station; Energy*Solutions,* LLC Radioactive Materials License; Energy*Solutions,* LLC Export Licenses

AGENCY: Nuclear Regulatory Commission.

ACTION: Indirect transfer of licenses; order.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an order to Energy*Solutions,* LLC (Energy*Solutions*) approving the indirect transfer of control of Facility Operating License Nos. DPR–39 and DPR–48 for Zion Nuclear Power Station, Units 1 and 2, respectively, and the general license for the Zion independent spent fuel storage installation (ISFSI); Possession Only License No. DPR–73 for Three Mile Island Nuclear Station, Unit 2; Possession Only License No. DPR–45 for La Crosse Boiling Water Reactor and the general license for the La Crosse ISFSI; Renewed Facility Operating License No. DPR–43 for Kewaunee Power Station and the general license for the Kewaunee ISFSI; Radioactive Materials License No. 39–35044–01; Export License XW010/04; and Export License XW018/01, to the extent that these licenses may be held by Energy*Solutions* or its wholly-owned subsidiaries at the time of the consummation of the indirect transfer. The indirect transfer of control of these licenses would result from the consummation of a stock purchase agreement dated November 16, 2021, involving the current principal shareholders of the corporate parent company of Energy*Solutions* and other investors.

DATES: The order was issued on May 3, 2022, and is effective for 1 year.

ADDRESSES: Please refer to Docket ID NRC–2021–0232 and NRC–2022–0092 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document by using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0232 and NRC–2022–0092. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–287–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the ''For Further Information Contact'' section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The indirect license transfer order and the NRC staff safety evaluation supporting the order are available in ADAMS under Package Accession No. ML22076A008.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jack D. Parrott, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3178; email: *Jack.Parrott@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the order is attached.

Dated: May 4, 2022.

For the Nuclear Regulatory Commission.

Jack D. Parrott,

Senior Project Manager, Reactor Decommissioning Branch, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety and Safeguards.

Attachment—Order Approving Indirect Transfer of Licenses

United States of America Nuclear Regulatory Commission

In the Matter of ENERGYSOLUTIONS, LLC Zion Nuclear Power Station, Units 1 and 2, and the Associated Independent Spent Fuel Storage Installation; Three Mile Island Nuclear Station, Unit 2; La Crosse Boiling Water Reactor, and the Associated Independent Spent Fuel Storage Installation; Kewaunee Power Station, and the Associated Independent Spent Fuel Storage Installation; Radioactive Materials License; and Export Licenses EA–22–024

Docket Nos. 50–295, 50–304, 72–1037, 50–320, 50–409, 72–046, 50–305, 72–64, 030–39013, 11005620, and 11005897

License Nos. DPR–39, DPR–48, DPR–73, DPR–45, DPR–43, 39–35044–01, W010/04, and XW018/01

Order Approving Indirect Transfer of Licenses

I.

This order pertains to the following licenses held, or potentially held during the effectiveness of this order, by Energy*Solutions,* LLC (Energy*Solutions,* the Applicant) or its wholly-owned subsidiaries (collectively, the Licenses):

- Facility Operating License Nos. DPR–39 and DPR–48 for Zion Nuclear Power Station (ZNPS), Units 1 and 2, respectively, and the general license for the ZNPS independent spent fuel storage installation (ISFSI) located in Zion, Illinois. The ZNPS licenses are currently held by the Applicant's licensed subsidiary, Zion*Solutions,* LLC, a wholly-owned special purpose subsidiary under the Applicant, for the purpose of decommissioning the site. However, there is a pending U.S. Nuclear Regulatory Commission (NRC, the Commission) order approving the transfer of the ZNPS licenses from Zion*Solutions,* LLC to Exelon Generation Company, LLC (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21229A027).
- Possession Only License No. DPR–73 for Three Mile Island Nuclear Station, Unit 2 (TMI–2) located near Middletown, Pennsylvania. The TMI–2 facility and site are owned and operated by the Applicant's licensed subsidiary, TMI–2 Solutions, LLC, a wholly-owned special purpose subsidiary under the Applicant, for the purpose of decommissioning the site.
- Possession Only License No. DPR–45 for La Crosse Boiling Water Reactor (LACBWR), located on the east bank of the Mississippi River in Vernon County, Wisconsin, and the general license for the LACBWR ISFSI. The LACBWR licenses are currently held by LaCrosse*Solutions,* LLC, a wholly-owned special purpose subsidiary under the Applicant, for the purpose of decommissioning the site. However, there is a pending NRC order approving the transfer of the LACBWR licenses from LaCrosse*Solutions,* LLC to Dairyland Power Cooperative (ADAMS Accession No. ML21228A107).
- Renewed Facility Operating License No. DPR–43 for Kewaunee Power Station (KPS), located in the Town of Carlton along the coast of Lake Michigan in Kewaunee County, Wisconsin, and the general license for the KPS ISFSI. The KPS licenses are currently indirectly held by Dominion Nuclear Projects, Inc.; however, there is a pending NRC order approving the transfer of the KPS licenses from Dominion Nuclear Projects, Inc. to Energy*Solutions* (ADAMS Accession No. ML22014A387).
- Radioactive Materials License No. 39–35044–01 for use at temporary job sites to support a variety of possible work scope activities at those sites.
- Export License XW010/04 for return of radioactive waste to Canada.
- Export License XW018/01 for return of radioactive waste to Germany.

II.

By application dated December 7, 2021, as supplemented by letters dated March 30, 2022, and April 18, 2022 (ADAMS Accession Nos. ML21344A114, ML22091A275, and ML22110A030, respectively), the Applicant, on behalf of itself and its wholly-owned subsidiaries, requested that the NRC consent to the indirect transfer of control of the Licenses, to the extent that the Licenses may be held by the Applicant or its wholly owned subsidiaries at the time of the indirect transfer, pursuant to Section 184 of the Atomic Energy Act of 1954, as amended (the Act), and Title 10 of the *Code of Federal Regulations* (10 CFR) Sections 30.34(b), 50.80, 72.50, and 110.50(d).

Specifically, the Applicant requested that the NRC consent to the indirect transfer of control of the Licenses to support a proposed stock purchase transaction involving the current principal shareholders of the corporate parent company of the Applicant and other investors. The Applicant is a wholly-owned subsidiary of Energy*Solutions* Finance Holdings, LLC, which is a privately held company whose shares are directly owned by Energy*Solutions,* Inc., which in turn is a privately held company whose shares are directly owned by Rockwell Holdco, Inc. (Rockwell).

Rockwell is approximately 58 percent owned primarily by a number of affiliated passive investment funds controlled by Energy Capital Partners GP II, LP (collectively, the ECP II Partnerships). The ECP II Partnerships are each controlled by Energy Capital Partners GP II, LP as general partner. The general partner in turn is controlled by Energy Capital Partners II, LLC. Collectively, these entities are referred to as ''ECP.'' Rockwell is also approximately 40 percent owned by passive investment funds controlled by TriArtisan ES Partners, LLC. TriArtisan ES Partners, LLC is in turn controlled by TriArtisan ES MM LLC, which is in turn managed by TriArtisan Capital Advisors LLC. Collectively, these entities are referred to as the ''TriArtisan Entities.''

The indirect transfer arises from a Stock Purchase Agreement (SPA) dated November 16, 2021. Pursuant to the SPA, a passive investment fund established by the TriArtisan Entities, known as TriArtisan ES Partners II LP, will acquire most of the existing majority shareholder interest held by ECP, as well as most of the current TriArtisan Entities' shares. As a result, TriArtisan ES Partners II LP and the TriArtisan Entities (collectively, TriArtisan) would own a majority shareholder interest of approximately 88 percent and would have governance control over Rockwell.

On January 21, 2022, the NRC published a notice of consideration of approval of the application in the **Federal Register** (87 FR 3372). The supplemental letter dated March 30, 2022, provided additional information that expanded the scope of the application as originally noticed and, therefore, the NRC published a notice of consideration of approval of the application, as supplemented, in the **Federal Register** on April 8, 2022 (87 FR 20889). The supplemental letter dated April 18, 2022, provided additional information that clarified the application and did not expand the scope of the application as noticed. The notices provided an opportunity to comment, request a hearing, and petition for leave to intervene on the application. One request for a hearing on the application was filed by Eric Epstein, on behalf of himself, on February 10, 2022 (ADAMS Accession No. ML22041A773). This hearing request is pending before the Commission. The NRC received no comment submissions on the license transfer application.

In accordance with 10 CFR 50.80, no license for a production or utilization facility, or any right thereunder, shall be transferred, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission gives its consent in writing. In accordance with 10 CFR 72.50, no license or any part included in a license for an ISFSI shall be transferred, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission gives its consent in writing. In accordance with 10 CFR 30.34, no license issued or granted pursuant to 10 CFR part 30 nor any right under a license shall be transferred, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provision of the Act and shall give its consent in writing. In accordance with 10 CFR 110.50, a specific license may be transferred to another person only with the approval of the Commission.

Upon review of the information in the application, as supplemented, and other information before the NRC, and relying upon the representations and agreements contained in the application, the NRC staff has determined that Energy*Solutions* is qualified to hold the Licenses, to the extent described in the application, and that transfer of the Licenses is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto, subject to the conditions set forth below. The NRC staff has also determined that: (1) There is reasonable assurance that the health and safety of the public will not be endangered by operation in the proposed manner, (2) there is reasonable assurance that such activities will be conducted in compliance with the Commission's regulations, and (3) the transfer will not be inimical to the common defense and security or to the health and safety of the public. The findings set forth above are supported by an NRC staff safety evaluation dated May 3, 2022.

III.

Accordingly, pursuant to Sections 161b, 161i, and 184 of the Act, 42 U.S.C. 2201(b), 2201(i), and 2234; and 10 CFR 30.34(b), 50.80, 72.50, and 110.50(d), *it is hereby ordered* that the application regarding the proposed indirect license transfer is approved, subject to the following conditions:

(1) The NRC staff's approval of the license transfer is subject to the Commission's authority to rescind, modify, or condition the approved transfer based on the outcome of any post-effectiveness hearing on the license transfer application.

(2) If Energy*Solutions* does not indirectly hold Facility Operating License Nos. DPR–39 and DPR–48 for ZNPS, Units 1 and 2, respectively, and the general license for the ZNPS ISFSI, at the time of the closing of the proposed indirect license transfer, then the ZNPS licenses shall not be transferred as part of the indirect license transfer.

(3) If Energy*Solutions* does not indirectly hold Possession Only License No. DPR–45 for LACBWR, and the general license for the LACBWR ISFSI, at the time of the closing of the proposed indirect license transfer, then the LACBWR licenses shall not be transferred as part of the indirect license transfer.

(4) If Energy*Solutions* does not indirectly hold Renewed Facility Operating License No. DPR–43 for KPS, and the general license for the KPS ISFSI, at the time of the closing of the proposed indirect license transfer, then the KPS licenses shall not be transferred as part of the indirect license transfer.

Should the proposed indirect license transfer not be completed within one year of the date of this order, this order shall become null and void, provided, however, that upon written application and for good cause shown, such date may be extended by order. The conditions of this order may be amended upon application by the Applicant and approval by the NRC.

This order is effective upon issuance.

For further details with respect to this order, see the application dated December 7, 2021, as supplemented by letters dated March 30, 2022, and April 18, 2022, and the associated NRC staff safety evaluation dated May 3, 2022. Publicly available documents created or received at the NRC are accessible electronically through ADAMS in the NRC Library at *https://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems accessing the documents located in ADAMS, should contact the NRC Public Document Room reference staff by telephone at 1–800–397–4209, or 301–415–4737, or by email to *pdr.resource@nrc.gov.*

Dated: May 3, 2022.

For the Nuclear Regulatory Commission.

/RA/

John W. Lubinski,

Director, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2022–09971 Filed 5–9–22; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

[OMB Control No. 3206–0278]

Submission for Review: Renewal of An Existing Information Collection, USA Staffing's, Onboarding Features

AGENCY: U.S. Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on a revised information collection request (ICR) 3206–0278, USA Staffing, Onboarding).

DATES: Comments are encouraged and will be accepted until July 11, 2022. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection by one of the following means:

Federal Rulemaking Portal: http://www.regulations.gov All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Email *bridget.dongarra@opm.gov.* Please put ''USA Staffing, Onboarding'' in the subject line of the email.

FOR FURTHER INFORMATION CONTACT: A copy of this information collection request, with applicable supporting documentation, may be obtained by contacting the USA Staffing, Office of Personnel Management, 1900 E Street NW, Washington, DC 20415, Attention: Bridget Dongarra, or via electronic mail to *bridget.dongarra@opm.gov.*

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection. USA Staffing is OPM's talent acquisition solution. Federal agencies use USA Staffing to onboard candidates for Federal positions while complying with appropriate rules and procedures. Federal agencies purchase the services of USA Staffing through an Interagency Agreement (IAA) under the provisions of the Revolving Fund, 5 U.S.C. 1304 (e)(1), which permits OPM to perform human resources management services for Federal agencies on a cost-recovery basis.

USA Staffing's public facing web page for new hires provides a single interface to submit data and forms required during the Federal onboarding process. New Hires are individuals selected for Federal employment but who have not yet entered on duty and authenticate at USA Staffing using their *USAJOBS.gov* accounts. USA Staffing captures the essential information Federal agencies require to onboard applicants for Federal jobs under the authority of sections 1104, 1302, 3301–3320, 3361, 3393, and 3394 of Title 5 United States Code. This information includes questions related to selectee background, biographic, contact, employee benefits enrollment, employment history, and payroll information. Responses to these questions address required suitability and background investigation requirements, and also facilitate timely and efficient entry on duty. This revision proposes to renew a currently approved collection. Therefore, we invite comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Analysis

Agency: Office of Personnel Management.

Title: USA Staffing, Onboarding.

OMB Number: 3206–0278.

Frequency: Annually.

Affected Public: Individuals.

Number of Respondents: 570,000.

Estimated Time per Respondent: 20 Minutes.

Total Burden Hours: 189,625.

U.S. Office of Personnel Management.

Kellie Cosgrove Riley,

Director, Office of Privacy and Information Management.

[FR Doc. 2022–09983 Filed 5–9–22; 8:45 am]

BILLING CODE 6325–XX–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2022–55 and CP2022–60]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 12, 2022.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2022–55 and CP2022–60; *Filing Title:* USPS Request to Add Priority Mail Contract 739 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 4, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* May 12, 2022.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2022–10013 Filed 5–9–22; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94842; File No. SR–NYSENAT–2022–06]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing of Proposed Rule Change To Modify Rule 7.31 To Add Subparagraph (f)(4) Regarding Directed Orders

May 4, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on April 20, 2022, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify Rule 7.31 to add subparagraph (f)(4) regarding Directed Orders and make other conforming changes. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify Rule 7.31 (Orders and Modifiers) to add new subparagraph (f)(4) to provide for Directed Orders and to make other conforming changes to its Rules in connection with the addition of this new order type on the Exchange. The Directed Order, as further defined below, would be an order sent to the Exchange to be routed directly to an alternative trading system (''ATS'') specified by an ETP Holder.

The Exchange proposes to add Rule 7.31(f)(4), which would define a Directed Order as a Limit Order with instructions to route on arrival at its limit price to a specified ATS with which the Exchange maintains an electronic linkage. Proposed Rule 7.31(f)(4) would also provide that Directed Orders would be available for all securities eligible to trade on the Exchange and would not be assigned a working time or interact with interest on the Exchange Book. The Exchange also proposes to provide in Rule 7.31(f)(4) that the ATS to which a Directed Order is routed would be responsible for validating whether the order is eligible to be accepted, and if such ATS

determines to reject the order, the order would be cancelled.

Proposed Rule 7.31(f)(4)(A) would provide that a Directed Order must be designated for the Exchange's Core Trading Session, as defined in Rule 7.34(a)(2).[4]

Proposed Rule 7.31(f)(4)(A) would further provide that a Directed Order must be designated with a Time in Force modifier of IOC[5] or Day[6] and would be routed to the specified ATS with such modifier. The Exchange proposes that a Directed Order designated IOC would be traded in whole or in part on the ATS to which it is routed after receipt of the order, and any untraded quantity would be cancelled. The Exchange proposes that a Directed Order designated Day would expire at the end of the Core Trading Session on the day it is entered. Proposed Rule 7.31(f)(1)(A) would also provide that a Directed Order may not be designated with any other modifiers defined in Rule 7.31.

Proposed Rule 7.31(f)(4)(B) would provide that, during a trading halt or pause, an incoming Directed Order would be rejected.

Proposed Rule 7.31(f)(4)(C) would provide that a request to cancel a Directed Order designated Day would be routed to the ATS to which the order was routed.

The Exchange also proposes a conforming change to Rule 7.19 (Pre-Trade Risk Controls). The Exchange proposes to modify Rule 7.19(a)(5), which sets forth the definition of Gross Credit Risk Limit and currently provides that unexecuted orders in the Exchange Book, orders routed on arrival pursuant to Rule 7.37(a)(1), and executed orders are included for purposes of calculating the Gross Credit Risk Limit. The Exchange proposes to modify Rule 7.19(a)(5) to specify that orders routed on arrival pursuant to Rule 7.31(f)(4) would also be included for purposes of the Gross Credit Risk Limit calculation.

The Exchange believes that the proposed rule change would facilitate additional trading opportunities by offering ETP Holders the ability to designate orders submitted to the Exchange to be routed to an ATS of their choosing for execution. The Exchange believes the proposed change would encourage ETP Holders to utilize the Exchange as a venue for order entry and further believes that the proposed change could create efficiencies for ETP Holders by enabling them to send orders that they wish to route to an alternate destination through the Exchange, thereby enabling them to leverage order entry protocols and specifications already configured for their interactions with the Exchange. The Exchange notes that the Directed Order, as proposed, would operate similarly to the Primary Only Order already offered by the Exchange, which is an order that is routed directly to the primary listing market on arrival, without being assigned a working time or interacting with interest on the Exchange Book.[7] The Exchange also believes that the Directed Order would offer ETP Holders functionality akin to order types and routing options that currently exist on other equities exchanges.[8]

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date by Trader Update.[9] Subject to effectiveness of this proposed rule change, the Exchange anticipates that the proposed change will be implemented in the second quarter of 2022.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934,[10] in general, and furthers the objectives of Section 6(b)(5),[11] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market and promote just and equitable principles of trade because the Directed Order would offer ETP Holders access to additional trading opportunities by permitting them to designate orders submitted to the Exchange to be routed directly to a specified ATS for execution. The Exchange further believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market by offering ETP Holders the option to send orders that they wish to route to an alternate destination for execution through the Exchange, which would create efficiencies to the extent

[4] Because the Exchange proposes that Directed Orders may only be designated for the Core Trading Session, the Exchange also proposes conforming changes to Rule 7.34 (Trading Sessions). Specifically, the Exchange proposes to modify Rule 7.34(c)(1)(E) to provide that Directed Orders designated for the Early Trading Session would be rejected and Rule 7.34(c)(3)(C) to provide that Directed Orders designated for the Late Trading Session would be rejected.

[5] *See* Rule 7.31(b)(2), which provides that a Limit Order may be designated with an Immediate-or-Cancel (''IOC'') modifier.

[6] *See* Rule 7.31(b)(1), which provides that orders may be designated with a Day modifier, and that an order to buy or sell designated Day, if not traded, will expire at the end of the designated session on the day on which it was entered.

[7] *See* Rule 7.31(f)(1). NYSE National also offers variations of the Primary Only Order, including the Primary Only Until 9:45 Order, which is a Limit or Inside Limit Order that, on arrival and until 9:45 a.m. Eastern Time, routes to the primary listing market, and the Primary Only Until 3:55 Order, which is a Limit or Inside Limit Order entered on the Exchange until 3:55 p.m. Eastern Time, after which time the order is cancelled on the Exchange and routed to the primary listing market. *See* Rules 7.31(f)(2) and (f)(3). The Exchange's affiliated exchanges NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), and NYSE Chicago, Inc. (''NYSE Chicago'') (collectively, the ''Affiliated Exchanges'') also offer the Primary Only Order and variations thereof. *See* NYSE American Rules 7.31E(f)(1)–(f)(3); NYSE Arca Rules 7.31–E(f)(1)—(f)(3); NYSE Chicago Rules 7.31(f)(1)—(f)(3).

[8] *See, e.g.,* Nasdaq Stock Market LLC (''Nasdaq''), Equity 4, Equity Trading Rules, Rule 4758(a)(ix) (defining the Nasdaq Directed Order as an order designed to use a routing strategy under which the order is directed to an automated trading center other than Nasdaq, as directed by the entering party, without checking the Nasdaq Book); Cboe EDGX Exchange, Inc. (''EDGX'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGX system and is immediately routed by EDGX to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe EDGA Exchange, Inc. (''EDGA'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGA system and is immediately routed by EDGA to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe BZX Exchange, Inc. (''BZX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BZX system and be sent to a specified away trading center); Cboe BYX Exchange, Inc. (''BYX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BYX system and be sent to a specified away trading center). The Exchange also believes that the Directed Order would provide functionality similar to the C–LNK routing strategy formerly offered by EDGA, in which C–LNK orders bypassed EDGA's local book and routed directly to a specified Single Dealer Platform destination. *See* Securities Exchange Act Release No. 82904 (March 20, 2018), 83 FR 12995 (March 26, 2018) (SR-CboeEDGA–2018–004) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Expand an Offering Known a Cboe Connect To Provide Connectivity to Single-Dealer Platforms Connected to the Exchange's Network and To Propose a Per Share Executed Fee for Such Service).

[9] The Exchange will also provide information regarding the ATS(s) to which a Directed Order may be designated to route by Trader Update.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

ETP Holders are able to leverage existing protocols and specifications. Finally, the Exchange notes that the proposed functionality is not novel, as both the Exchange and other exchanges offer their members functionality whereby an exchange routes orders on behalf of a member to a specified trading center without such order interacting with the exchange's book.[12]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rules governing Directed Orders would promote competition because they would provide for an order type on the Exchange that would facilitate additional trading opportunities for market participants. The Exchange further believes that the proposed rules would allow it to offer its ETP Holders functionality similar to order types and routing options that exist on other equities exchanges, thereby enabling the Exchange to compete with such exchanges.[13]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or *up to 90 days* (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSENAT–2022–06 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSENAT–2022–06. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSENAT–2022–06 and should be submitted on or before May 31, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09955 Filed 5–9–22; 8:45 am]

BILLING CODE 8011–01–P

[12] *See* notes 7 & 8, *supra.*

[13] *See* note 8, *supra.*

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94844; File No. SR–NYSEArca–2021–90]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Amendment No. 1 to, and Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove, a Proposed Rule Change To List and Trade Shares of Grayscale Bitcoin Trust (BTC) Under NYSE Arca Rule 8.201–E

May 4, 2022.

On October 19, 2021, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of Grayscale Bitcoin Trust (BTC) under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares). The proposed rule change was published for comment in the **Federal Register** on November 8, 2021.[3] On December 15, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On February 4, 2022, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act[6] to determine whether to approve or disapprove the proposed rule change.[7]

On April 21, 2022, the Exchange filed Amendment No. 1 to the proposed rule change, which supersedes the original filing in its entirety, and is described in Items I and II below, which Items have been prepared by the Exchange.[8] The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 93504 (Nov. 2, 2021), 86 FR 61804. Comments on the proposed rule change can be found at: *https://www.sec.gov/comments/sr-nysearca-2021-90/srnysearca202190.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 93788, 86 FR 72291 (Dec. 21, 2021).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 94151, 87 FR 7889 (Feb. 10, 2022).

[8] In Amendment No. 1, the Exchange, among other things, provided updates to: (1) Certain statistical data, (2) information on the Index Price (as defined herein), and (3) information on the creation and redemption of Shares (as defined herein).

1, from interested persons, and is designating a longer period within which to approve or disapprove the proposed rule change, as modified by Amendment No. 1.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade shares of the following under NYSE Arca Rule 8.201–E: Grayscale Bitcoin Trust (BTC) (the ''Trust'').[9] This Amendment No. 1 to SR–NYSEArca–2021–90 replaces SR–NYSEArca–2021–90 as originally filed and supersedes such filing in its entirety. The proposed change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Under NYSE Arca Rule 8.201–E, the Exchange may propose to list and/or trade pursuant to unlisted trading privileges ''Commodity-Based Trust Shares.'' [10] The Exchange proposes to list and trade shares (''Shares'') [11] of the Trust pursuant to NYSE Arca Rule 8.201–E.[12]

The sponsor of the Trust is Grayscale Investments, LLC (''Sponsor''), a Delaware limited liability company. The Sponsor is a wholly-owned subsidiary of Digital Currency Group, Inc. (''Digital Currency Group''). The trustee for the Trust is Delaware Trust Company (''Trustee''). The custodian for the Trust is Coinbase Custody Trust Company, LLC (''Custodian'').[13] The administrator of the Trust is BNY Mellon Asset Servicing, a division of The Bank of New York Mellon (the ''Administrator''). The distribution and marketing agent for the Trust is Genesis (the ''Marketing Agent''). The index provider for the Trust is CoinDesk Indices, Inc., formerly known as TradeBlock, Inc. (the ''Index Provider'').

The Trust is a Delaware statutory trust, organized on September 13, 2013, that operates pursuant to a trust agreement between the Sponsor and the Trustee (''Trust Agreement''). The Trust has no fixed termination date.

Operation of the Trust

According to the Annual Report, the Trust's assets consist solely of Bitcoins, Incidental Rights,[14] IR Virtual

[9] The Trust was previously named Bitcoin Investment Trust, whose name was changed pursuant to a Certificate of Amendment to the Certificate of Trust of Bitcoin Investment Trust filed with the Delaware Secretary of State on January 11, 2019.

[10] Commodity-Based Trust Shares are securities issued by a trust that represent investors' discrete identifiable and undivided beneficial ownership interest in the commodities deposited into the Trust.

[11] The Shares are expected to be listed under the ticker symbol ''BTC.''

[12] On March 22, 2016, the Trust confidentially filed its draft registration statement on Form 10 under the Securities Act of 1933 (15 U.S.C. 77a) (the ''Securities Act'' or ''33 Act'') (File No. 377–01289) (the ''Draft Registration Statement on Form S–1''). On May 31, 2016, the Trust confidentially filed Amendment No. 1 to the Draft Registration Statement on Form S–1. On July 29, 2016, the Trust confidentially filed Amendment No. 2 to the Draft Registration Statement on Form S–1. On November 2, 2016, the Trust confidentially filed Amendment No. 3 to the Draft Registration Statement on Form S–1. The Jumpstart Our Business Startups Act (the ''JOBS Act''), enacted on April 5, 2012, added Section 6(e) to the Securities Act. Section 6(e) of the Securities Act provides that an ''emerging growth company'' may confidentially submit to the Commission a draft registration statement for confidential, non-public review by the Commission staff prior to public filing, provided that the initial confidential submission and all amendments thereto shall be publicly filed not later than 21 days before the date on which the issuer conducts a road show, as such term is defined in Securities Act Rule 433(h)(4). An emerging growth company is defined in Section 2(a)(19) of the Securities Act as an issuer with less than $1,000,000,000 total annual gross revenues during its most recently completed fiscal year. The Trust meets the definition of an emerging growth company and consequently submitted its Draft Registration Statement on Form S–1 to the Commission on a confidential basis.

On January 20, 2017, the Trust filed its registration statement on Form S–1 under the Securities Act (File No. 333–215627) (the ''Registration Statement on Form S–1''). On March 24, 2017, the Trust filed Amendment No. 1 to the Registration Statement on Form S–1. On May 4, 2017, the Trust filed Amendment No. 2 to the Registration Statement on Form S–1. On October 25, 2017, the Trust requested the withdrawal of the Registration Statement on Form S–1.

On October 3, 2018, the Trust confidentially filed its draft registration statement on Form 10 under the Securities Act (File No. 377–02297) (the ''Draft Registration Statement on Form 10''). On December 6, 2018, the Trust confidentially filed Amendment No. 1 to the Draft Registration Statement on Form 10. On February 25, 2019, the Trust confidentially filed Amendment No. 2 to the Draft Registration Statement on Form 10. On April 15, 2019, the Trust confidentially filed Amendment No. 3 to the Draft Registration Statement on Form 10. On September 9, 2019, the Trust confidentially filed Amendment No. 4 to the Draft Registration Statement on Form 10. As noted above, the Trust meets the definition of an emerging growth company under the JOBS Act and consequently submitted its Draft Registration Statement on Form 10 to the Commission on a confidential basis.

On November 19, 2019, the Trust filed its registration statement on Form 10 under the Securities Act (File No. 000–56121) (the ''Registration Statement on Form 10''). On December 31, 2019, the Trust filed Amendment No. 1 to the Registration Statement on Form 10. On January 21, 2020, the Registration Statement on Form 10 was automatically deemed effective.

On March 20, 2020, the Trust filed its annual report on Form 10–K under the Securities Act (File No. 000–56121). On May 8, 2020, August 7, 2020 and November 6, 2020, the Trust filed its quarterly reports on Form 10–Q under the Securities Act (File No. 000–56121). On March 5, 2021 and February 25, 2022, the Trust filed its annual report on Form 10–K under the Securities Act (File No. 000–56121) (the ''Annual Report''). On May 7, 2021, August 6, 2021 and November 5, 2021, the Trust filed its quarterly reports on Form 10–Q under the Securities Act (File No. 000–56121) (the ''Quarterly Reports''). The descriptions of the Trust, the Shares, and Bitcoin contained herein are based, in part, on the Annual Report and Quarterly Reports.

On January 17, 2019, the Trust submitted to the Commission an amended Form D as a business trust. Shares of the Trust have been quoted on OTC Market's OTCQX Best Marketplace under the symbol ''GBTC'' since March 26, 2015. On February 22, 2019 and March 20, 2020, the Trust published annual reports for GBTC for the periods ended December 31, 2018 and December 31, 2019, respectively. On May 14, 2019, August 8, 2019, November 14, 2019, May 8, 2020, August 7, 2020 and November 6, 2020, the Trust published quarterly reports for GBTC for the periods ended March 31, 2019, June 30, 2019, September 30, 2019, March 31, 2020, June 30, 2020 and September 30, 2020 respectively. Reports published before January 11, 2020, the date on which the Trust's Shares became registered pursuant to Section 12(g) of the Act, can be found on OTC Market's website (*http://www.otcmarkets.com/stock/GBTC/disclosure*), and reports published on or after January 11, 2020 can be found on OTC Market's website (*http://www.otcmarkets.com/stock/GBTC/disclosure*) and the Commission's website (*https://www.sec.gov/cgi-bin/browse-edgar?CIK=gbtc&owner=exclude&action=getcompany*). The Shares will be of the same class and will have the same rights as shares of GBTC. Effective October 28, 2014, the Trust suspended its redemption program for shares of GBTC, in which shareholders were permitted to request the redemption of their shares through Genesis Global Trading, Inc. (formerly known as SecondMarket, Inc.), an affiliate of the Sponsor and the Trust (''Genesis''). According to the Sponsor, freely tradeable shares of GBTC will remain freely tradeable Shares on the date of the listing of the Shares that are unregistered under the Securities Act. Restricted shares of GBTC will remain subject to private placement restrictions and the holders of such restricted shares will continue to hold those Shares subject to those restrictions until they become freely tradable Shares.

[13] According to the Annual Report, Digital Currency Group owns a minority interest in Coinbase, Inc., which is the parent company of the Custodian, representing less than 1.0% of its equity.

[14] ''Incidental Rights'' are rights to acquire, or otherwise establish dominion and control over, any virtual currency or other asset or right, which rights are incident to the Trust's ownership of Bitcoins and arise without any action of the Trust, or of the Sponsor or Trustee on behalf of the Trust.

Currency,[15] proceeds from the sale of Bitcoins, Incidental Rights, and IR Virtual Currency pending use of such cash for payment of Additional Trust Expenses [16] or distribution to shareholders, and any rights of the Trust pursuant to any agreements, other than the Trust Agreement, to which the Trust is a party. Each Share represents a proportional interest, based on the total number of Shares outstanding, in each of the Trust's assets as determined by reference to the Index Price,[17] less the Trust's expenses and other liabilities (which include accrued but unpaid fees and expenses). The Sponsor expects that the market price of the Shares will fluctuate over time in response to the market prices of Bitcoin. In addition, because the Shares reflect the estimated accrued but unpaid expenses of the Trust, the number of Bitcoins represented by a Share will gradually decrease over time as the Trust's Bitcoins are used to pay the Trust's expenses. The Trust does not expect to take any Incidental Rights or IR Virtual Currency it may hold into account for purposes of determining the Trust's ''Digital Asset Holdings'' (as described below) or the Digital Asset Holdings per Share.

The activities of the Trust are limited to (i) issuing ''Baskets'' (as defined below) in exchange for Bitcoins transferred to the Trust as consideration in connection with the creations, (ii) transferring or selling Bitcoins, Incidental Rights, and IR Virtual Currency as necessary to cover the ''Sponsor's Fee'' and/or certain Trust expenses, (iii) transferring Bitcoins in exchange for Baskets surrendered for redemption (subject to obtaining regulatory approval from the SEC and approval of the Sponsor), (iv) causing the Sponsor to sell Bitcoins, Incidental Rights, and IR Virtual Currency on the termination of the Trust, (v) making distributions of Incidental Rights and/or IR Virtual Currency or cash from the sale thereof, and (vi) engaging in all administrative and security procedures necessary to accomplish such activities in accordance with the provisions of the Trust Agreement, the Custodian Agreement, the Index License Agreement and the Participant Agreements.

In addition, the Trust may engage in any lawful activity necessary or desirable in order to facilitate shareholders' access to Incidental Rights or IR Virtual Currency, provided that such activities do not conflict with the terms of the Trust Agreement. The Trust will not be actively managed. It will not engage in any activities designed to obtain a profit from, or to ameliorate losses caused by, changes in the market prices of Bitcoins.

Investment Objective

According to the Annual Report, and as further described below, the Trust's investment objective is for the value of the Shares (based on Bitcoin per Share) to reflect the value of the Bitcoins held by the Trust, as determined by reference to the Index Price, less the Trust's expenses and other liabilities. While an investment in the Shares is not a direct investment in Bitcoin, the Shares are designed to provide investors with a cost-effective and convenient way to gain investment exposure to Bitcoin. A substantial direct investment in Bitcoin may require expensive and sometimes complicated arrangements in connection with the acquisition, security and safekeeping of the Bitcoin and may involve the payment of substantial fees to acquire such Bitcoin from third-party facilitators through cash payments of U.S. dollars. Because the value of the Shares is correlated with the value of Bitcoin held by the Trust, it is important to understand the investment attributes of, and the market for, Bitcoin.

Bitcoin and the Bitcoin Network

According to the Annual Report, Bitcoin is a digital asset that is created and transmitted through the operations of the peer-to-peer ''Bitcoin Network,'' a decentralized network of computers that operates on cryptographic protocols. No single entity owns or operates the Bitcoin Network, the infrastructure of which is collectively maintained by a decentralized user base. The Bitcoin Network allows people to exchange tokens of value, called Bitcoin, which are recorded on a public transaction ledger known as a Blockchain. Bitcoin can be used to pay for goods and services, or it can be converted to fiat currencies, such as the U.S. dollar, at rates determined on ''Digital Asset Markets'' [18] that trade Bitcoin or in individual end-user-to-end-user transactions under a barter system.

The Bitcoin Network is decentralized and does not require governmental authorities or financial institution intermediaries to create, transmit, or determine the value of Bitcoin. Rather, Bitcoin is created and allocated by the Bitcoin Network protocol through a ''mining'' process. The value of Bitcoin is determined by the supply of and demand for Bitcoin on the Digital Asset Markets or in private end-user-to-end-user transactions.

New Bitcoin are created and rewarded to the miners of a block in the Blockchain for verifying transactions. The Blockchain is effectively a decentralized database that includes all blocks that have been solved by miners, and it is updated to include new blocks as they are solved. Each Bitcoin transaction is broadcast to the Bitcoin Network and, when included in a block, recorded in the Blockchain. As each new block records outstanding Bitcoin transactions, and outstanding transactions are settled and validated through such recording, the Blockchain represents a complete, transparent and unbroken history of all transactions of the Bitcoin Network.

Summary of a Bitcoin Transaction

Prior to engaging in Bitcoin transactions directly on the Bitcoin Network, a user generally must first install on its computer or mobile device a Bitcoin Network software program that will allow the user to generate a private and public key pair associated with a Bitcoin address, commonly referred to as a ''wallet.'' The Bitcoin Network software program and the Bitcoin address also enable the user to connect to the Bitcoin Network and transfer

[15] ''IR Virtual Currency'' is any virtual currency tokens, or other asset or right, acquired by the Trust through the exercise (subject to the applicable provisions of the Trust Agreement) of any Incidental Right.

[16] ''Additional Trust Expenses'' are any expenses incurred by the Trust in addition to the Sponsor's Fee that are not Sponsor-paid Expenses, including, but not limited to, (i) taxes and governmental charges, (ii) expenses and costs of any extraordinary services performed by the Sponsor (or any other service provider) on behalf of the Trust to protect the Trust or the interests of shareholders (including in connection with any Incidental Rights and any IR Virtual Currency), (iii) any indemnification of the Custodian or other agents, service providers or counterparties of the Trust, (iv) the fees and expenses related to the listing, quotation or trading of the Shares on any Secondary Market (including legal, marketing and audit fees and expenses) to the extent exceeding $600,000 in any given fiscal year and (v) extraordinary legal fees and expenses, including any legal fees and expenses incurred in connection with litigation, regulatory enforcement or investigation matters.

[17] The ''Index Price'' means the U.S. dollar value of a Bitcoin derived from the Digital Asset Exchanges that are reflected in the Index, calculated at 4:00 p.m., New York time, on each business day. For purposes of the Trust Agreement, the term Bitcoin Index Price has the same meaning as the Index Price as defined herein.

[18] A ''Digital Asset Market'' is a ''Brokered Market,'' ''Dealer Market,'' ''Principal-to-Principal Market'' or ''Exchange Market,'' as each such term is defined in the Financial Accounting Standards Board Accounting Standards Codification Master Glossary. The ''Digital Asset Exchange Market'' is the global exchange market for the trading of Bitcoins, which consists of transactions on electronic Digital Asset Exchanges. A ''Digital Asset Exchange'' is an electronic marketplace where exchange participants may trade, buy and sell Bitcoins based on bid-ask trading. The largest Digital Asset Exchanges are online and typically trade on a 24-hour basis, publishing transaction price and volume data.

Bitcoin to, and receive Bitcoin from, other users.

Each Bitcoin Network address, or wallet, is associated with a unique ''public key'' and ''private key'' pair. To receive Bitcoin, the Bitcoin recipient must provide its public key to the party initiating the transfer. This activity is analogous to a recipient for a transaction in U.S. dollars providing a routing address in wire instructions to the payor so that cash may be wired to the recipient's account. The payor approves the transfer to the address provided by the recipient by ''signing'' a transaction that consists of the recipient's public key with the private key of the address from where the payor is transferring the Bitcoin. The recipient, however, does not make public or provide to the sender its related private key.

Neither the recipient nor the sender reveal their private keys in a transaction, because the private key authorizes transfer of the funds in that address to other users. Therefore, if a user loses his private key, the user may permanently lose access to the Bitcoin contained in the associated address. Likewise, Bitcoin is irretrievably lost if the private key associated with them is deleted and no backup has been made. When sending Bitcoin, a user's Bitcoin Network software program must validate the transaction with the associated private key. In addition, since every computation on the Bitcoin Network requires processing power, there is a transaction fee involved with the transfer that is paid by the payor. The resulting digitally validated transaction is sent by the user's Bitcoin Network software program to the Bitcoin Network miners to allow transaction confirmation.

Bitcoin Network miners record and confirm transactions when they mine and add blocks of information to the Blockchain. When a miner mines a block, it creates that block, which includes data relating to (i) the satisfaction of the consensus mechanism to mine the block, (ii) a reference to the prior block in the Blockchain to which the new block is being added and (iii) transactions that have submitted to the Bitcoin Network but have not yet been added to the Blockchain. The miner becomes aware of outstanding, unrecorded transactions through the data packet transmission and distribution discussed above.

Upon the addition of a block included in the Blockchain, the Bitcoin Network software program of both the spending party and the receiving party will show confirmation of the transaction on the Blockchain and reflect an adjustment to the Bitcoin balance in each party's Bitcoin Network public key, completing the Bitcoin transaction. Once a transaction is confirmed on the Blockchain, it is irreversible.

Some Bitcoin transactions are conducted ''off-blockchain'' and are therefore not recorded in the Blockchain. Some ''off-blockchain transactions'' involve the transfer of control over, or ownership of, a specific digital wallet holding Bitcoin or the reallocation of ownership of certain Bitcoin in a pooled-ownership digital wallet, such as a digital wallet owned by a Digital Asset Exchange. In contrast to on-blockchain transactions, which are publicly recorded on the Blockchain, information and data regarding off-blockchain transactions are generally not publicly available. Therefore, off-blockchain transactions are not truly Bitcoin transactions in that they do not involve the transfer of transaction data on the Bitcoin Network and do not reflect a movement of Bitcoin between addresses recorded in the Blockchain. For these reasons, off-blockchain transactions are subject to risks, as any such transfer of Bitcoin ownership is not protected by the protocol behind the Bitcoin Network or recorded in, and validated through, the blockchain mechanism.

Custody of the Trust's Bitcoins

Digital assets and digital asset transactions are recorded and validated on blockchains, the public transaction ledgers of a digital asset network. Each digital asset blockchain serves as a record of ownership for all of the units of such digital asset, even in the case of certain privacy-focused digital assets, where the transactions themselves are not publicly viewable. All digital assets recorded on a blockchain are associated with a public blockchain address, also referred to as a digital wallet. Digital assets held at a particular public blockchain address may be accessed and transferred using a corresponding private key.

Key Generation

Public addresses and their corresponding private keys are generated by the Custodian in secret key generation ceremonies at secure locations inside faraday cages, which are enclosures used to block electromagnetic fields and mitigate attacks. The Custodian uses quantum random number generators to generate the public and private key pairs.

Once generated, private keys are encrypted, separated into ''shards,'' and then further encrypted. After the key generation ceremony, all materials used to generate private keys, including computers, are destroyed. All key generation ceremonies are performed offline. No party other than the Custodian has access to the private key shards of the Trust.

Key Storage

Private key shards are distributed geographically in secure vaults around the world, including in the United States. The locations of the secure vaults may change regularly and are kept confidential by the Custodian for security purposes.

The Digital Asset Account [19] uses offline storage, or ''cold storage'', mechanisms to secure the Trust's private keys. The term cold storage refers to a safeguarding method by which the private keys corresponding to digital assets are disconnected and/or deleted entirely from the internet. Cold storage of private keys may involve keeping such keys on a non-networked (or ''airgapped'') computer or electronic device or storing the private keys on a storage device (for example, a USB thumb drive) or printed medium (for example, papyrus, paper, or a metallic object). A digital wallet may receive deposits of digital assets but may not send digital assets without use of the digital assets' corresponding private keys. In order to send digital assets from a digital wallet in which the private keys are kept in cold storage, either the private keys must be retrieved from cold storage and entered into an online, or ''hot,'' digital asset software program to sign the transaction, or the unsigned transaction must be transferred to the cold server in which the private keys are held for signature by the private keys and then transferred back to the online digital asset software program. At that point, the user of the digital wallet can transfer its digital assets.

Security Procedures

The Custodian is the custodian of the Trust's private keys in accordance with the terms and provisions of the Custodian Agreement. Transfers from the Digital Asset Account require certain security procedures, including, but not limited to, multiple encrypted private key shards, usernames, passwords and 2-step verification. Multiple private key shards held by the Custodian must be combined to reconstitute the private key to sign any transaction in order to transfer the Trust's assets. Private key shards are distributed geographically in secure

[19] The Digital Asset Account is a segregated custody account controlled and secured by the Custodian to store private keys, which allows for the transfer of ownership or control of the Trust's Bitcoins on the Trust's behalf.

vaults around the world, including in the United States.

As a result, if any one secure vault is ever compromised, this event will have no impact on the ability of the Trust to access its assets, other than a possible delay in operations, while one or more of the other secure vaults is used instead. These security procedures are intended to remove single points of failure in the protection of the Trust's assets.

Transfers of Bitcoins to the Digital Asset Account will be available to the Trust once processed on the Blockchain.

Subject to obtaining regulatory approval to operate a redemption program and authorization of the Sponsor, the process of accessing and withdrawing Bitcoin from the Trust to redeem a Basket by an Authorized Participant will follow the same general procedure as transferring Bitcoins to the Trust to create a Basket by an Authorized Participant, only in reverse.

Digital Asset Holdings

According to the Annual Report, the Trust's assets consist solely of Bitcoins, Incidental Rights, IR Virtual Currency, proceeds from the sale of Bitcoins, Incidental Rights, and IR Virtual Currency pending use of such cash for payment of Additional Trust Expenses or distribution to the shareholders, and any rights of the Trust pursuant to any agreements, other than the Trust Agreement, to which the Trust is a party. Each Share represents a proportional interest, based on the total number of Shares outstanding, in each of the Trust's assets as determined in the case of Bitcoin by reference to the Index Price, less the Trust's expenses and other liabilities (which include accrued but unpaid fees and expenses). The Sponsor expects that the market price of the Shares will fluctuate over time in response to the market prices of Bitcoin. In addition, because the Shares reflect the estimated accrued but unpaid expenses of the Trust, the number of Bitcoin represented by a Share will gradually decrease over time as the Trust's Bitcoin is used to pay the Trust's expenses. The Trust does not expect to take any Incidental Rights or IR Virtual Currency it may hold into account for purposes of determining the Trust's Digital Asset Holdings or the Digital Asset Holdings per Share.

The Sponsor will evaluate the Bitcoin held by the Trust and determine the Digital Asset Holdings of the Trust in accordance with the relevant provisions of the Trust Documents. The following is a description of the material terms of the Trust Documents as they relate to valuation of the Trust's Bitcoin and the Digital Asset Holdings calculations.

On each business day at 4:00 p.m., New York time, or as soon thereafter as practicable (the ''Evaluation Time''), the Sponsor will evaluate the Bitcoin held by the Trust and calculate and publish the Digital Asset Holdings of the Trust. To calculate the Digital Asset Holdings, the Sponsor will:

1. Determine the Index Price as of such business day.

2. Multiply the Index Price by the Trust's aggregate number of Bitcoins owned by the Trust as of 4:00 p.m., E.T. on the immediately preceding day, less the aggregate number of Bitcoins payable as the accrued and unpaid Sponsor's Fee as of 4:00 p.m., E.T. on the immediately preceding day.

3. Add the U.S. dollar value of Bitcoins, calculated using the Index Price, receivable under pending creation orders, if any, determined by multiplying the number of the Baskets represented by such creation orders by the Basket Amount and then multiplying such product by the Index Price.[20]

4. Subtract the U.S. dollar amount of accrued and unpaid Additional Trust Expenses, if any.

5. Subtract the U.S. dollar value of the Bitcoins, calculated using the Index Price, to be distributed under pending redemption orders, if any, determined by multiplying the number of Baskets to be redeemed represented by such redemption orders by the Basket Amount and then multiplying such product by the Index Price (the amount derived from steps 1 through 5 above, the ''Digital Asset Holdings Fee Basis Amount'').

6. Subtract the U.S. dollar amount of the Sponsor's Fee that accrues for such business day, as calculated based on the Digital Asset Holdings Fee Basis Amount for such business day.

In the event that the Sponsor determines that the primary methodology used to determine the Index Price is not an appropriate basis for valuation of the Trust's Bitcoins, the Sponsor will utilize the cascading set of rules as described in ''Trust Valuation of Bitcoin'' below. In addition, in the event that the Trust holds any Incidental Rights and/or IR Virtual Currency, the Sponsor may, at its discretion, include the value of such Incidental Rights and/or IR Virtual Currency in the determination of the Digital Asset Holdings, provided that the Sponsor has determined in good faith a method for assigning an objective value to such Incidental Rights and/or IR Virtual Currency. At this time, the Trust does not expect to take any Incidental Rights or IR Virtual Currency it may hold into account for the purposes of determining the Digital Asset Holdings or the Digital Asset Holdings per Share.

Limits on Bitcoin Supply

The supply of new Bitcoin is mathematically controlled so that the number of Bitcoin grows at a limited rate pursuant to a pre-set schedule. The number of Bitcoin awarded for solving a new block is automatically halved after every 210,000 blocks are added to the Blockchain. Currently, the fixed reward for solving a new block is 6.25 Bitcoin per block and this is expected to decrease by half to become 3.125 Bitcoin after the next 210,000 blocks have entered the Bitcoin Network, which is expected to be mid-2024. This deliberately controlled rate of Bitcoin creation means that the number of Bitcoin in existence will increase at a controlled rate until the number of Bitcoin in existence reaches the pre-determined 21 million Bitcoin. As of December 31, 2021, approximately 18.9 million Bitcoins were outstanding and the date when the 21 million Bitcoin limitation will be reached is estimated to be the year 2140.

Bitcoin Value

Digital Asset Exchange Valuation

According to the Annual Report, the value of Bitcoin is determined by the value that various market participants place on Bitcoin through their transactions. The most common means of determining the value of a Bitcoin is by surveying one or more Digital Asset Exchanges where Bitcoin is traded publicly (*e.g.,* Coinbase Pro, Bitstamp, Kraken, and LMAX Digital). Additionally, there are over-the-counter dealers or market makers that transact in Bitcoin.

Digital Asset Exchange Public Market Data

On each online Digital Asset Exchange, Bitcoin is traded with publicly disclosed valuations for each executed trade, measured by one or more fiat currencies such as the U.S. dollar or Euro. Over-the-counter dealers or market makers do not typically disclose their trade data.

As of December 31, 2021, the Digital Asset Exchanges included in the Index are Coinbase Pro, Bitstamp, Kraken and LMAX Digital. As further described below, each of these Digital Asset Exchanges are in compliance with applicable U.S. federal and state

[20] ''Baskets'' and ''Basket Amount'' have the meanings set forth in ''Creation of Shares'' below.

licensing requirements and practices regarding AML and KYC regulations.

Coinbase Pro: A U.S.-based exchange registered as a money services business (''MSB'') with FinCen and licensed as a virtual currency business under the NYDFS BitLicense as well as money transmitter in various U.S. states.

Bitstamp: A U.K.-based exchange registered as an MSB with FinCen and licensed as a virtual currency business under the NYDFS BitLicense as well as money transmitter in various U.S. states.

Kraken: A U.S.-based exchange registered as an MSB with FinCen and licensed as money transmitter in various U.S. states. Kraken does not hold a BitLicense.

LMAX Digital: A U.K.-based exchange registered as a broker with FCA. LMAX Digital does not hold a BitLicense.

Currently, there are several Digital Asset Exchanges operating worldwide, and online Digital Asset Exchanges represent a substantial percentage of Bitcoin buying and selling activity and provide the most data with respect to prevailing valuations of Bitcoins. These exchanges include established exchanges such as exchanges included in the Index, which provide a number of options for buying and selling Bitcoins. The below table reflects the trading volume in Bitcoins and market share of the BTC–U.S. dollar trading pair of each of the Digital Asset Exchanges included in the Index as of December 31, 2021 using data reported by the Index Provider from May 1, 2015 to December 31, 2021:

Digital Asset Exchanges included in the Index as of December 31, 2021 [21]	Volume (BTC)	Market share [22] (%)
Coinbase Pro	32,019,298	20.76
Bitstamp	22,030,291	14.28
Kraken	11,009,299	7.14
LMAX Digital	6,329,133	4.10
Total BTC–U.S. dollar trading pair	71,388,021	46.28

The domicile, regulation, and legal compliance of the Digital Asset Exchanges included in the Index varies. Information regarding each Digital Asset Exchange may be found, where available, on the websites for such Digital Asset Exchanges, among other places.

The Index and the Index Price

The Index is a U.S. dollar-denominated composite reference rate for the price of Bitcoin. The Index is designed to (i) mitigate the effects of fraud, manipulation and other anomalous trading activity from impacting the Bitcoin reference rate, (ii) provide a real-time, volume-weighted fair value of Bitcoin and (iii) appropriately handle and adjust for non-market related events.

The Index Price is determined by the Index Provider through a process in which trade data is cleansed and compiled in such a manner as to algorithmically reduce the impact of anomalistic or manipulative trading. This is accomplished by adjusting the weight of each data input based on price deviation relative to the observable set, as well as recent and long-term trading volume at each venue relative to the observable set.

Constituent Exchange Selection

According to the Annual Report, the Digital Asset Exchanges that are included in the Index are selected by the Index Provider utilizing a methodology that is guided by the International Organization of Securities Commissions (''IOSCO'') principles for financial benchmarks. For an exchange to become a Digital Asset Exchange included in the Index (a ''Constituent Exchange''), it must satisfy the criteria listed below (the ''Inclusion Criteria''):

- Compliance with applicable U.S. federal and state licensing requirements and practices regarding anti-money laundering (''AML'') and know-your-customer (''KYC'') regulations;
- Publicly known ownership;
- No restrictions on deposits and/or withdrawals of Bitcoin;
- No restrictions on deposits and/or withdrawals of U.S. dollars;
- Reliably displays new trade prices and volumes on a real-time basis through APIs;
- Programmatic trading [23] of the Bitcoin/U.S. dollar spot price;
- Liquid market in the Bitcoin/U.S. dollar spot price;
- Trading volume must represent a minimum of total Bitcoin/U.S. dollar trading volumes (5% for U.S. exchanges and 10% non-U.S. exchanges); and
- Discretion of the Index Provider's analysts [24]

A Digital Asset Exchange is removed from the Index when it no longer satisfies the Inclusion Criteria. The Index Provider does not currently include data from over-the-counter markets or derivatives platforms among the Constituent Exchanges. According to the Annual Report, over-the-counter data is not currently included because of the potential for trades to include a significant premium or discount paid for larger liquidity, which creates an uneven comparison relative to more active markets. There is also a higher potential for over-the-counter transactions to not be arms-length, and thus not be representative of a true market price. Bitcoin derivative markets are also not currently included as the markets remain relatively thin. The Index Provider will consider IOSCO principles for financial benchmarks and the management of trading venues of Bitcoin derivatives when considering inclusion of over-the-counter or derivative platform data in the future.

The Index Provider and the Sponsor have entered into an index license agreement, dated as of February 1, 2022 (the ''Index License Agreement''), governing the Sponsor's use of the Index

[21] On January 19, 2020, the Index Provider removed Bittrex due to a lack of trading volume and added LMAX Digital based on the exchange meeting the liquidity thresholds for inclusion in the Index. On April 6, 2020, the Index Provider removed itBit due to a lack of trading volume and did not add any constituents as part of its scheduled quarterly review.

[22] Market share is calculated using trading volume data (in Bitcoins) provided by the Index Provider for certain Digital Asset Exchanges, including Coinbase Pro, Bitstamp, Kraken, and LMAX Digital, as well as certain other large U.S.-dollar denominated Digital Asset Exchanges that are not currently included in the Index, including Binance. US (data included from April 1, 2020), Bitfinex, Bitflyer (data included from December 24, 2018), Bittrex (data included from July 31, 2018), ErisX (data included from October 1, 2020), Gemini, itBit, LakeBTC (data included from May 1, 2015 to June 1, 2018 and from January 27, 2019), HitBTC (data included from April 1, 2019 to March 31, 2020) and OKCoin.

[23] Exchanges with programmatic trading offer traders an application programming interface that permits trading by sending programmed commands to the exchange.

[24] This includes additional due diligence conducted by the Index Provider's analysts.

Price.[25] Pursuant to the terms of the Index License Agreement, the Index Provider may adjust the calculation methodology for the Index Price without notice to, or consent of, the Trust or its shareholders. The Index Provider may decide to change the calculation methodology to maintain the integrity of the Index Price calculation should it identify or become aware of previously unknown variables or issues with the existing methodology that it believes could materially impact its performance and/or reliability. The Index Provider has sole discretion over the determination of Index Price and may change the methodologies for determining the Index Price from time to time. Shareholders will be notified of any material changes to the calculation methodology or the Index Price in the Trust's current reports and will be notified of all other changes that the Sponsor considers significant in the Trust's periodic reports. The Trust will determine the materiality of any changes to the Index Price on a case-by-case basis, in consultation with external counsel.

The Index Provider may change the trading venues that are used to calculate the Index or otherwise change the way in which the Index is calculated at any time. For example, the Index Provider has scheduled quarterly reviews in which it may add or remove Constituent Exchanges that satisfy or fail the Inclusion Criteria. The Index Provider does not have any obligation to consider the interests of the Sponsor, the Trust, the shareholders, or anyone else in connection with such changes. The Index Provider is not required to publicize or explain the changes or to alert the Sponsor to such changes. Although the Index methodology is designed to operate without any manual intervention, rare events would justify manual intervention. Intervention of this kind would be in response to non-market-related events, such as the halting of deposits or withdrawals of funds on a Digital Asset Exchange, the unannounced closure of operations on a Digital Asset Exchange, insolvency or the compromise of user funds. In the event that such an intervention is necessary, the Index Provider would issue a public announcement through its website, API and other established communication channels with its clients.

[25] Upon entering into the Index License Agreement, the Sponsor and the Index Provider terminated the license agreement between the parties dated as of February 28, 2019.

Determination of the Index Price

The Index applies an algorithm to the price of Bitcoin on the Constituent Exchanges calculated on a per second basis over a 24-hour period. The Index's algorithm is expected to reflect a four-pronged methodology to calculate the Index Price from the Constituent Exchanges:

- *Volume Weighting:* Constituent Exchanges with greater liquidity receive a higher weighting in the Index Price, increasing the ability to execute against (*i.e.,* replicate) the Index in the underlying spot markets.
- *Price-Variance Weighting:* The Index Price reflects data points that are discretely weighted in proportion to their variance from the rest of the other Constituent Exchanges. As the price at a particular exchange diverges from the prices at the rest of the Constituent Exchanges, its weight in the Index Price consequently decreases.
- *Inactivity Adjustment:* The Index Price algorithm penalizes stale activity from any given Constituent Exchange. When a Constituent Exchange does not have recent trading data, its weighting in the Index Price is gradually reduced until it is de-weighted entirely. Similarly, once trading activity at a Constituent Exchange resumes, the corresponding weighting for that Constituent Exchange is gradually increased until it reaches the appropriate level.
- *Manipulation Resistance:* In order to mitigate the effects of wash trading and order book spoofing, the Index Price only includes executed trades in its calculation. Additionally, the Index Price only includes Constituent Exchanges that charge trading fees to its users in order to attach a real, quantifiable cost to any manipulation attempts.

The Index Provider formally re-evaluates the weighting algorithm quarterly, but maintains discretion to change the way in which an Index Price is calculated based on its periodic review or in extreme circumstances. The Index is designed to limit exposure to trading or price distortion of any individual Digital Asset Exchange that experiences periods of unusual activity or limited liquidity by discounting, in real-time, anomalous price movements at individual Digital Asset Exchanges.

The Sponsor believes the Index Provider's selection process for Constituent Exchanges as well as the methodology of the Index Price's algorithm provides a more accurate picture of Bitcoin price movements than a simple average of Digital Asset Exchange spot prices, and that the weighting of Bitcoin prices on the Constituent Exchanges limits the inclusion of data that is influenced by temporary price dislocations that may result from technical problems, limited liquidity or fraudulent activity elsewhere in the Bitcoin spot market. By referencing multiple trading venues and weighting them based on trade activity, the Sponsor believes that the impact of any potential fraud, manipulation or anomalous trading activity occurring on any single venue is reduced.

If the Index Price becomes unavailable, or if the Sponsor determines in good faith that such Index Price does not reflect an accurate price for Bitcoin, then the Sponsor will, on a best efforts basis, contact the Index Provider to obtain the Index Price directly from the Index Provider. If after such contact such Index Price remains unavailable or the Sponsor continues to believe in good faith that such Index Price does not reflect an accurate price for the relevant digital asset, then the Sponsor will employ a cascading set of rules to determine the Index Price, as described below in ''Determination of the Index Price When Index Prices are Unavailable.''

The Trust values its Bitcoin for operational purposes by reference to the Index Price. The Index Price is the value of a Bitcoin as represented by the Index, calculated at 4:00 p.m., New York time, on each business day. The Index Provider develops, calculates and publishes the Index on a continuous basis using the price at the Digital Asset Benchmark Exchanges, as selected by the Index Provider.

Illustrative Example

For the purposes of illustration, outlined below are examples of how the attributes that impact weighting and adjustments in the aforementioned methodology may be utilized to generate the Index Price for a digital asset. For example, the Constituent Exchanges for the Index Price of the digital asset are Coinbase Pro, Kraken, LMAX Digital and Bitstamp.

The Index Price algorithm, as described above, accounts for manipulation at the outset by only including data from executed trades on Constituent Exchanges that charge trading fees. Then, the below-listed elements may impact the weighting of the Constituent Exchanges on the Index price as follows:

- *Volume Weighting:* Each Constituent Exchange will be weighted to appropriately reflect the trading volume share of the Constituent Exchange relative to all the Constituent Exchanges during this same period. For

example, an average hourly weighting of 52.17%, 11.88%, 24.46% and 11.49% for Coinbase Pro, Kraken, LMAX Digital and Bitstamp, respectively, would represent each Constituent Exchange's share of trading volume during the same period.

• *Inactivity Adjustment:* Assume that a Constituent Exchange's trading engine represented a 14% influence on the trading price of the digital asset and then went offline for approximately two hours. The index algorithm automatically recognizes inactivity and de-weights that Constituent Exchange's influence in the Index Price—for example, from 14% to 0%—until trading activity resumes. At which point it would re-weight the Constituent Exchange activity to a weight lower than its original weighting—for example, to 12%.

• *Price-Variance Weighting:* Assume that for a one-hour period, the digital asset's execution prices on one Constituent Exchange were trading more than 7% higher than the average execution prices on another Constituent Exchange. The algorithm will automatically detect the anomaly and reduce that specific Constituent Exchange's weighting to 0% for that one-hour period, ensuring a reliable spot reference unaffected by the localized event.

Determination of the Index Price When Index Price is Unavailable

The Sponsor will use the following cascading set of rules to calculate the Index Price.[26] For the avoidance of doubt, the Sponsor will employ the below rules sequentially and in the order as presented below, should one or more specific rule(s) fail.

1. Index Price = The price set by the Index as of 4:00 p.m., New York time, on the valuation date. If the Index becomes unavailable, or if the Sponsor determines in good faith that the Index does not reflect an accurate price, then the Sponsor will, on a best efforts basis, contact the Index Provider to obtain the Index Price directly from the Index Provider. If after such contact the Index remains unavailable or the Sponsor continues to believe in good faith that the Index does not reflect an accurate price, then the Sponsor will employ the next rule to determine the Index Price. There are no predefined criteria to make a good faith assessment and it will be made by the Sponsor in its sole discretion.

2. Index Price = The price set by Coin Metrics Real-Time Rate (the ''Secondary Index'') as of 4:00 p.m., New York time, on the valuation date (the ''Secondary Index Price''). The Secondary Index Price is a real-time reference rate price, calculated using trade data from constituent markets selected by Coin Metrics (the ''Secondary Index Provider''). The Secondary Index Price is calculated by applying weighted-median techniques to such trade data where half the weight is derived from the trading volume on each constituent market and half is derived from inverse price variance, where a constituent market with high price variance as a result of outliers or market anomalies compared to other constituent markets is assigned a smaller weight. If the Secondary Index becomes unavailable, or if the Sponsor determines in good faith that the Secondary Index does not reflect an accurate price, then the Sponsor will, on a best efforts basis, contact the Secondary Index Provider to obtain the Secondary Index Price directly from the Secondary Index Provider. If after such contact the Secondary Index remains unavailable or the Sponsor continues to believe in good faith that the Secondary Index does not reflect an accurate price, then the Sponsor will employ the next rule to determine the Index Price. There are no predefined criteria to make a good faith assessment and it will be made by the Sponsor in its sole discretion.

3. Index Price = The price set by the Trust's principal market (the ''Tertiary Pricing Option'') as of 4:00 p.m., New York time, on the valuation date. The Tertiary Pricing Option is a spot price derived from the principal market's public data feed that is believed to be consistently publishing pricing information as of 4:00 p.m., New York time, and is provided to the Sponsor via an application programming interface. If the Tertiary Pricing Option becomes unavailable, or if the Sponsor determines in good faith that the Tertiary Pricing Option does not reflect an accurate price, then the Sponsor will, on a best efforts basis, contact the Tertiary Pricing Provider to obtain the Tertiary Pricing Option directly from the Tertiary Pricing Provider. If after such contact the Tertiary Pricing Option remains unavailable after such contact or the Sponsor continues to believe in good faith that the Tertiary Pricing Option does not reflect an accurate price, then the Sponsor will employ the next rule to determine the Index Price. There are no predefined criteria to make a good faith assessment and it will be made by the Sponsor in its sole discretion.

4. Index Price = The Sponsor will use its best judgment to determine a good faith estimate of the Index Price. There are no predefined criteria to make a good faith assessment and it will be made by the Sponsor in its sole discretion.

In the event of a fork, the Index Provider may calculate the Index Price based on a virtual currency that the Sponsor does not believe to be the appropriate asset that is held by the Trust.[27] In this event, the Sponsor has full discretion to use a different index provider or calculate the Index Price itself using its best judgment.

The Structure and Operation of the Trust Protects Investors and Satisfies Commission Requirements for Bitcoin-Based Exchange Traded Products

The Commission has expressed legitimate concerns about the underlying Digital Asset Market due to the potential for fraud and manipulation and has clearly outlined the reasons why prior Bitcoin-based ETP proposals have been unable to satisfy these concerns in orders disapproving the proposed listing and trading of the Winklevoss Bitcoin Trust, Bitwise Bitcoin ETF Trust, United States Bitcoin and Treasury Investment Trust, and

[26] The Sponsor updated these rules on January 11, 2022.

[27] According to the Annual Report, when a modification is introduced and a substantial majority of users and miners consent to the modification, the change is implemented and the network remains uninterrupted. However, if less than a substantial majority of users and miners consent to the proposed modification, and the modification is not compatible with the software prior to its modification, the consequence would be what is known as a ''hard fork'' of the Bitcoin Network, with one group running the pre-modified software and the other running the modified software. The effect of such a fork would be the existence of two versions of Bitcoin running in parallel, yet lacking interchangeability. For example, in August 2017, Bitcoin ''forked'' into Bitcoin and a new digital asset, Bitcoin Cash, as a result of a several-year dispute over how to increase the rate of transactions that the Bitcoin Network can process. In the event of a hard fork of the Bitcoin Network, the Sponsor will, if permitted by the terms of the Trust Agreement, use its discretion to determine, in good faith, which peer-to-peer network, among a group of incompatible forks of the Bitcoin Network, is generally accepted as the Bitcoin Network and should therefore be considered the appropriate network for the Trust's purposes. The Sponsor will base its determination on a variety of then relevant factors, including, but not limited to, the Sponsor's beliefs regarding expectations of the core developers of Bitcoin, users, services, businesses, miners, and other constituencies, as well as the actual continued acceptance of, mining power on, and community engagement with, the Bitcoin Network. There is no guarantee that the Sponsor will choose the digital asset that is ultimately the most valuable fork, and the Sponsor's decision may adversely affect the value of the Shares as a result. The Sponsor may also disagree with shareholders, security vendors, and the Index Provider on what is generally accepted as Bitcoin and should therefore be considered ''Bitcoin'' for the Trust's purposes, which may also adversely affect the value of the Shares as a result.

various Bitcoin-based trust issued receipts.[28]

In these disapproval orders, the Commission outlined that a proposal relating to a Bitcoin-based ETP could satisfy its concerns regarding potential for fraud and manipulation by demonstrating:

(1) *Inherent Resistance to Fraud and Manipulation:* That the underlying commodity market is inherently resistant to fraud and manipulation;

(2) *Other Means to Prevent Fraud and Manipulation:* That there are other means to prevent fraudulent and manipulative acts and practices that are sufficient; or

(3) *Surveillance Sharing:* That the listing exchange has entered into a surveillance sharing agreement with a regulated market of significant size relating to the underlying or reference assets.

As described below, the Sponsor believes the structure and operation of the Trust are designed to prevent fraudulent and manipulative acts and practices, to protect investors and the public interest, and to respond to the specific concerns that the Commission has identified with respect to potential fraud and manipulation in the context of a Bitcoin-based ETP.

[28] *See* Order Setting Aside Action by Delegated Authority and Disapproving a Proposed Rule Change, as Modified by Amendments No. 1 and 2, To List and Trade Shares of the Winklevoss Bitcoin Trust, Securities Exchange Act Release No. 83723 (July 26, 2018), 83 FR 37579 (Aug. 1, 2018) (SR–BatsBZX–2016–30) (the ''Winklevoss Order''); Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, Relating to the Listing and Trading of Shares of the Bitwise Bitcoin ETF Trust Under NYSE Arca Rule 8.201–E, Securities Exchange Act Release No. 87267 (Oct. 9, 2019), 84 FR 55382 (Oct. 16, 2019) (SR–NYSEArca–2019–01) (the ''Bitwise Order''); Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, to Amend NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares) and to List and Trade Shares of the United States Bitcoin and Treasury Investment Trust Under NYSE Arca Rule 8.201–E, Securities Exchange Act Release No. 88284 (February 26, 2020), 85 FR 12595 (March 3, 2020) (SR–NYSEArca–2019–39) (the ''Wilshire Phoenix Order''); Order Disapproving a Proposed Rule Change to List and Trade the Shares of the ProShares Bitcoin ETF and the ProShares Short Bitcoin ETF, Securities Exchange Act Release No. 83904 (Aug. 22, 2018), 83 FR 43934 (Aug. 28, 2018) (SR–NYSEArca–2017–139) (the ''ProShares Order''); Order Disapproving a Proposed Rule Change Relating to Listing and Trading of the Direxion Daily Bitcoin Bear 1X Shares, Direxion Daily Bitcoin 1.25X Bull Shares, Direxion Daily Bitcoin 1.5X Bull Shares, Direxion Daily Bitcoin 2X Bull Shares, and Direxion Daily Bitcoin 2X Bear Shares Under NYSE Arca Rule 8.200–E, Securities Exchange Act Release No. 83912 (Aug. 22, 2018), 83 FR 43912 (Aug. 28, 2018) (SR–NYSEArca–2018–02) (the ''Direxion Order''); Order Disapproving a Proposed Rule Change to List and Trade the Shares of the GraniteShares Bitcoin ETF and the GraniteShares Short Bitcoin ETF, Securities Exchange Act Release No. 83913 (Aug. 22, 2018), 83 FR 43923 (Aug. 28, 2018) (SR–CboeBZX–2018–01) (the ''GraniteShares Order'').

How the Trust Meets Standards in the Winklevoss Order, Bitwise Order and Wilshire Phoenix Order

1. Resistance to or Prevention of Fraud and Manipulation

In the Bitwise Order, the Commission disagreed with the proposition that Bitcoin's fungibility, transportability and exchange tradability combine to provide unique protections against, and allow Bitcoin to be uniquely resistant to, attempts at price manipulation. The Commission reached its conclusion based on concessions by Bitwise that 95% of the reported trading in Bitcoin is ''fake'' or non-economic, effectively admitting that the properties of Bitcoin do not make it inherently resistant to manipulation. Bitwise's concessions were further compounded by evidence of potential and actual fraud and manipulation in the historical trading of Bitcoin on certain marketplaces such as (1) ''wash'' trading, (2) trading based on material, non-public information, including the dissemination of false and misleading information, (3) manipulative activity involving Tether, and (4) fraud and manipulation.[29]

The Sponsor acknowledges the possibility that fraud and manipulation may exist and that Bitcoin trading *on any given exchange* may be no more uniquely resistant to fraud and manipulation than other commodity markets.[30] However, the Sponsor believes that the fundamental features of Bitcoin's fungibility, transportability and exchange tradability offer novel protections beyond those that exist in traditional commodity markets or equity markets when combined with other means, as discussed further below.

2. Other Means To Prevent Fraud and Manipulation

The Commission has recognized that a listing exchange could demonstrate that other means to prevent fraudulent and manipulative acts and practices are sufficient to justify dispensing with the requisite surveillance-sharing agreement.[31] In evaluating the effectiveness of this type of resistance, the Commission does not apply a ''cannot be manipulated'' standard. Instead, the Commission requires that such resistance to fraud and manipulation be novel and beyond those protections that exist in traditional commodity markets or equity markets for which the Commission has long required surveillance-sharing agreements in the context of listing derivative securities products.[32]

The Sponsor believes the Index represents a novel means to prevent fraud and manipulation from impacting a reference price for Bitcoin and that it offers protections beyond those that exist in traditional commodity markets or equity markets. Specifically, Bitcoin is novel and exists outside traditional commodity markets. It therefore stands to reason that the methods in which it trades will be novel and that the market for Bitcoin will have different attributes than traditional commodity markets. Bitcoin was only introduced within the past decade, twenty years after the first U.S. ETFs were offered [33] and 150 years after the first futures were offered.[34] In contrast to older commodities such as gold, silver, platinum, palladium or copper, which the Commission has noted all had at least one significant, regulated market for trading futures on the underlying commodity at the time commodity trust ETPs were approved for listing and trading, the first trading in Bitcoin took place entirely in an open, transparent and online setting where other commodities cannot trade.

The Trust has priced its Shares consistently for more than six years based on the Index. The Sponsor believes the Trust's use of the Index specifically addresses the Commission's concerns in that the Index serves as an alternative means to prevent fraud and manipulation. Specifically, the Index can (i) mitigate the effects of fraud, manipulation and other anomalous trading activity on the Bitcoin reference rate, (ii) provide a real-time, volume-weighted fair value of Bitcoin and (iii) appropriately handle and adjust for non-market related events.

As described in more detail below, the Sponsor believes that the Index

[29] *See* Bitwise Order, 84 FR at 55383 (discussing analysis of the Bitcoin spot market that asserts that 95% of the spot market is dominated by fake and non-economic activity, such as wash trades), 55391 (discussing possible sources of fraud and manipulation in the bitcoin spot market). *See also* Winklevoss Order, 83 FR at 37585–86 (discussing pending litigation against a Bitcoin trading platform for fraudulent conduct relating to Tether); Bitwise Order, 84 FR at 55391 n.140, 55402 & n.331 (same); Winklevoss Order, 83 FR at 37584–86 (discussing potential types of manipulation in the Bitcoin spot market). The Commission has also noted that fraud and manipulation in the Bitcoin spot market could persist for a significant duration. *See, e.g.,* Bitwise Order, 84 FR at 55405 & n.379.

[30] *See generally* Bitwise Order.

[31] *See* Winklevoss Order, 84 FR at 37580, 37582–91; Bitwise Order, 84 FR at 55383, 55385–406; Wilshire Phoenix Order, 85 FR at 12597.

[32] *See* Winklevoss Order, 84 FR at 37582; Wilshire Phoenix Order, 85 FR at 12597.

[33] SEC, ''Investor Bulletin: Exchange-Traded Funds (ETFs),'' August 2012, *https://www.sec.gov/investor/alerts/etfs.pdf.*

[34] CFTC, ''History of the CFTC,'' *https://www.cftc.gov/About/HistoryoftheCFTC/history_precftc.html.*

accomplishes those objectives in the following ways:

1. The Index tracks the Digital Asset Exchange Market Price through trading activity at ''U.S.-Compliant Exchanges'';[35]

2. The Index mitigates the impact of instances of fraud, manipulation and other anomalous trading activity in real-time through systematic adjustments;

3. The Index is constructed and maintained by an expert third-party index provider, allowing for prudent handling of non-market-related events; and

4. The Index mitigates the impact of instances of fraud, manipulation and other anomalous trading activity concentrated on any one specific exchange through a cross-exchange composite index rate.

1. The Index tracks the Digital Asset Exchange Market Price through trading activity at ''U.S.-Compliant Exchanges''.

To reduce the risk of fraud, manipulation, and other anomalous trading activity from impacting the Index, only U.S.-Compliant Exchanges are eligible to be included in the Index.

The Index maintains a minimum number of three exchanges and a maximum number of five exchanges to track the Digital Asset Exchange Market while offering replicability for traders and market makers.[36]

U.S.-Compliant Exchanges possess safeguards that protect against fraud and manipulation. For example, U.S.-Compliant Exchanges regulated by the New York State Department of Financial Services (''NYDFS'') under the BitLicense program have regulatory requirements to implement measures designed to effectively detect, prevent, and respond to fraud, attempted fraud, market manipulation, and similar wrongdoing, and to monitor, control, investigate and report back to the NYDFS regarding any wrongdoing.[37] These exchanges also have the following obligations:[38]

- Submission of audited financial statements including income statements, statement of assets/liabilities, insurance, and banking;
- Compliance with capitalization requirements set at NYDFS's discretion;
- Prohibitions against the sale or encumbrance to protect full reserves of custodian assets;
- Fingerprints and photographs of employees with access to customer funds;
- Retention of a qualified Chief Information Security Officer and annual penetration testing/audits;
- Documented business continuity and disaster recovery plan, independently tested annually; and
- Participation in an independent exam by NYDFS.

Other U.S.-Compliant Exchanges have voluntarily implemented measures to protect against common forms of market manipulation.[39]

Furthermore, all U.S.-Compliant Exchanges are considered Money Services Businesses (''MSBs'') that are subject to federal and state reporting requirements of the U.S Department of Treasury's FinCEN division that provide additional safeguards. For example, unscrupulous traders may be less likely to engage in fraudulent or manipulative acts and practices on exchanges that (1) report suspicious activity to FinCEN as money services businesses, (2) report to state regulators as money transmitters, and/or (3) require customer identification through KYC procedures. U.S.-Compliant Exchanges are required to:[40]

- Identify people with ownership stakes or controlling roles in the MSB;
- Establish a formal Anti-Money Laundering (AML) policy in place with documentation, training, independent review, and a named compliance officer;
- Implement strict customer identification and verification policies and procedures;
- File Suspicious Activity Reports (SARs) for suspicious customer transactions;
- File Currency Transaction Reports (CTRs) for cash-in or cash-out transactions greater than $10,000; and
- Maintain a five-year record of currency exchanges greater than $1,000 and money transfers greater than $3,000.

Lastly, because of Bitcoin's classification as a commodity, the CFTC has authority to police fraud and manipulation on U.S.-Compliant Exchanges.

The Sponsor acknowledges that there are substantial differences between FinCEN and New York state regulations and the Commission's regulation of the national securities exchanges.[41] The Sponsor does not believe the inclusion of U.S.-Compliant Exchanges is in and of itself sufficient to prove that the Index is an alternative means to prevent fraud and manipulation such that surveillance sharing agreements are not required, but does believe that the inclusion of only U.S.-Compliant Exchanges in the Index is one significant way in which the Index is protected from the potential impacts of fraud and manipulation.

2. The Index mitigates the impact of instances of fraud, manipulation and other anomalous trading activity in real-time through systematic adjustments.

The Index is calculated once every second according to a systematic methodology that relies on observed trading activity on the Constituent Exchanges. While the precise methodology underlying the Index is currently proprietary, the key elements of the Index are outlined below:

- *Volume Weighting:* Constituent Exchanges with greater liquidity receive a higher weighting in the Index, increasing the ability to execute against (*i.e.,* replicate) the Index in the underlying spot markets.
- *Price-Variance Weighting:* The Index reflects data points that are discretely weighted in proportion to their variance from the rest of the Constituent Exchanges. As the price at a Constituent Exchange diverges from the prices at the rest of the Constituent Exchanges, its weight in the Index consequently decreases.
- *Inactivity Adjustment:* The Index algorithm penalizes stale activity from any given Constituent Exchange. When a Constituent Exchange does not have recent trading data, its weighting in the

[35] ''U.S.-Compliant Exchanges'' are exchanges in the Digital Asset Exchange Market that are compliant with applicable U.S. federal and state licensing requirements and practices regarding AML and KYC regulations. All Constituent Exchanges are U.S.-Compliant Exchanges. ''Non-U.S.-Compliant Exchanges'' are all other exchanges in the Digital Asset Exchange Market. As of December 31, 2021, the U.S.-Compliant Exchanges that the Index Provider considered for inclusion in the Index were Bitstamp, Coinbase Pro, Kraken and LMAX Digital. From these U.S.-Compliant Exchanges, the Index Provider then applies additional Inclusion Criteria to determine the Constituent Exchange. As of December 31, 2021, the Constituent Exchanges were Bitstamp, Coinbase Pro, Kraken, and LMAX Digital.

[36] According to the Sponsor, the more exchanges included in the Index, the more ability there is for traders and market makers to trade against the Index by arbitraging price differences. For example, in the event of variances between Bitcoin prices on Constituent Exchanges and non-Constituent Exchanges, arbitrage trading opportunities would exist. These discrepancies generally consolidate over time, as price differences across exchanges are realized and capitalized upon by traders and market makers.

[37] *See, e.g.,* ''DFS Takes Action to Deter Fraud and Manipulation in Virtual Currency Markets,'' *available at: https://www.dfs.ny.gov/about/press/pr1802071.htm.*

[38] *See* ''New York's Final ''BitLicense'' Rule: Overview and Changes from July 2014 Proposal,'' June 5, 2015, Davis Polk, *available at: https://www.davispolk.com/files/new_yorks_final_bitlicense_rule_overview_changes_july_2014_proposal.pdf.*

[39] As of the date of filing, two of the four Constituent Exchanges, Bitstamp and Coinbase Pro, are regulated by NYDFS.

[40] *See* BSA Requirements for MSBs, FinCEN website: *https://www.fincen.gov/bsarequirements-msbs.*

[41] *See* Bitwise Order, 84 FR at 55392; Wilshire Phoenix Order, 85 FR at 12603.

Index is gradually reduced, until it is de-weighted entirely. Similarly, once trading activity at the Constituent Exchange resumes, the corresponding weighting for that Constituent Exchange is gradually increased until it reaches the appropriate level.

• *Manipulation Resistance:* In order to mitigate the effects of wash trading and order book spoofing, the Index only includes executed trades in its calculation. Additionally, the Index only includes Constituent Exchanges that charge trading fees to its users in order to attach a real, quantifiable cost to any manipulation attempts.

The Index Provider reviews and periodically updates the exchanges included in the Index by utilizing a methodology that is guided by the IOSCO principles for financial benchmarks.

3. The Index is constructed and maintained by an expert third-party index provider, allowing for prudent handling of non-market-related events.

The Index Provider reviews and periodically updates which exchanges are included in the Index by utilizing a methodology that is guided by the IOSCO principles for financial benchmarks.

For an exchange to become a Constituent Exchange, it must satisfy the following Inclusion Criteria:

• Compliance with any applicable U.S. federal and state licensing requirements and practices regarding AML and KYC regulations (*i.e.,* the Constituent Exchange must be a U.S.-Compliant Exchange);

• Publicly known ownership entity;

• No restrictions on deposits and/or withdrawals of Bitcoin;

• No restrictions on deposits and/or withdrawals of USD;

• Reliably publish trade prices and volumes on a real-time basis through APIs;

• Charges trading fees to its users in order to attach a real, quantifiable cost to any manipulation attempts;

• Offer programmatic trading of the Bitcoin/USD spot price;

• Liquid market in the Bitcoin/USD pair;

• Trading volume that represents a minimum of total Bitcoin/USD trading volumes (5% for U.S. exchanges and 10% non-U.S. exchanges); and

• Discretion of the Index Provider's analysts.

Although the Index methodology is designed to operate without any human interference, rare events would justify manual intervention. Manual intervention would only be in response to ''non-market-related events'' (*e.g.,* halting of deposits or withdrawals of funds, unannounced closure of exchange operations, insolvency, compromise of user funds, etc.). In the event that such an intervention is necessary, the Index Provider would issue a public announcement through its website, API and other established communication channels with its clients.[42]

4. The Index mitigates the impact of instances of fraud, manipulation and other anomalous trading activity concentrated on any one specific exchange through a cross-exchange composite index rate.

The Index is based on the price and volume data of multiple U.S.-Compliant Exchanges that satisfy the Index Provider's Inclusion Criteria. By referencing multiple trading venues and weighting them based on trade activity, the impact of any potential fraud, manipulation, or anomalous trading activity occurring on any single venue is reduced. Specifically, the effects of fraud, manipulation, or anomalous trading activity occurring on any single venue are de-weighted and consequently diluted by non-anomalous trading activity from other Constituent Exchanges.

Although the Index is designed to accurately capture the market price of Bitcoin, third parties may be able to purchase and sell Bitcoin on public or private markets included or not included among the Constituent Exchanges, and such transactions may take place at prices materially higher or lower than the Index Price. For example, based on data provided by the Index Provider, on any given day during the year ended December 31, 2021, the maximum differential between the 4:00 p.m., New York time spot price of any single Digital Asset Exchange included in the Index and the Index Price was 0.64% and the average of the maximum differentials of the 4:00 p.m., New York time spot price of each Digital Asset Exchange included in the Index and the Index Price was 0.32%. During this same period, the average differential between the 4:00 p.m., New York time spot prices of all the Digital Asset Exchanges included in the Index and the Index Price was 0.0003%.[43]

Since November 1, 2014, the Trust has consistently priced its Shares at 4:00 p.m., E.T. based on the Index Price.[44] While that pricing would be known to the market, the Sponsor believes that, even if efforts to manipulate the price of Bitcoin at 4:00 p.m., E.T. were successful on any exchange, such activity would have had a negligible effect on the pricing of the Trust, due to the controls embedded in the structure of the Index.

Accordingly, the Sponsor believes that the Index has proven its ability to (i) mitigate the effects of fraud, manipulation and other anomalous trading activity on the Bitcoin reference rate, (ii) provide a real-time, volume-weighted fair value of Bitcoin and (iii) appropriately handle and adjust for non-market related events. For these reasons, the Sponsor believes that the Index represents an effective alternative means to prevent fraud and manipulation and the Trust's reliance on the Index addresses the Commission's concerns with respect to potential fraud and manipulation.

3. A Significant, Regulated and Surveilled Market Exists and Is Closely Connected With Spot Market for Bitcoin

In the Winklevoss Order, Bitwise Order and Wilshire Phoenix Order, the Commission described both the need for and the definition of a surveilled market of significant size for commodity-trust ETPs like the Trust to date.[45] Specifically, the Commission explained that:

> for the commodity-trust ETPs approved to date for listing and trading, there has been in every case at least one significant, regulated market for trading futures on the underlying commodity—whether gold, silver, platinum, palladium, or copper—and the ETP listing exchange has entered into surveillance-sharing agreements with, or held Intermarket Surveillance Group membership in common with, that market.[46]

[42] To the extent any such intervention has a material impact on the Trust, the Sponsor will also issue a public announcement.

[43] All Digital Asset Exchanges that were included in the Index throughout the period were considered in this analysis.

[44] Prior to February 1, 2022, the Trust valued its Bitcoins for operational purposes by reference to the volume-weighted average Index Price (the ''Old Index Price''). The Old Index Price was calculated by applying a weighting algorithm to the price and trading volume data for the immediately preceding 24-hour period as of 4:00 p.m., New York time, derived from the Constituent Exchanges reflected in the Index on such trade date, and overlaying an averaging mechanism to the price produced. Thus, whereas the Old Index Price reflected the price of a Bitcoin at 4:00 p.m., New York time, calculated by taking the average of each price of a Bitcoin produced by the Index over the preceding 24-hour period, the Index Price now is the price of a Bitcoin at 4:00 p.m., New York time, calculated based on the price and trading volume data of the Digital Asset Exchanges included in the Index over the preceding 24-hour period. The Index Price differs from the Old Index Price only in that it does not use an additional averaging mechanism; the Index Price otherwise uses the same methodology as the Old Index Price, and there has been no change to the Index used to determine the Index Price or the criteria used to select the Constituent Exchanges.

[45] *See* Winklevoss Order, 83 FR at 37593–94; Bitwise Order, 84 FR at 55383, 55410; Wilshire Phoenix Order, 85 FR at 12609.

[46] *See* Winklevoss Order, 83 FR at 37594.

Further, the Commission stated that its interpretation of the term ''market of significant size'' depends on the interrelationship between the market with which the listing exchange has a surveillance-sharing agreement and the proposed ETP.[47] Accordingly, the terms ''significant market'' and ''market of significant size'' could mean:

> a market (or group of markets) as to which (a) there is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to successfully manipulate the ETP, so that a surveillance-sharing agreement would assist in detecting and deterring misconduct, and (b) it is unlikely that trading in the ETP would be the predominant influence on prices in that market.[48]

In the context of Bitcoin-based ETPs specifically, the Commission has stated that establishing a lead-lag relationship between the Bitcoin futures market and the spot market is central to understanding whether it is reasonably likely that a would-be manipulator of the ETP would need to trade on the Bitcoin futures market to successfully manipulate prices on those spot platforms that feed into the proposed ETP's pricing mechanism such that a surveillance-sharing agreement would assist the ETP listing market in detecting and deterring misconduct.[49] In particular, if the spot market leads the futures market, this would indicate that it would not be necessary to trade on the futures market to manipulate the proposed ETP, even if arbitrage worked efficiently, because the futures price would move to meet the spot price.

The Sponsor has conducted a lead/lag analysis of per minute data comparing the Bitcoin futures market, as represented by the CME futures market, to the Bitcoin spot market, as represented by the Index. Based on this analysis, the Sponsor has concluded that there does not appear to be a significant lead/lag relationship between the two instruments for the period of November 1, 2019 to August 31, 2021. However, the Sponsor notes that other studies prior to and since such date have found that the CME futures market does lead the Bitcoin spot market.[50]

Although there have been mixed findings regarding the lead/lag relationship between the CME futures and Bitcoin spot markets, the Sponsor believes that the CME futures market represents a large, surveilled and regulated market. For example, from November 1, 2019 to August 31, 2021, the CME futures market trading volume was over $432 billion, compared to $624 billion in trading volume across the Constituent Exchanges included in the Index. With over 69% of the Index trading volume, the CME futures market represents significant coverage of U.S.-Compliant Exchanges in the Bitcoin market. In addition, the CME futures market trading volume from November 1, 2019 to August 31, 2021 was approximately 50% of the trading volume of the U.S. dollar-denominated Bitcoin spot markets referenced in the Bitwise Order.[51]

Given the significant size of the CME futures markets, the Sponsor believes there is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to successfully manipulate the ETP, since arbitrage between the derivative and spot markets would tend to counter an attempt to manipulate the spot market alone. As a result, the Exchange's ability to obtain information regarding trading in the Shares and futures from markets and other entities that are members of the Intermarket Trading Group (''ISG''), including the CME, would assist the Exchange in detecting and deterring misconduct.

The Sponsor also believes it is unlikely that the ETP would become the predominant influence on prices in the market.

While future inflows to the proposed Trust cannot be predicted, to provide comparable data, the Sponsor examined the change in market capitalization of Bitcoin with net inflows into the Trust, which currently trades on OTC Markets and is largest and most liquid Bitcoin investment product in the world.[52] From November 1, 2019 to August 31, 2021, the market capitalization of Bitcoin grew from $166 billion to $888 billion, a $721 billion increase. Over the same period, the Trust experienced $6.6 billion of inflows. The cumulative inflow into the Trust over the stated time period was only 0.9% of the aggregate growth of Bitcoin's market capitalization.

Additionally, the Trust experienced approximately $98.5 billion of trading volume from November 1, 2019 to August 31, 2021, only 23% of the CME futures market and 16% of the Index over the same period.

* * * * *

In summary, the Sponsor believes that the foregoing responds to the Commission's articulated concerns with respect to potential fraud and manipulation in Bitcoin-based ETPs. Specifically, the Sponsor believes that, although Bitcoin is not itself inherently resistant to fraud and manipulation, the Index represents an effective means to prevent fraudulent and manipulative acts and practices. As discussed above, the Trust has used the Index to price the Shares for more than six years, and the Index has proven its ability to (i) mitigate the effects of fraud, manipulation and other anomalous trading activity on the Bitcoin reference rate, (ii) provide a real-time, volume-weighted fair value of bitcoin and (iii) appropriately handle and adjusts for non-market related events. The Sponsor also believes that the CME futures market is a significant, surveilled and regulated market that is closely connected with the spot market for Bitcoin and may fulfill the requirements for surveillance sharing given the Exchange's ability to obtain information from markets and other entities that are members of the ISG to assist in detecting and deterring misconduct.

The Approval of Bitcoin-Based ETFs Registered Under the Investment Company Act of 1940 and Bitcoin Based ETPs Registered Under the Securities Act of 1933 and Securities Exchange Act 1934

In an August 3, 2021 speech at the Aspen Security Forum, the Chair stated that he looked forward to the Commission's review of Bitcoin-based

[47] *See* Winklevoss Order, 83 FR at 37594; Bitwise Order, 84 FR at 55410; ProShares Order, 83 FR at 43936; GraniteShares Order, 83 FR at 43925; Direxion Order, 83 FR at 43914; Wilshire Phoenix Order, 85 FR at 12609.

[48] *See* Winklevoss Order, 83 FR at 37594. This definition is illustrative and not exclusive. There could be other types of ''significant markets'' and ''markets of significant size,'' but this definition is an example that will provide guidance to market participants.

[49] *See* Bitwise Order, 84 FR at 55411; Wilshire Phoenix Order, 85 FR at 12612.

[50] *See* Memorandum to File from Neel Maitra, Senior Special Counsel (Fintech & Crypto Specialist), Division of Trading and Markets, U.S. Securities and Exchange Commission re: Meeting with Representatives from Fidelity Digital Assets, et al. and attachment (SR-CboeBZX–2021–039) (September 8, 2021), *available at: https://www.sec.gov/comments/sr-cboebzx-2021-039/srcboebzx2021039-250110.pdf;* Letter from Bitwise Asset Management, Inc. re: File Number SR–NYSEArca–2021–89 (February 25, 2022), *available at: https://www.sec.gov/comments/sr-nysearca-2021-89/srnysearca202189-20117902-270822.pdf;* Letter from Wilson Sonsini Goodrich and Rosati, P.C. and Chapman and Cutler LLP, on behalf of Bitwise Asset Management, Inc. re: File No. SR–NYSEArca–2021–89 (March 7, 2022), *available at: https://www.sec.gov/comments/sr-nysearca-2021-89/srnysearca202189-20118794-271630.pdf.*

[51] These Bitcoin spot markets include Binance, Coinbase Pro, Bitfinex, Kraken, Bitstamp, BitFlyer, Poloniex, Bittrex and itBit.

[52] To further illustrate the size and liquidity of the Trust, as of October 31, 2020, compared with global commodity ETPs, the Trust would rank fourth in assets under management and seventh in notional trading volume from November 1, 2019 to October 31, 2020.

ETF proposals registered under the Investment Company Act of 1940 (the ''40 Act''), ''particularly if those are limited to [the] CME-traded Bitcoin futures,'' noting the ''significant investor protection'' offered by the '40 Act.[53] In this same speech, the Chair specifically identified the Trust in the context of existing investment vehicles that provide exposure to Bitcoin, noting that the Trust, which is a Bitcoin-based ETP proposal that would be registered under the '33 Act and '34 Act, rather than the '40 Act, is ''the largest among them having been around for eight years and worth more than $20 billion.'' [54] Since that speech, the first Bitcoin-based ETFs registered under the '40 Act were approved for trading,[55] subsequent Bitcoin-based ETPs that would be registered under the '33 Act and '34 Act were disapproved [56] and a subsequent Bitcoin-based ETP that will be registered under the '33 Act and '34 Act was approved for trading.[57]

As described above, the Commission has outlined the reasons why prior Bitcoin-based ETF and ETP proposals registered under both the '40 Act and '33 Act and '34 Act, respectively, have been unable to satisfy its concerns about pricing in the underlying Digital Asset Market due to the potential for fraud and manipulation and described how such concerns could be addressed. It has been the Sponsor's understanding that none of the stated requirements have indicated a preference for Bitcoin-based ETF and ETP proposals registered under the '40 Act versus the '33 Act and '34 Act, respectively. Nor does the Sponsor believe that such requirements can be addressed by gaining exposure to Bitcoin through Bitcoin futures in an ETF registered under the '40 Act rather than physical Bitcoin in an ETP registered under the '33 Act because both products would be reliant on Bitcoin's underlying price in the spot markets.

For instance, Bitcoin-based ETFs registered under the '40 Act that hold Bitcoin futures are priced by referencing the CME CF Bitcoin Reference Rate (''BRR''), which itself references the Digital Asset Markets: Bitstamp, Coinbase, Gemini, itBit, and Kraken. Similarly, Bitcoin-based ETPs that would be registered under the '33 Act and '34 Act, like the Trust, would be priced by referencing Digital Asset Markets included in the BRR, such as through the Index. As a result, the Sponsor believes that any potential fraud or manipulation in the underlying Digital Asset Market would impact both types of ETP proposals. Thus, in light of the Commission's recent approval of a futures-based ETP registered under the '33 Act and '34 Act,[58] which suggests that the Commission believes that both Bitcoin-based ETFs registered under the '40 Act and Bitcoin-based ETPs registered under the '33 Act and '34 Act could meet the requirements of the Exchange Act, the Sponsor believes that the Commission should take the same view towards both types of proposals and that differences between the '40 Act on the one hand, and the '33 Act and '34 Act on the other, should not form the basis for denial of proposed Bitcoin-based ETPs registered under the '33 Act and '34 Act, like the Trust.

Creation of Shares

According to the Annual Report, the Trust will issue Shares to Authorized Participants from time to time, but only in one or more Baskets (with a Basket being a block of 100 Shares). The Trust will not issue fractions of a Basket. The creation of Baskets will be made only in exchange for the delivery to the Trust, or the distribution by the Trust, of the number of whole and fractional Bitcoins represented by each Basket being created, which is determined by dividing (x) the number of Bitcoins owned by the Trust at 4:00 p.m., E.T., on the trade date of a creation order, after deducting the number of Bitcoins representing the U.S. dollar value of accrued but unpaid fees and expenses of the Trust (converted using the Index Price at such time, and carried to the eighth decimal place), by (y) the number of Shares outstanding at such time (with the quotient so obtained calculated to one one-hundred-millionth of one Bitcoin (*i.e.,* carried to the eighth decimal place)), and multiplying such quotient by 100 (the ''Basket Amount''). All questions as to the calculation of the Basket Amount will be conclusively determined by the Sponsor and will be final and binding on all persons interested in the Trust. The Basket Amount multiplied by the number of Baskets being created is the ''Total Basket Amount.'' The number of Bitcoins represented by a Share will gradually decrease over time as the Trust's Bitcoins are used to pay the Trust's expenses. As of December 31, 2021, each Share represented approximately 0.0009 of one Bitcoin.

Authorized Participants are the only persons that may place orders to create Baskets. Each Authorized Participant must (i) be a registered broker-dealer, (ii) enter into an agreement with the Sponsor and the Liquidity Provider (as defined below), if applicable, that provides the procedures for the creation and redemption of Baskets and for the delivery of Bitcoins required for Creation Baskets and Redemption Baskets (each, a ''Participant Agreement'') and (iii) in the case of creation or redemption in-kind, own a Bitcoin wallet address that is known to the Custodian as belonging to the Authorized Participant. An Authorized Participant may act for its own account or as agent for broker-dealers, custodians and other securities market participants that wish to create or redeem Baskets. Shareholders who are not Authorized Participants will only be able to redeem their Shares through an Authorized Participant.

Although the creation of Baskets requires the delivery to the Trust of the Total Basket Amount, an Authorized Participant may deposit cash with the Administrator, which will facilitate the purchase or sale of Bitcoins on behalf of the Authorized Participant through one or more eligible companies (each, a ''Liquidity Provider'') that have entered into a Participant Agreement with the Sponsor, the Administrator, the Marketing Agent and the relevant Authorized Participant.

The Participant Agreement provides the procedures for the creation of Baskets and for the delivery of the whole and fractional Bitcoins required for such creations. The Participant Agreement and the related procedures attached thereto may be amended by the Sponsor and the relevant Authorized Participant. Under the Participant Agreement, the Sponsor has agreed to indemnify each Authorized Participant against certain liabilities, including liabilities under the Securities Act.

[53] Chair Gary Gensler Public Statement, ''Remarks Before the Aspen Security Forum,'' (August 3, 2021), *https://www.sec.gov/news/public-statement/gensler-aspen-security-forum-2021-08-03*.

[54] *Id.*

[55] ProShares Bitcoin Strategy ETF (BITO); VanEck Bitcoin Strategy ETF (XBTF); Valkyrie Bitcoin Strategy ETF (BTF).

[56] *See, e.g.,* Securities Exchange Act Release Nos. 93559 (November 12, 2021), 86 FR 64539 (November 18, 2021) (SR-CboeBZX–2021–019) (Order Disapproving a Proposed Rule Change To List and Trade Shares of the VanEck Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares); 94080 (January 27, 2022), 87 FR 5527 (February 1, 2022) (SR-CboeBZX–2021–029) (Order Disapproving a Proposed Rule Change To List and Trade Shares of the Wise Origin Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares); 94571 (March 31, 2022), 87 FR 20014 (April 6, 2022) (SR-CboeBZX–2021–051) (Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of the ARK 21Shares Bitcoin ETF Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares).

[57] *See* Securities Exchange Act Release No. 94620 (April 6, 2022), 87 FR 21676 (April 12, 2022) (SR–NYSEArca–2021–53) (Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 2, to List and Trade Shares of the Teucrium Bitcoin Futures Fund under NYSE Arca Rule 8.200–E, Commentary .02 (Trust Issued Receipts)).

[58] *See id.*

Authorized Participants do not pay a transaction fee to the Trust in connection with the creation of Baskets, but there may be transaction fees associated with the validation of the transfer of Bitcoins by the Bitcoin Network. Authorized Participants who deposit Bitcoins with the Trust in exchange for Baskets will receive no fees, commissions or other form of compensation or inducement of any kind from either the Sponsor or the Trust, and no such person has any obligation or responsibility to the Sponsor or the Trust to effect any sale or resale of Shares.

Creation Procedures

On any business day, an Authorized Participant may place an order with the Administrator to create one or more Baskets. Orders for creations may be placed either ''in-kind'' or ''in-cash.'' Orders for creation in-kind must be placed with the Administrator no later than 3:59:59 p.m., New York time, and no later than 4:59:59 p.m., New York time, for creations in-cash (in each case, the ''Order Cutoff Time'').

In-kind creations will take place as follows, where ''T'' is the trade date and each day in the sequence must be a business day:

T	T+1
• The Authorized Participant places a creation order with the Administrator. • The Marketing Agent accepts (or rejects) the creation order, which is communicated to the Authorized Participant by the Administrator. • The Total Basket Amount is determined as soon as practicable after 4:00 p.m., New York time.	• The Authorized Participant transfers the Total Basket Amount to the Custodian no later than 4:00 p.m., New York time. • Once the Total Basket Amount is received by the Custodian, the Administrator directs the Transfer Agent to credit the number of Baskets created to the Authorized Participant's DTC account.

In-cash creations will take place as follows, where ''T'' is the trade date and each day in the sequence must be a business day:

T–1	T	T+1
• The Authorized Participant places a creation order with the Administrator. • The Marketing Agent accepts (or rejects) the creation order, which is communicated to the Authorized Participant by the Administrator. • The Authorized Participant sends 110% of the U.S. dollar value of the number of baskets ordered pursuant to such creation order, as calculated using the Index Price as of the order date (the ''Cash Collateral Amount'') to the Administrator.	• The Sponsor notifies the Liquidity Provider of the creation order and the Liquidity Provider may begin purchasing Bitcoin to deliver the Total Basket Amount. • The Total Basket Amount is determined as soon as practicable after 4:00 p.m., New York time.	• The Liquidity Provider delivers the Total Basket Amount to the Custodian no later than 4:00 p.m., New York time. • Once the Total Basket Amount is received by the Custodian, the Administrator directs the Transfer Agent to credit the number of Baskets created to the Authorized Participant's DTC account. • The Administrator sends the Liquidity Provider cash equal to the U.S. dollar value of the Total Basket Amount, as determined on the trade date, plus the Variable Fee, and returns the remaining amount of the Cash Collateral Amount (if any) to the Authorized Participant.

Redemption of Shares

The Trust may redeem Shares from time to time but only in Baskets. A Basket equals a block of 100 Shares. The number of outstanding Shares is expected to decrease from time to time as a result of the redemption of Baskets. The redemption of Baskets requires the distribution by the Trust of the number of Bitcoins represented by the Baskets being redeemed. The redemption of a Basket will be made only in exchange for the distribution by the Trust of the number of whole and fractional Bitcoins represented by each Basket being redeemed, the number of which is determined by dividing (x) the number of Bitcoins owned by the Trust at 4:00 p.m., New York time, on the relevant trade date of a redemption order, after deducting the number of Bitcoins representing the U.S. dollar value of accrued but unpaid fees and expenses of the Trust (converted using the Index Price at such time, and carried to the eighth decimal place) by (y) the number of Shares outstanding at such time (with the quotient so obtained calculated to one one-hundred-millionth of one Bitcoin (*i.e.,* carried to the eighth decimal place)), and multiplying such quotient by 100.

Authorized Participants are the only persons that may place orders to redeem Baskets. Shareholders who are not Authorized Participants will be able to redeem their Shares only through an Authorized Participant.

Each Participant Agreement provides the procedures for the redemption of Baskets and for the delivery of the whole and fractional Bitcoins required for such redemption. The Participant Agreement and the related procedures attached thereto may be amended by the

Sponsor and the relevant Authorized Participant.

Authorized Participants do not pay a transaction fee to the Trust in connection with the redemption of Baskets, but there may be transaction fees associated with the validation of the transfer of Bitcoins by the Bitcoin Network.

Redemption Procedures

The Trust will also redeem Shares on a continuous basis but only in Baskets of 100 Shares. The procedures by which an Authorized Participant can redeem one or more Baskets mirror the procedures for the creation of Baskets. On any business day, an Authorized Participant may place an order with the Administrator to redeem one or more Baskets. Redemption orders must be placed with the Administrator no later than the Order Cutoff Time.

In-kind redemptions will take place as follows, where ''T'' is the trade date and each day in the sequence must be a business day:

T	T+2
• The Authorized Participant places a redemption order with the Administrator. • The Marketing Agent accepts (or rejects) the redemption order, which is communicated to the Authorized Participant by the Administrator. • The Total Basket Amount is determined as soon as practicable after 4:00 p.m., New York time.	• The Authorized Participant delivers Baskets from its DTC account to the Transfer Agent no later than 4:00 p.m., New York time. • Once the Baskets are received by the Transfer Agent, the Custodian transfers the Total Basket Amount to the Authorized Participant and the Transfer Agent cancels the Shares.

In-cash redemptions will take place as follows, where ''T'' is the trade date and each day in the sequence must be a business day:

T–1	T	T+2
• The Authorized Participant places a redemption order with the Administrator. • The Marketing Agent accepts (or rejects) the redemption order, which is communicated to the Authorized Participant by the Administrator.	• The Sponsor notifies the Liquidity Provider of the redemption order and the Liquidity Provider may begin selling Bitcoin to deliver the Total Basket Amount. • The Total Basket Amount is determined as soon as practicable after 4:00 p.m., New York time.	• The Authorized Participant delivers Baskets to be redeemed to the Transfer Agent no later than 4:00 p.m., New York time. • The Liquidity Provider deposits with the Administrator cash equal to the U.S. dollar value of the Total Basket Amount, as determined on the trade date. • Once the Baskets are received by the Transfer Agent and the Administrator sends the above-mentioned cash equal to the U.S. dollar value of the Total Basket Amount less the Transaction Fee, the Variable Fee and all other charges and fees payable in connection with the redemption order to the Authorized Participant, the Transfer Agent cancels the Shares. • The Custodian sends the Liquidity Provider the number of Bitcoins equal to the Total Basket Amount and the Administrator sends the Variable Fee to the Liquidity Provider.

Suspension of Orders

The creation or redemption of Shares may be suspended generally, or refused with respect to particular requested creations or redemptions, during any period when the transfer books of the Transfer Agent are closed or if circumstances outside the control of the Sponsor or its delegates make it for all practical purposes not feasible to process creation orders or redemption orders. The Administrator may reject an order or, after accepting an order, may cancel such order by rejecting the Total Basket Amount if: (i) Such order is not presented in proper form as described in the Participant Agreement, (ii) the transfer of the Total Basket Amount comes from an account other than a Bitcoin wallet address that is known to the Custodian as belonging to the Authorized Participant or (iii) the fulfillment of the order, in the opinion of counsel, might be unlawful, among other reasons. None of the Sponsor or its delegates will be liable for the suspension, rejection or acceptance of any creation order or redemption order.

In particular, upon the Trust's receipt of any Incidental Rights and/or IR Virtual Currency in connection with a fork, airdrop or similar event, the Sponsor may suspend redemptions until it is able to cause the Trust to sell or distribute such Incidental Rights and/or IR Virtual Currency.

Availability of Information

The Trust's website (*https://grayscale.com/products/grayscale-bitcoin-trust/*) will include quantitative information on a per Share basis updated on a daily basis, including, (i) the current Digital Asset Holdings per Share daily and the prior business day's Digital Asset Holdings and the reported closing price; (ii) the mid-point of the bid-ask price [59] in relation to the Digital Asset Holdings as of the time the Digital Asset Holdings is calculated (''Bid-Ask Price'') and a calculation of the

[59] The bid-ask price of the Trust is determined using the highest bid and lowest offer on the Consolidated Tape as of the time of calculation of the closing day Digital Asset Holdings.

premium or discount of such price against such Digital Asset Holdings; and (iii) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid-Ask Price against the Digital Asset Holdings, within appropriate ranges, for each of the four previous calendar quarters (or for the life of the Trust, if shorter). In addition, on each business day the Trust's website will provide pricing information for the Shares.

The Trust's website, as well as one or more major market data vendors, will provide an intra-day indicative value (''IIV'') per Share updated every 15 seconds, as calculated by the Exchange or a third party financial data provider during the Exchange's Core Trading Session (9:30 a.m. to 4:00 p.m., E.T.).[60] The IIV will be calculated using the same methodology as the Digital Asset Holdings of the Trust (as described above), specifically by using the prior day's closing Digital Asset Holdings per Share as a base and updating that value during the NYSE Arca Core Trading Session to reflect changes in the value of the Trust's Digital Asset Holdings during the trading day.

The IIV disseminated during the NYSE Arca Core Trading Session should not be viewed as an actual real-time update of the Digital Asset Holdings, which will be calculated only once at the end of each trading day. The IIV will be widely disseminated on a per Share basis every 15 seconds during the NYSE Arca Core Trading Session by one or more major market data vendors. In addition, the IIV will be available through on-line information services.

The Digital Asset Holdings for the Trust will be calculated by the Sponsor once a day and will be disseminated daily to all market participants at the same time. To the extent that the Sponsor has utilized the cascading set of rules described in ''Index Price'' above, the Trust's website will note the valuation methodology used and the price per Bitcoin resulting from such calculation. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the Consolidated Tape Association (''CTA'').

Quotation and last sale information for Bitcoin will be widely disseminated through a variety of major market data vendors, including Bloomberg and Reuters. In addition, the complete real-time price (and volume) data for Bitcoin is available by subscription from Reuters and Bloomberg. The spot price of Bitcoin is available on a 24-hour basis from major market data vendors, including Bloomberg and Reuters. Information relating to trading, including price and volume information, in Bitcoin will be available from major market data vendors and from the exchanges on which Bitcoin are traded. The normal trading hours for Digital Asset Exchanges are 24-hours per day, 365-days per year.

The Sponsor will publish the Index Price, the Trust's Digital Asset Holdings, and the Digital Asset Holdings per Share on the Trust's website as soon as practicable after its determination. If the Digital Asset Holdings and Digital Asset Holdings per Share have been calculated using a price per Bitcoin other than the Index Price for such Evaluation Time, the publication on the Trust's website will note the valuation methodology used and the price per Bitcoin resulting from such calculation.

The Trust will provide website disclosure of its Digital Asset Holdings daily. The website disclosure of the Trust's Digital Asset Holdings will occur at the same time as the disclosure by the Sponsor of the Digital Asset Holdings to Authorized Participants so that all market participants are provided such portfolio information at the same time. Therefore, the same portfolio information will be provided on the public website as well as in electronic files provided to Authorized Participants. Accordingly, each investor will have access to the current Digital Asset Holdings of the Trust through the Trust's website, as well as from one or more major market data vendors.

The value of the Index, as well as additional information regarding the Index, may be found at *https://tradeblock.com/markets/index/xbx.*

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the NYSE Arca Marketplace from 4:00 a.m. to 8:00 p.m., E.T. in accordance with NYSE Arca Rule 7.34–E (Early, Core, and Late Trading Sessions). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Rule 7.6–E, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00, for which the MPV for order entry is $0.0001.

The Shares will conform to the initial and continued listing criteria under NYSE Arca Rule 8.201–E. The trading of the Shares will be subject to NYSE Arca Rule 8.201–E(g), which sets forth certain restrictions on Equity Trading Permit (''ETP'') Holders acting as registered Market Makers in Commodity-Based Trust Shares to facilitate surveillance. The Exchange represents that, for initial and continued listing, the Trust will be in compliance with Rule 10A–3[61] under the Act, as provided by NYSE Arca Rule 5.3–E. A minimum of 100,000 Shares of the Trust will be outstanding at the commencement of trading on the Exchange.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Trust.[62] Trading in Shares of the Trust will be halted if the circuit breaker parameters in NYSE Arca Rule 7.12–E have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.

The Exchange may halt trading during the day in which an interruption to the dissemination of the IIV or the value of the Index occurs. If the interruption to the dissemination of the IIV or the value of the Index persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption. In addition, if the Exchange becomes aware that the Digital Asset Holdings per Share is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the Digital Asset Holdings per Share is available to all market participants.

Surveillance

The Exchange represents that trading in the Shares of the Trust will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[63] The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares

[60] The IIV on a per Share basis disseminated during the Core Trading Session should not be viewed as a real-time update of the Digital Asset Holdings, which is calculated once a day.

[61] 17 CFR 240.10A–3.

[62] *See* NYSE Arca Rule 7.12–E.

[63] FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares with other markets and other entities that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement (''CSSA'').[64] The Exchange is also able to obtain information regarding trading in the Shares in connection with such ETP Holders' proprietary or customer trades which they effect through ETP Holders on any relevant market.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

All statements and representations made in this filing regarding (a) the description of the portfolios of the Trust, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange listing rules specified in this rule filing shall constitute continued listing requirements for listing the Shares on the Exchange.

The Sponsor has represented to the Exchange that it will advise the Exchange of any failure by the Trust to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Trust is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Rule 5.5–E(m).

[64] For a list of the current members of ISG, *see www.isgportal.org.* The Exchange notes that not all components of the Trust may trade on markets that are members of ISG or with which the Exchange has in place a CSSA.

Information Bulletin

Prior to the commencement of trading, the Exchange will inform its ETP Holders in an ''Information Bulletin'' of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (1) The procedures for creations of Shares in Baskets; (2) NYSE Arca Rule 9.2–E(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) information regarding how the value of the Index and the IIV are disseminated; (4) the possibility that trading spreads and the resulting premium or discount on the Shares may widen during the Opening and Late Trading Sessions, when an updated IIV will not be calculated or publicly disseminated; and (5) trading information. The Exchange notes that investors purchasing Shares directly from the Trust will receive a prospectus.

In addition, the Information Bulletin will reference that the Trust is subject to various fees and expenses as described in the Annual Report. The Information Bulletin will disclose that information about the Shares of the Trust is publicly available on the Trust's website.

The Information Bulletin will also discuss any relief, if granted, by the Commission or the staff from any rules under the Act.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)[65] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Rule 8.201–E. The Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares with other markets that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares from such markets. In addition, the Exchange may obtain information regarding trading in the Shares from markets that are members of ISG or with which the Exchange has in place a CSSA. Also, pursuant to NYSE Arca Rule 8.201–E(g), the Exchange is able to obtain information regarding trading in the Shares and the underlying Bitcoin or any Bitcoin derivative through ETP Holders acting as registered Market Makers, in connection with such ETP Holders' proprietary or customer trades through ETP Holders which they effect on any relevant market.

The proposed rule change is also designed to prevent fraudulent and manipulative acts and practices because, although the Digital Asset Exchange Market is not inherently resistant to fraud and manipulation, the Index serves as a means sufficient to mitigate the impact of instances of fraud and manipulation on a reference price for Bitcoin. Specifically, the Index provides a better benchmark for the price of Bitcoin than the Digital Asset Exchange Market Price because it (1) tracks the Digital Asset Exchange Market Price through trading activity at U.S.-Compliant Exchanges; (2) mitigates the impact of instances of fraud, manipulation and other anomalous trading activity in real-time through systematic adjustments; (3) is constructed and maintained by an expert third-party index provider, allowing for prudent handling of non-market-related events; and (4) mitigates the impact of instances of fraud, manipulation and other anomalous trading activity concentrated on any one specific exchange through a cross-exchange composite index rate. The Trust has used the Index to price the Shares for more than six years, and the Index has proven its ability to (i) mitigate the effects of fraud, manipulation and other anomalous trading activity from impacting the Bitcoin reference rate, (ii) provide a real-time, volume-weighted fair value of bitcoin and (iii) appropriately handle and adjusts for non-market related events, such that efforts to manipulate the price of Bitcoin would have had a negligible effect on the pricing of the Trust, due to the controls embedded in the structure of the Index. In addition, certain of the Index's Constituent Exchanges also have or have begun to implement market surveillance infrastructure to further detect, prevent,

[65] 15 U.S.C. 78f(b)(5).

and respond to fraud, attempted fraud, and similar wrongdoing, including market manipulation. The proposed rule change is also designed to prevent fraudulent and manipulative acts and practices based on the existence of the CME futures market as a large, surveilled and regulated market that is closely connected with the spot market for Bitcoin and through which the Exchange could obtain information to assist in detecting and deterring potential fraud or manipulation.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that there is a considerable amount of Bitcoin price and market information available on public websites and through professional and subscription services. Investors may obtain, on a 24-hour basis, Bitcoin pricing information based on the spot price for Bitcoin from various financial information service providers. The closing price and settlement prices of Bitcoin are readily available from the Digital Asset Exchanges and other publicly available websites. In addition, such prices are published in public sources, or on-line information services such as Bloomberg and Reuters. The Digital Asset Holdings per Share will be calculated daily and made available to all market participants at the same time. The Trust will provide website disclosure of its Digital Asset Holdings daily. One or more major market data vendors will disseminate for the Trust on a daily basis information with respect to the most recent Digital Asset Holdings per Share and Shares outstanding. In addition, if the Exchange becomes aware that the Digital Asset Holdings per Share is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the Digital Asset Holdings is available to all market participants. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA. The IIV will be widely disseminated on a per Share basis every 15 seconds during the NYSE Arca Core Trading Session (normally 9:30 a.m., E.T., to 4:00 p.m., E.T.) by one or more major market data vendors. In addition, the IIV will be available on the Trust's website through on-line information services. The Exchange represents that the Exchange may halt trading during the day in which an interruption to the dissemination of the IIV or the value of the Index occurs. If the interruption to the dissemination of the IIV or the value of the Index persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a CSSA. In addition, as noted above, investors will have ready access to information regarding the Trust's Digital Asset Holdings, IIV, and quotation and last sale information for the Shares.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that the proposed rule change will facilitate the listing and trading of an additional type of exchange-traded product, and the first such product based on Bitcoin, which will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 1

Section 19(b)(2) of the Act[66] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for comment in the **Federal Register** on November 8, 2021.[67] The 180th day after publication of the proposed rule change is May 7, 2022. The Commission is extending the time period for approving or disapproving the proposed rule change for an additional 60 days.

The Commission finds that it is appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change, as modified by Amendment No. 1, and the issues raised in the comments that have been submitted in connection therewith. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[68] designates July 6, 2022, as the date by which the Commission shall either approve or disapprove the proposed rule change, as modified by Amendment No. 1 (File No. SR–NYSEArca–2021–90).

IV. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning whether the proposed rule change, as modified by Amendment No. 1, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–NYSEArca–2021–90 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. SR–NYSEArca–2021–90. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements

[66] 15 U.S.C. 78s(b)(2).

[67] *See supra* note 3.

[68] 15 U.S.C. 78s(b)(2).

with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NYSEArca–2021–90 and should be submitted on or before May 31, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[69]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09957 Filed 5–9–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94848; File No. SR–CBOE–2022–022]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Update Its Fees Schedule in Connection With the Launch of the Curb Trading Hours Session

May 4, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 25, 2022, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to update its Fees Schedule in connection with the launch of the Curb Trading Hours Session. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule in connection with its plans to launch the Curb Trading Hours (''Curb'') session, effective April 25, 2022.

By way of background, the Exchange currently offers two trading sessions, the Regular Trading Hours session (''RTH'')[3] and the Global Trading Hours session (''GTH'').[4] Beginning Monday, April 25, 2022, the Exchange will operate an additional trading session following RTH called the ''Curb Trading Hours'' or ''Curb'' session. The Curb session will provide an extra forty-five-minute electronic only session for trading between 4:15 p.m. and 5:00 p.m. ET for designated classes, which will be added Monday through Friday. Currently, only SPX (including SPXW) and VIX options will be available for trading on the Exchange during the Curb session. FLEX Options with the same underlying index will also be deemed eligible for trading during the Curb session. Transactions effected during the Curb session will have the same trade date as the immediately preceding RTH session (*i.e.,* the day on which the transactions were effected), whereas transactions effected during a GTH session have a different trade date than the immediately preceding RTH session (*i.e.,* the trading day following the RTH session that immediately preceded it).

In connection with the launch of the Curb session, the Exchange proposes to update its Fees Schedule to reflect and incorporate references to the Curb session and make clear which fees, surcharges and programs also apply during Curb. Specifically, the fees (including surcharges)[5] and programs[6] applicable during RTH for SPX, SPXW and VIX will apply in the same manner during Curb. To make clear that such fees, surcharges and programs also apply during Curb, the Exchange proposes to adopt and append Footnote 42 to all applicable fees, surcharges and programs.[7] Footnote 42 would also make clear that Curb is a separate trading session from RTH and GTH for VIX, SPX and SPW and commences at 3:15PM CST and terminates at 4:00PM CST,[8] and is conducted on an all-electronic trading model with no open outcry capability.

The Exchange also proposes to update the notes sections of certain tables in the Fees Schedule to incorporate references to the Curb session. First, the Exchange

[69] 17 CFR 200.30–3(a)(12) and (57).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] RTH for transactions in equity options (including options on individual stocks, ETFs, ETNs, and other securities) are the normal business days and hours set forth in the rules of the primary market currently trading the securities underlying the options, except for options on ETFs, ETNs, Index Portfolio Shares, Index Portfolio Receipts, and Trust Issued Receipts the Exchange designates to remain open for trading beyond 4:00 p.m. Eastern Time (ET) but in no case later than 4:15 p.m. ET. RTH for transactions in index options are from 9:30 a.m. to 4:15 p.m. ET, subject to certain exceptions.

[4] The GTH session currently begins at 8:15 p.m. (previous day) and goes until 9:15 a.m. ET on Monday through Friday.

[5] *See* Cboe Options Fees Schedule, Rate Table—Underlying Symbol List A (including all surcharges), Electronic Trading Permit Fees, Trade Processing Services fee and Regulatory Fees.

[6] *See* Cboe Options Fees Schedule, SPX/SPXW and SPESG Liquidity Provider Sliding Scale, Cboe Options Clearing Trading Permit Holder Proprietary Products Sliding Scale, Cboe Options Clearing Trading Permit Holder VIX Sliding Scale, Select Customer Options Reduction (''SCORe'') Program, Customer Large Trade Discount, Large Trade Discount, Trading Permit Holder Transaction Fee Policies and Rebate Programs, and Frequent Trader Program.

[7] Only applicable RTH fees, surcharges and programs will apply during Curb. For example, since Curb will operate as an all-electronic trading session, no floor related fees such as floor brokerage fees will apply during Curb.

[8] The Exchange notes that although its rulebook references time in Eastern Time, its Fees Schedule uses Central Standard Time (''CST'').

proposes to make clear in the tables of the Clearing Trading Permit Holder Proprietary Products Sliding Scale and Clearing Trading Permit Holder VIX Sliding Scale that volume in Curb, in addition to GTH and RTH, will all be aggregated for purposes of calculating the volume thresholds. The Exchange also proposes to add a reference to the Curb session in the Frequent Trader Program making clear that Customers can obtain unique Frequent Trader IDs which can be appended by executing agents to orders submitted to the Exchange during Curb, in addition to RTH and GTH. The Exchange lastly proposes to update the notes section of the Electronic Trading Permit Fees table to make clear that Market-Maker Electronic Access Permits, Electronic Access Permits, and Clearing TPH Permits all entitle the holder to access the Exchange in the respective capacity during Curb, in addition to RTH and GTH.

The Exchange also proposes to make clarifying updates to the Fees Schedule as it relates to fees assessed during GTH. First, the Exchange proposes to update Footnote 37 of the Fees Schedule, which currently provides that GTH is a separate trading session from RTH for VIX, SPX and SPW and also that GTH commences at 7:15 p.m. CST and terminates at 8:15AM CST and is conducted on an all-electronic trading model with no open outcry capability. Specifically, the Exchange proposes to update Footnote 37 to clarify that GTH is a separate trading session from both RTH and Curb trading sessions. The Exchange also proposes to modify the way Footnote 37 is appended to various fees, surcharges and programs. Currently anywhere that Footnote 37 is appended, the Exchange also states ''(Also applies to GTH)'' immediately preceding the appended Footnote 37 reference. The Exchange proposes to eliminate this language in order to streamline the Fees Schedule and make it easier to read. The Exchange does not believe this language is necessary or needed to understand when a fee, surcharge or program applies during GTH since the Exchange will still maintain all appended references to Footnote 37 itself. However, to alleviate any potential confusion, the Exchange also proposes to add the language ''[a]pplies during Global Trading Hours (''GTH'')'' to the Footnote 37 Description.

The Exchange next proposes to append Footnote 37 to the SPX/SPXW and SPESG Liquidity Provider Sliding Scale, SCORe Program, and Frequent Trader Program tables as it was inadvertently not added to the headers of those tables previously, notwithstanding its application during GTH as well as RTH. Lastly, the Exchange proposes to update the header relating to AIM Agency/Primary and AIM Contra fees included in the Rate Table—Underlying Symbol List A. Particularly, the header currently provides that such fees apply to ''VIX Only'' and in ''SPX (incl[uding] SPXW in GTH Only''. The Exchange notes that previously AIM was only activated for SPX and SPXW during GTH (and not RTH). The Exchange notes however, that currently SPX and SPXW are currently eligible to participate in AIM during either session, and will also be eligible to participate in AIM during Curb. As such, the Exchange proposes to eliminate this reference and provide instead that the rates (which currently are the same as non-AIM rates) apply to VIX and SPX (including SPXW), as well as append Footnotes 37 and 42 to clarify the applicability to each trading session.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[9] in general, and furthers the objectives of Section 6(b)(4),[10] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and issuers and other persons using its facilities. The Exchange also believes that the proposed rule change is consistent with the objectives of Section 6(b)(5) [11] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and, particularly, is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

First, the Exchange believes that the proposed rule change is reasonable, equitable and not unfairly discriminatory because all applicable fees, surcharges and programs that apply to SPX, SPWX and VIX during RTH will also apply during Curb, which although is a separate trading session from RTH, merely provides an additional 45 minutes of trading in these products during which transactions effected will have the same trade date as the immediately preceding RTH session. The Exchange believes proposed Footnote 42 will add clarity and transparency to the Fees Schedule by providing details around the Curb session as well as making clear that the fees, surcharges, and programs listed in the Fees Schedule apply to Curb just as they apply to RTH. The proposed updates related to Footnote 37 are also meant to streamline the Fees Schedule, make it easier to read and alleviate potential confusion as to the applicability of certain fees and programs.

The Exchange believes that the proposed rule change is equitable and not unfairly discriminatory because current fees, surcharges and programs currently applicable during RTH for SPX, SPXW and VIX will apply in the same manner during Curb. Also, the fee amounts for each separate type of market participant will continue to be assessed equally for each product to all such market participants (*i.e.* all Broker-Dealer orders will be assessed the same amount, all Joint Back-Office orders will be assessed the same amount, etc.). The Exchange lastly notes that the newly adopted Curb session will apply equally to all market participants, in that, all market participants may choose to trade during Curb.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes the proposed amendments to its Fee Schedule will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed changes apply uniformly to all market participants that choose to participate in the new Curb session. As discussed, all fees, surcharges and programs applicable during RTH will also apply in the same manner during the Curb session.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed rule changes apply only to products exclusively listed on the Exchange. Additionally, the Exchange notes it operates in a highly competitive market. In addition to Cboe Options, TPHs have numerous alternative venues that they may

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(4).

[11] 15 U.S.C. 78f.(b)(5).

participate on and direct their order flow, including 15 other options exchanges, as well as off-exchange venues, where competitive products are available for trading. Based on publicly available information, no single options exchange has more than 16% of the market share of executed volume of options trades.[12] Therefore, no exchange possesses significant pricing power in the execution of option order flow. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [13] The fact that this market is competitive has also long been recognized by the courts. In NetCoalition v. Securities and Exchange Commission, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . ..''.[14] Accordingly, the Exchange does not believe its proposed changes to the incentive programs impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [15] and paragraph (f) of Rule 19b–4 [16] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2022–022 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2022–022. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2022–022 and should be submitted on or before May 31, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09959 Filed 5–9–22; 8:45 am]

BILLING CODE 8011–01–P

[12] *See* Cboe Global Markets, U.S. Options Market Volume Summary by Month (April 21, 2022), *available at http://markets.cboe.com/us/options/market_share/.*

[13] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[14] NetCoalition v. SEC, 615 F.3d 525, 539 (DC Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–247, OMB Control No. 3235–0259]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 19h–1

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 19h–1 (17 CFR 240.19h–1), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 19h–1 prescribes the form and content of notices and applications by self-regulatory organizations (''SROs'') regarding proposed admissions to, or continuances in, membership, participation or association with a member of any person subject to a statutory disqualification.

The Commission uses the information provided in the submissions filed pursuant to Rule 19h–1 to review decisions by SROs to permit the entry into or continuance in the securities business of persons who have committed serious misconduct. The filings submitted pursuant to the Rule also permit inclusion of an application to the Commission for consent to associate with a member of an SRO notwithstanding a Commission order barring such association.

The Commission reviews filings made pursuant to the Rule to ascertain whether it is in the public interest to permit the employment in the securities business of persons subject to statutory disqualification. The filings contain information that is essential to the staff's review and ultimate determination on whether an association or employment is in the public interest and consistent with investor protection.

It is estimated that approximately 20 respondents will make submissions pursuant to this Rule annually. With respect to submissions for Rule 19h–1(a) notices, and based upon past submissions, the staff estimates that respondents will make a total of 11 submissions per year. The staff estimates that the average number of hours necessary to complete a submission pursuant to Rule 19h–1(a) notices is 80 hours (for a total annual burden for all respondents in the amount of 17,600 hours). With respect to submissions for Rule 19h–1(a)(4) notifications, and based upon past submissions, the staff estimates that respondents will make a total of 9 submissions per year. The staff estimates that the average number of hours necessary to complete a submission pursuant to Rule 19h–1(a)(4) notifications is 80 hours (for a total annual burden for all respondents in the amount of 14,400 hours). With respect to submissions for Rule 19h–1(b), and based upon past submissions, the staff estimates that respondents will make a total of 28 submissions per year. The staff estimates that the average number of hours necessary to complete a submission pursuant to Rule 19h–1(b) is 13 hours (for a total annual burden for all respondents in the amount of 7,280 hours). With respect to submissions for Rule 19h–1(d), and based upon past submissions, the staff estimates that respondents will make a total of 5 submissions per year. The staff estimates that the average number of hours necessary to complete a submission pursuant to Rule 19h–1(d) is 80 hours (for a total annual burden for all respondents in the amount of 8,000 hours). The aggregate annual burden for all respondents is thus approximately 47,280 hours (17,600 +14,400 + 7,280 + 8,000).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: May 4, 2022.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09951 Filed 5–9–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94847; File No. SR–MEMX–2022–10]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing of a Proposed Rule Change To Adopt Rules To Govern the Trading of Options on the Exchange for a New Facility Called MEMX Options

May 4, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b-4 thereunder,[2] notice is hereby given that on April 21, 2022, MEMX LLC (''MEMX'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to adopt rules to govern the trading of options on the Exchange. The text of the proposed rule change is provided in Exhibit 5.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Purpose

The Exchange is proposing to adopt a series of rules in connection with MEMX Options, which will be a facility of the Exchange. MEMX Options will operate an electronic trading system developed to trade options (the ''System'') leveraging the Exchange's existing robust and resilient technology platform that it uses to operate its cash equities market today. The fundamental premise of the proposal is that the Exchange will operate its options market much as it operates its cash equities market today and in a manner similar to that of other options exchanges, with a simplified suite of conventional order types and functionality that is designed to provide for an efficient, robust, and transparent order matching process. Much of the proposed functionality for MEMX Options is substantially similar to that offered by other options exchanges, primarily Cboe BZX Exchange, Inc. (''BZX''). Thus, the Exchange proposes to adopt rules applicable to MEMX Options that are substantively identical or substantially similar to the approved rules of BZX applicable to the BZX options market (''BZX Options''), with certain proposed changes or omissions that are described below.

The System will provide for the electronic display and execution of orders in price/time priority without regard to the status of the entities that are entering orders. All Exchange Members will be eligible to participate in MEMX Options provided that the Exchange specifically authorizes them to trade in the System. The System will

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

provide a routing service for orders when trading interest is not present on MEMX Options and will comply with all applicable securities laws and regulations and the obligations of the Options Order Protection and Locked/Crossed Market Plan.

MEMX Options Members

Pursuant to the proposed rules in Chapter 17 (Participation on MEMX Options), the Exchange will authorize any Exchange Member who meets certain enumerated qualification requirements (any such Member, an ''Options Member'') and any Options Member's Sponsored Participants to obtain access to, and transact business on, MEMX Options.

There will be two types of Options Members—Options Order Entry Firms (''OEFs'') and Options Market Makers. OEFs will be those Options Members representing Customer Orders as agent on MEMX Options or trading as principal on MEMX Options. Options Market Makers will be those Options Members registered with the Exchange as Options Market Makers pursuant to proposed Rule 22.2. To become an Options Market Maker, an Options Member will be required to register by filing a written application. The Exchange will not place any limit on the number of entities that may become Options Market Makers, the number of appointments an Options Market Maker may have, or the number of Options Market Makers that may have appointments in a class unless the Exchange determines to impose any such limit based on system constraints, capacity restrictions, or other factors relevant to protecting the integrity of the System. The Exchange will not impose any such limitations until it has submitted objective standards for imposing the limits to the Commission for its review and approval.

Options Market Makers will be required to electronically engage in a course of dealing reasonably calculated to contribute to the maintenance of fair and orderly markets. Among other things, an Options Market Maker would generally have to satisfy the following responsibilities and duties during trading: (1) On a daily basis maintain a two-sided market on a continuous basis in at least 60% of the cumulative number of seconds, or such higher percentage as the Exchange may announce in advance, for which that Options Market Maker's appointed classes are open for trading, excluding any adjusted series, any intraday add-on series on the day during which such series are added for trading, any Quarterly Option Series, and any series with an expiration of greater than 270 days; [3] (2) enter a size of at least one contract for its best bid and its best offer; and (3) maintain minimum net capital in accordance with Commission and Exchange rules. Substantial or continued failure by an Options Market Maker to meet any of its obligations and duties will subject the Options Market Maker to disciplinary action, suspension, or revocation of the Options Market Maker's registration as such or its appointment in one or more of its appointed options classes.

Options Market Makers receive certain benefits for carrying out their duties. For example, a lender may extend credit to a broker-dealer without regard to the restrictions in Regulation T of the Board of Governors of the Federal Reserve System if the credit is to be used to finance the broker-dealer's activities as a specialist or market maker on a national securities exchange. Thus, an Options Market Maker has a corresponding obligation to hold itself out as willing to buy and sell options for its own account on a regular or continuous basis to justify this favorable treatment.

Every Options Member shall at all times maintain membership in another registered options exchange that is not registered solely under Section 6(g) of the Exchange Act [4] or in FINRA. OEF's that transact business with Public Customers must at all times be members of FINRA. Pursuant to proposed Rule 17.2(g), every Options Member will be required to have at least one registered Options Principal who satisfies the criteria of that rule, including the satisfaction of a proper qualification examination. An OEF may only transact business with Public Customers if such Options Member also is an Options Member of another registered national securities exchange or association with which the Exchange has entered into an agreement under Rule 17d-2 under the Exchange Act [5] pursuant to which such other exchange or association shall be the designated options examining authority for the OEF.

The proposed rules relating to qualification and participation on MEMX Options as an Options Member (including as an OEF and an Options Market Maker) are substantively identical to the relevant rules of BZX Options.[6]

As provided in proposed Rule 16.2, existing Exchange Rules applicable to the MEMX equities market contained in Chapters 1 through 15 of the Exchange Rules will apply to Options Members unless a specific Exchange Rule applicable to the MEMX Options market (proposed Chapters 16 through 29 of the Exchange Rules) governs or unless the context otherwise requires. Options Members can therefore provide sponsored access to the MEMX Options Exchange to a non-Member (*i.e.,* a Sponsored Participant) pursuant to Rule 11.3 of the Exchange Rules.

Definitions

The Exchange proposes to define a series of terms under proposed Rule 16.1 (Definitions), which are to be used in proposed Chapters 16 to 29 relating to the trading of options contracts on the Exchange. Each of the terms defined in proposed Rule 16.1 is either identical or substantially similar to definitions included in BZX Rule 16.1.

The definitions under proposed Rule 16.1 are as follows:

• *ABBO.* The term ''ABBO'' means the best bid(s) or offer(s) disseminated by other Eligible Exchanges (as defined in proposed Rule 27.1) and calculated by the Exchange based on market information the Exchange receives from OPRA.

• *Aggregate Exercise Price.* The term ''aggregate exercise price'' means the exercise price of an options contract multiplied by the number of units of the underlying security covered by the options contract.

• *American-Style Option.* The term ''American-style option'' means an options contract that, subject to the provisions of proposed Rule 23.1 (relating to the cutoff time for exercise instructions) and to the Rules of the Clearing Corporation, may be exercised at any time from its commencement time until its expiration.

• *Associated Person and Person Associated with an Options Member.* The terms ''associated person'' and ''person associated with an Options Member'' mean any partner, officer, director, or branch manager of an Options Member (or any person occupying a similar status or performing similar functions), any person directly or indirectly controlling, controlled by, or under common control with an Options Member or any employee of an Options Member.

[3] The Exchange notes that it also proposes to adopt provisions that exclude from the calculation of continuous quoting those times that an Options Market Maker is experiencing a technical failure or limitation, during a trading halt, suspension or pause in the underlying security, or when the underlying security is in a limit up-limit down state.

[4] 15 U.S.C. 78f(g).

[5] 17 CFR 240.17d–2.

[6] *See* BZX Rules, Chapters XVII and XXII.

• *Bid.* The term ''bid'' means a limit order to buy one or more options contracts.

• *Board.* The term ''Board'' means the Board of Directors of MEMX LLC.

• *Call.* The term ''call'' means an options contract under which the holder of the option has the right, in accordance with the terms of the option, to purchase from the Clearing Corporation the number of shares of the underlying security covered by the options contract.

• *Capacity.* The term ''Capacity'' means the capacity in which a User submits an order, which the User specifies by applying the corresponding code to the order according to the specifications for MEMX Options.

• *Class of Options.* The terms ''class'' or ''class of options'' mean all options contracts with the same unit of trading covering the same underlying security or index.

• *Clearing Corporation and OCC.* The terms ''Clearing Corporation'' and ''OCC'' mean The Options Clearing Corporation.

• *Clearing Member.* The term ''Clearing Member'' means an Options Member that is self-clearing or an Options Member that clears MEMX Options Transactions for other Members of MEMX Options.

• *Closing Purchase Transaction.* The term ''closing purchase transaction'' means a MEMX Options Transaction that reduces or eliminates a short position in an options contract.

• *Closing Writing Transaction.* The term ''closing writing transaction'' means a MEMX Options Transaction that reduces or eliminates a long position in an options contract.

• *Covered Short Position.* The term ''covered short position'' means (i) an options position where the obligation of the writer of a call option is secured by a ''specific deposit'' or an ''escrow deposit'' meeting the conditions of Rules 610(f) or 610(g), respectively, of the Rules of the Clearing Corporation, or the writer holds in the same account as the short position, on a share-for-share basis, a long position either in the underlying security or in an options contract of the same class of options where the exercise price of the options contract in such long position is equal to or less than the exercise price of the options contract in such short position; and (ii) an options position where the writer of a put option holds in the same account as the short position, on a share-for-share basis, a long position in an options contract of the same class of options where the exercise price of the options contract in such long position is equal to or greater than the exercise price of the options contract in such short position.

• *Customer.* The term ''Customer'' means a Public Customer or a broker-dealer.

• *Customer Order.* The term ''Customer Order'' means an agency order for the account of a Customer.

• *Discretion.* The term ''discretion'' means the authority of a broker or dealer to determine for a Customer the type of option, the class or series of options, the number of contracts, or whether options are to be bought or sold.

• *European-Style Option.* The term ''European-style option'' means an options contract that, subject to the provisions of proposed Rule 23.1 (relating to the cutoff time for exercise instructions) and to the Rules of the Clearing Corporation, can be exercised only on its expiration date.

• *Exchange Act.* The term ''Exchange Act'' means the Securities Exchange Act of 1934, as amended, or Rules thereunder.

• *Exercise Price.* The term ''exercise price'' means the specified price per unit at which the underlying security may be purchased or sold upon the exercise of an options contract.

• *He, Him, and His.* The terms ''he,'' ''him'' and ''his'' are deemed to refer to persons of female as well as male gender, and to include organizations, as well as individuals, when the context so requires.

• *Index Option.* The term ''index option'' means an options contract that is an option on a broad-based, narrow-based or micro narrow-based index of equity securities prices.

• *Individual Equity Option.* The term ''individual equity option'' means an options contract which is an option on an equity security.

• *Long Position.* The term ''long position'' means a person's interest as the holder of one or more options contracts.

• *MEMX Exchange and Exchange.* The terms ''MEMX Exchange'' and ''Exchange'' mean MEMX LLC.

• *MEMX Exchange Rules and Exchange Rules.* The terms ''MEMX Exchange Rules'' and ''Exchange Rules'' mean the rules of the Exchange, including those for equities and options.

• *MEMX Options.* The term ''MEMX Options'' means the MEMX LLC Options Market, an options trading facility of the Exchange under Section 3(a)(2) of the Exchange Act.

• *MEMX Options Book.* The term ''MEMX Options Book'' means the electronic book of options orders maintained by the Trading System.

• *MEMX Options Transaction.* The term ''MEMX Options Transaction'' means a transaction involving an options contract that is effected on or through MEMX Options or its facilities or systems.

• *NBB, NBO, and NBBO.* The term ''NBB'' means the national best bid, the term ''NBO'' means the national best offer, and the term ''NBBO'' means the national best bid or offer as calculated by MEMX Options based on market information received by MEMX Options from OPRA.

• *Offer.* The term ''offer'' means a limit order to sell one or more options contracts.

• *OPRA.* The term ''OPRA'' means the Options Price Reporting Authority.

• *Opening Purchase Transaction.* The term ''opening purchase transaction'' means a MEMX Options Transaction that creates or increases a long position in an options contract.

• *Opening Writing Transaction.* The term ''opening writing transaction'' means a MEMX Options Transaction that creates or increases a short position in an options contract.

• *Options Contracts.* The term ''options contract'' means a put or a call issued, or subject to issuance by the Clearing Corporation pursuant to the Rules of the Clearing Corporation.

• *Options Market Close and Market Close.* The terms ''options market close'' and ''market close'' mean the time the Exchange specifies for the end of a trading session on the Exchange on that trading day.

• *Options Market-Maker and Market-Maker.* The terms ''Options Market-Maker'' and ''Market-Maker'' mean an Options Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in proposed Chapter 22.

• *Options Market Open and Market Open.* The terms ''options market open'' and ''market open'' mean the time the Exchange specifies for the beginning of a trading session on the Exchange on that trading day.

• *Options Member.* The term ''Options Member'' means a firm, or organization that is registered with the Exchange pursuant to proposed Chapter 17 for purposes of participating in options trading on MEMX Options as an ''Options Order Entry Firm'' or ''Options Market-Maker.''

• *Options Member Agreement.* The term ''Options Member Agreement'' means the agreement to be executed by Options Members to qualify to participate on MEMX Options.

• *Options Order Entry Firm, Order Entry Firm, and OEF.* The terms ''Options Order Entry Firm'' and ''Order

Entry Firm'' or ''OEF'' mean those Options Members representing as agent Customer Orders on MEMX Options and those non-Market-Maker Members conducting proprietary trading.

• *Options Principal.* The term ''Options Principal'' means a person engaged in the management and supervision of the Options Member's business pertaining to options contracts that has responsibility for the overall oversight of the Options Member's options related activities on the Exchange.

• *Order.* The term ''order'' means a firm commitment to buy or sell options contracts as defined in proposed Rule 21.1(c).

• *Outstanding.* The term ''outstanding'' means an options contract which has been issued by the Clearing Corporation and has neither been the subject of a closing writing transaction nor has reached its expiration date.

• *Primary Market.* The term ''primary market'' means, in the case of securities listed on Nasdaq Stock Market, LLC (''Nasdaq''), the market that is identified as the listing market pursuant to Section X(d) of the approved national market system plan governing the trading of Nasdaq-listed securities, and, in the case of securities listed on another national securities exchange, the market that is identified as the listing market pursuant to Section XI of the Consolidated Tape Association Plan.

• *Priority Customer and Priority Customer Order.* The term ''Priority Customer'' means any person or entity that is not: (A) A broker or dealer in securities; or (B) a Professional. The term ''Priority Customer Order'' means an order for the account of a Priority Customer.

• *Professional.* The term ''Professional'' means any person or entity that (A) is not a broker or dealer in securities; and (B) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). All Professional orders shall be appropriately marked by Options Members.

• *Protected Quotation.* The term ''Protected Quotation'' has the meaning provided in proposed Rule 27.1.[7]

• *Public Customer.* The term ''Public Customer'' means a person that is not a broker or dealer in securities.

• *Put.* The term ''put'' means an options contract under which the holder of the option has the right, in accordance with the terms and provisions of the option and the Rules of the OCC, to sell to the Clearing Corporation the number of units of the underlying security covered by the options contract, at a price per unit equal to the exercise price, upon the timely exercise of such option.

• *Quarterly Options Series.* The term ''Quarterly Options Series'' means a series in an options class that is approved for listing and trading on the Exchange in which the series is opened for trading on any business day and expires at the close of business on the last business day of a calendar quarter.

• *Quote and Quotation.* The terms ''quote'' and ''quotation'' mean a bid or offer entered by a Market-Maker as a firm order that updates the Market-Maker's previous bid or offer, if any.

• *Responsible Person.* The term ''Responsible Person'' means a U.S.-based officer, director, or management-level employee of an Options Member, who is registered with the Exchange as an Options Principal, responsible for the direct supervision and control of associated persons of that Options Member.

• *Rules of MEMX Options.* The term ''Rules of MEMX Options'' mean the rules contained in proposed Chapters 16 to 29 of the MEMX LLC Exchange Rules governing the trading of options on the Exchange.

• *Rules of the Clearing Corporation and Rules of the OCC.* The terms ''Rules of the Clearing Corporation'' and ''Rules of the OCC'' mean the Certificate of Incorporation, the By-Laws and the Rules of the Clearing Corporation, and all written interpretations thereof, as may be in effect from time to time.

• *SEC and Commission.* The terms ''SEC'' and ''Commission'' mean the United States Securities and Exchange Commission.

• *Series of Options.* The terms ''series'' or ''series of options'' mean all options contracts of the same class that are the same type of options and have the same exercise price and expiration date.

• *Short Position.* The term ''short position'' means a person's interest as the writer of one or more options contracts.

• *Short Term Option Series.* The term ''Short Term Option Series'' means a series in an option class that is approved for listing and trading on the Exchange in which the series is opened for trading on any Monday, Tuesday, Wednesday, Thursday or Friday that is a business day and that expires on the Monday, Wednesday or Friday of the next business week, or, in the case of a series that is listed on a Friday and expires on a Monday, is listed one business week and one business day prior to that expiration. If a Tuesday, Wednesday, Thursday or Friday is not a business day, the series may be opened (or shall expire) on the first business day immediately prior to that Tuesday, Wednesday, Thursday or Friday, respectively. For a series listed pursuant to this section for Monday expiration, if a Monday is not a business day, the series shall expire on the first business day immediately following that Monday.

• *SRO.* The term ''SRO'' means a self-regulatory organization as defined in Section 3(a)(26) of the Exchange Act.

• *Trading System and System.* The terms ''Trading System'' and ''System'' mean the automated trading system used by MEMX Options for the trading of options contracts.

• *Type of Option*. The term ''type of option'' means the classification of an options contract as either a put or a call.

• *Uncovered.* The term ''uncovered'' means a short position in an options contract that is not covered.

• *Underlying Security.* The term ''underlying security'' means the security that the Clearing Corporation shall be obligated to sell (in the case of a call option) or purchase (in the case of a put option) upon the valid exercise of an options contract.

• *User.* The term ''User'' means any Options Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.3 (Access).

Execution System

The Exchange's options System will leverage the Exchange's current state-of-the-art technology, including its customer connectivity, messaging protocols, quotation and execution engine, order router, data feeds, and network infrastructure. This approach minimizes the technical effort required for existing Exchange Members to begin trading options on MEMX Options. As a result, MEMX Options will closely resemble the Exchange's equities market, as well as other options markets, such as BZX Options, that offer true price/time priority across all participants rather than differentiating between participant/trading interest.

Like the Exchange's system for equities, as well as the BZX Options market, all trading interest entered into the System will be automatically executable. Orders entered into the System will be displayed anonymously. Thus, the System will offer anonymous

[7] As defined in proposed Rule 27.1, the term ''Protected Quotation'' refers to a Protected Bid or Protected Offer, and the terms ''Protected Bid'' and ''Protected Offer'' refer to a Bid or Offer in an options series, respectively, that: (A) Is disseminated pursuant to the OPRA Plan; and (B) is the highest priced Bid or lowest priced Offer, respectively, displayed by an Eligible Exchange.

trading, however, options trades are not currently anonymous through settlement. Accordingly, as set forth in proposed Rule 21.10, aggregated and individual transaction reports produced by the System will indicate the details of a User's transactions, including the contra party's executing firm ID (''EFID''), capacity, and clearing firm account number.[8] The Exchange will become an exchange member of the Options Clearing Corporation (''OCC''). The System will be linked to OCC for the Exchange to transmit locked-in trades for clearance and settlement.

Hours of Operation. As stated in proposed Rule 21.2, the MEMX Options System will begin accepting orders after 9:30 a.m. Eastern Time pursuant to the market opening procedures described in proposed Rule 21.7. Orders and bids and offers shall be open and available until 4:00 p.m. Eastern Time except for option contracts on Fund Shares, as defined in proposed Rule 19.3(i), option contracts on exchange-traded notes including Index-Linked Securities, as defined in proposed Rule 19.3(l), and option contracts on broad-based indexes, as defined in proposed Rule 29.1(j), which may close as of 4:15 p.m. Eastern Time. The proposed hours of operation on MEMX Options are the same as on BZX Options, except that BZX Options begins accepting orders at 7:30 a.m. Eastern Time that are then processed in the BZX Options opening process beginning at 9:30 a.m. Eastern Time.

Units of Trading. As stated in proposed Rule 21.3, the unit of trading in each series of options traded on MEMX Options will be the unit of trading established for that series by the OCC pursuant to the rules of the OCC and the agreements of the Exchange with the OCC. The proposed determination of the unit of trading for a series of options traded on MEMX Options is the same as on BZX Options pursuant to BZX Rule 21.3.

Minimum Quotation and Trading Increments. As stated in proposed Rule 21.5(a), the Exchange is proposing to apply the following quotation increments: (1) If the options series is trading at less than $3.00, five (5) cents; (2) if the options series is trading at $3.00 or higher, ten (10) cents; and (3) if the options series is trading pursuant to the Penny Interval Program one (1) cent if the options series is trading at less than $3.00, five (5) cents if the options series is trading at $3.00 or higher, unless for QQQQ, SPY, or IWM where the minimum quoting increment will be one (1) cent for all series. In addition, as stated in proposed Rule 21.5(b), the Exchange is proposing that the minimum trading increment for options contracts traded on MEMX Options will be one (1) cent for all series. Such proposed minimum quotation and trading increments are the same as on BZX Options pursuant to BZX Rules 21.5(a) and (b).

Penny Interval Program. As set forth in proposed Rule 21.5(d), the Exchange is proposing to adopt a Penny Interval Program that is substantially similar to the penny programs of other exchanges, including BZX Options pursuant to BZX Rule 21.5(d), which includes minimum quoting requirements for option classes listed under the Penny Interval Program. However, eligibility for inclusion in the Penny Interval Program will be limited to those classes already operating under penny programs of other options exchanges at the time MEMX Options is launched. The list of option classes included in the Penny Interval Program will be announced by the Exchange via circular distributed to Options Members and published by the Exchange on its website.

Order Types and Handling Instructions. The System will make available to Users two Order Types (as defined in proposed Rule 21.1(d))—Limit Orders and Market Orders—as well as various other instructions and modifiers that can be appended to such orders. The characteristics and functionality of each Order Type is substantially similar to what is currently approved for use in the Exchange's equities trading facility or on other options exchanges, including BZX Options, except where described below. MEMX Options will support bulk messages for Options Market Makers as specified in the description of each Order Type or other instruction. Proposed Rule 21.1(d) includes the following details with respect to Limit Orders and Market Orders:

- *Limit Order.* Limit Orders are orders (including bulk messages) to buy or sell an option at a specified price or better. A Limit Order is marketable when, for a Limit Order to buy, at the time it is entered into the System, the order is priced at the current inside offer or higher, or for a Limit Order to sell, at the time it is entered into the System, the order is priced at the current inside bid or lower.
- *Market Order.* Market Orders are orders to buy or sell at the best price available at the time of execution. Market Orders to buy or sell an option traded on MEMX Options will be rejected if they are received when the underlying security is subject to a ''Limit State'' or ''Straddle State'' as defined in the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS under the Act (the ''Limit Up-Limit Down Plan''). Bulk messages may not be Market Orders.

The System will also make available to Users several additional instructions that can be designated on an order (''Handling Instructions''). A Handling Instruction applied to a bulk message applies to each bid and offer within that bulk message. The Handling Instructions available on MEMX Options are described in proposed Rule 21.1(e) and will include the following:

- *Book Only.* Book Only is an instruction that an order is to be ranked and executed on the Exchange pursuant to proposed Rule 21.8 (Order Display and Book Processing) or cancelled, as appropriate, without routing away to another options exchange. Users may designate bulk messages as Book Only as set forth in proposed Rule 21.1(l).
- *Post Only.* Post Only is an instruction that an order is to be ranked and executed on the Exchange pursuant to proposed Rule 21.8 (Order Display and Book Processing) or cancelled, as appropriate, without routing away to another options exchange except that the order will not remove liquidity from the MEMX Options Book. The Exchange notes that, unlike a Post Only Order on BZX Options, an order with a Post Only instruction on MEMX Options will not remove liquidity even if the value of price improvement associated with such execution equals or exceeds the sum of fees charged for such execution and the value of any rebate that would be provided if the order posted to the MEMX Options Book and subsequently provided liquidity.[9] A Market Order cannot be designated as Post Only.[10] Users may designate bulk messages as

[8] The Exchange shall also reveal a User's identity: (i) When a registered clearing agency ceases to act for a participant, or the User's clearing firm, and the registered clearing agency determines not to guarantee the settlement of the User's trades; and (ii) for regulatory purposes or to comply with an order of an arbitrator or court. *See* proposed Rule 21.10. The Exchange notes that proposed Rule 21.10 is identical to BZX Rule 21.10.

[9] The Exchange notes that other options exchanges offer functionality equivalent to the Post Only instruction that does not remove liquidity based on potential price improvement. *See, e.g.,* NYSE Arca Rule 6.62–O.(t) and NYSE Arca Rule 6.62P–O(e)(2), each of which defines an ALO Order, which is an order that does not remove liquidity from the NYSE Arca order book without any exception for removing liquidity when price improvement could be obtained.

[10] The Exchange notes that the comparable description of Post Only Orders on BZX Options in BZX Rule 21.1(d)(8) does not specify that Market Orders cannot be designated as Post Only, however, the Exchange believes the proposed functionality is the same.

Post Only as set forth in proposed Rule 21.1(l).

• *Intermarket Sweep Order (''ISO'').* ISOs are orders that shall have the meaning provided in proposed Rule 27.1, which relates to intermarket trading. Such orders may be executed at one or multiple price levels in the System without regard to Protected Quotations at other options exchanges (*i.e.,* may trade through such quotations). The Exchange relies on the marking of an order as an ISO order when handling such order, and thus, it is the entering Options Member's responsibility, not the Exchange's responsibility, to comply with the requirements relating to ISOs. ISOs are not eligible for routing pursuant to proposed Rule 21.9. A Market Order cannot be designated as an Intermarket Sweep Order.[11] Users may not designate bulk messages as ISOs.

The Exchange notes that, in contrast to BZX Options, it has proposed characterizing Book Only, Post Only, and ISO as Handling Instructions rather than Order Types, as each of these instructions represents an additional modifier that can be appended to a Market Order or Limit Order rather than a unique Order Type. The Exchange does not believe that this characterization changes anything with respect to the proposed operation of the Exchange but rather is a more accurate characterization of the proposed functionality. The Exchange notes that each of the proposed Order Types and Handling Instructions available on MEMX Options is substantially similar to the same order type available on BZX Options, except where described above or as relates to the display-price sliding process offered by BZX Options, which the Exchange is not proposing to adopt. The Exchange also notes that BZX Options offers additional order types, such as reserve orders, minimum quantity orders, price-improving orders, stop orders, and stop limit orders, none of which the Exchange proposes to adopt.

Time-in-Force Designations. Users entering orders into the System may designate such orders to remain in force and available for display and/or potential execution for varying periods of time. Unless cancelled earlier, once these time periods expire, the order (or the unexecuted portion thereof) is returned to the entering party. A Time-in-Force applied to a bulk message applies to each bid and offer within that bulk message. Unless otherwise specified in the Exchange Rules or the context indicates otherwise, the Exchange determines which of the following Times-in-Force are available on a class or system basis. The Time-in-Force designations available on MEMX Options are described in proposed Rule 21.1(f) and will include the following:

• *Immediate Or Cancel (''IOC'').* IOC means, for an order so designated, an order that is to be executed in whole or in part as soon as such order is received. The portion not so executed immediately on the Exchange or another options exchange is cancelled and is not posted to the MEMX Options Book. IOC orders that are not designated as Book Only and that cannot be executed in accordance with proposed Rule 21.8 on the System when reaching the Exchange will be eligible for routing away pursuant to proposed Rule 21.9. Users may designate bulk messages as IOC.

• *Day.* Day means, for an order so designated, an order to buy or sell which, if not executed expires at market close. Users may designate bulk messages as Day.

The Exchange notes that each of the proposed Time-in-Force designations available on MEMX Options is identical to the same Time-in-Force designation available on BZX Options, except that BZX Options rules describe Time-in-Force designations as applicable only to limit orders on BZX Options, whereas the Exchange has proposed allowing such designations to be placed on both Limit Orders and Market Orders. The Exchange also notes that BZX Options offers additional Times-in-Force, such as good til cancelled, fill-or-kill, at the open, limit-on-close, and market-on-close, none of which the Exchange proposes to adopt.

Member Match Trade Prevention Modifiers. As with its equities market, the Exchange will allow Users to use certain Match Trade Prevention (''MTP'') modifiers, which are described in proposed Rule 21.1(g). Any incoming order designated with an MTP modifier will be prevented from executing against a resting opposite side order also designated with an MTP modifier and originating from the same EFID, Exchange Member identifier, trading group identifier, or Exchange Sponsored Participant identifier. The Exchange will offer the following MTP modifiers: MTP Cancel Newest, described in proposed Rule 21.1(g)(1); MTP Cancel Oldest, described in proposed Rule 21.1(g)(2); and MTP Cancel Both, described in proposed Rule 21.1(g)(3). The Exchange notes that each of the proposed MTP modifiers available on MEMX Options is identical to the same MTP modifier available on BZX Options. The Exchange also notes that BZX Options offers additional MTP modifiers, such as MTP Decrement and Cancel and MTP Cancel Smallest, neither of which the Exchange proposes to adopt.

Re-Pricing Mechanism. Like other options exchanges, the Exchange proposes to offer a re-pricing mechanism to Users to comply with the order protection and trade through restrictions of the Options Order Protection and Locked/Crossed Market Plan. This re-pricing mechanism, described in proposed Rule 21.1(i), is referred to by the Exchange as Price Adjust and is identical to the Price Adjust mechanism offered by BZX Options pursuant to BZX Rule 21.1(i), with the exception of the handling of an order with a Post Only instruction subject to the Price Adjust process. Whereas BZX Options applies the Price Adjust process when a Post Only Order locks or crosses a Protected Quotation displayed on BZX Options and re-prices such Post Only Order pursuant to BZX Rule 21.1(i)(4), the Exchange is not proposing to adopt this clause and instead would cancel a Post Only Order that locks or crosses a Protected Quotation displayed on MEMX Options. As noted above, the Exchange is not proposing to offer a re-pricing mechanism equivalent to the display-price sliding process offered by BZX Options.

EFIDs. As proposed in Rule 21.1(j), the term ''EFIDs'' means Executing Firm IDs and shall refer to what the System uses to identify the User and the clearing number for the execution of orders and quotes submitted to the System with that EFID. A User may obtain one or more EFIDs from the Exchange (in a form and manner determined by the Exchange). The Exchange assigns an EFID to its Users. Each EFID corresponds to a single User and a single clearing number of a Clearing Member with the Clearing Corporation. A User may obtain multiple EFIDs, which may be for the same or different clearing numbers. A User is able (in a form and manner determined by the Exchange) to designate which of its EFIDs may be used for each of its ports. If a User submits an order or quote through a port with an EFID not enabled for that port, the System cancels or rejects the order or quote. The Exchange notes that its proposed Rule 21.1(j) is identical to BZX Rule 21.1(k) other than the use of the term ''User'' instead of ''Member.''

Ports and Bulk Messages. Proposed Rule 21.1(k) defines two types of ports:

[11] The Exchange notes that the comparable description of ISOs on BZX Options in BZX Rule 21.1(d)(9) does not specify that Market Orders cannot be designated as ISOs, however, the Exchange believes the proposed functionality is the same.

(1) A ''physical port,'' which provides a physical connection to the System and may provide access to multiple logical ports; and (2) a ''logical port'' or ''application session,'' which provides Users with the ability within the System to accomplish a specific function through a connection, such as order entry, data receipt, or access to information. The Exchange notes that each of the proposed types of ports available on MEMX Options is identical to the same types of ports on BZX Options, though instead of application session BZX Options also refers to logical ports as logical sessions. The Exchange also notes that BZX Options offers specific ports used for bulk messages whereas the Exchange proposes to offer bulk message functionality through the same logical ports as Users submit other messages to the Exchange. Other than this distinction, the Exchange proposes to adopt the same bulk message functionality as is offered by BZX Options. The term ''bulk message'' is proposed to mean a bid or offer included in a single electronic message a User submits with a Market Maker Capacity to the Exchange in which the User may enter, modify, or cancel up to an Exchange-specified number of bids and offers (which number the Exchange will announce via Exchange notice or publicly available technical specifications). The System handles a bulk message in the same manner as it handles an order or quote, unless the Exchange Rules specify otherwise.[12] Users may submit bulk messages through a logical port, subject to the following: bulk messages must contain a Time-in-Force of Day or IOC; a Market Maker with an appointment in a class must designate a bulk message for that class as Post Only or Book Only, and a non-appointed Market Maker must designate a bulk message for that class as Post Only; the System cancels or rejects a Post Only bulk message bid (offer) with a price that locks or crosses the Exchange best offer (bid) or ABO (ABB); the System executes a Book Only bulk message bid (offer) that locks or crosses the ABO (ABB) against offers (bids) resting in the Book at prices the same as or better than the ABO (ABB) and then cancels the unexecuted portion of that bid (offer).

Cancel Back. The term ''Cancel Back'' is proposed to mean an instruction a User designates on an order (including bulk messages) to not be subject to the Price Adjust process pursuant to proposed Rule 21.1(i). The System cancels or rejects an order with a Cancel Back instruction (immediately at the time the System receives the order or upon return to the System after being routed away) if displaying the order on the Book would create a violation of proposed Rule 27.3, or if the order cannot otherwise be executed or displayed in the Book at its limit price. The System executes a Book Only—Cancel Back order against resting orders. The proposed definition of Cancel Back in proposed Rule 21.1(m) is substantively identical to a Cancel Back Order defined in BZX Rule 21.1(m), except as relates to the display-price sliding process offered by BZX Options, which the Exchange is not proposing to adopt, and the fact that the Exchange has not proposed to execute an order with a Post Only instruction to the extent there is price improvement associated with such execution (including if such order also has a Cancel Back instruction).[13]

Market Opening Procedures. As stated in proposed Rule 21.7, the System shall open options, other than index options, for trading based on the first transaction after 9:30 a.m. Eastern Time in the securities underlying the options as reported on the first print disseminated pursuant to an effective national market system plan. With respect to index options, the System shall open for trading after a time period (which the Exchange determines for all classes) following the System's observation after 9:30 a.m. Eastern Time of the first disseminated index value for the index underlying an index option. Because the Exchange does not propose to adopt an opening cross or similar opening process, the opening trade that occurs on the Exchange will be a trade in the ordinary course of dealings on the Exchange. Accordingly, the System will ensure that the opening trade in an options series will not trade through a Protected Quotation at another options exchange, consistent with the general standard regarding trade throughs articulated in proposed Rule 21.6(e). The proposed market opening procedures for options other than index options are identical to the market opening procedures for such options that were initially adopted by BZX Options.[14] The proposed market opening procedures for index options are substantially similar to the market opening procedures for index options on BZX Options under current BZX Rule 21.7(d)(2) with respect to when the System opens. However, once the BZX Options system observes that an index value has been disseminated for the applicable index BZX Options then commences an opening rotation (*i.e.,* an opening process to match liquidity at a price determined by the BZX Options system) while the Exchange does not currently propose to adopt an opening process. Additionally, the Exchange proposes that it may delay the commencement of trading in any class of options in the interests of a fair and orderly market. As stated in proposed Rule 21.6(c), orders received prior to the opening of the System will be cancelled. The Exchange believes that it is appropriate to commence operations on MEMX Options with simplified procedures for when the System is open for trading because for a successful opening process to function, an exchange needs a critical mass of liquidity from market participants in order to price and execute opening transactions. In turn, as a new options exchange, MEMX Options does not know the amount of pre-opening interest it will have, and it will have to gain market share in order to accumulate such interest. MEMX Options will re-evaluate its opening procedures over time and may propose to add an opening process through a rule filing submitted to the Commission in the future.

Order Display/Matching System. The System will be based upon functionality currently approved for use in the Exchange's equities trading system. Specifically, the System will allow Users to enter Market Orders and priced Limit Orders to buy and sell MEMX Options-listed options. All orders (including bulk messages) will be designated for display (price and size) on an anonymous basis by the Exchange.

Routing. The MEMX Options Exchange will support orders that are designated to be routed to the National Best Bid and Offer (''NBBO'') as well as orders that will execute only within MEMX Options. Orders that are designated to execute at the NBBO will

[12] The Exchange notes that BZX Options maintains the definition of bulk message in BZX Rule 16.1 whereas MEMX Options has proposed to include this language in proposed Rule 21.1(l), where bulk messages are further described. Despite this distinction, as noted above, the functionality is the same other than the fact the Exchange does not propose to require a separate bulk port to submit bulk messages.

[13] *See supra* note 9 and accompanying text.

[14] *See* Securities Exchange Act Release No. 61419 (January 26, 2010), 75 FR 5157 (February 1, 2010) (SR–BATS–2009–031) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, To Establish Rules Governing the Trading of Options on the BATS Options Exchange).

be routed to other options markets to be executed when the Exchange is not at the NBBO consistent with the Options Order Protection and Locked/Crossed Market Plan. Subject to the exceptions contained in proposed Rule 27.2(b), the System will ensure that an order will not be executed at a price that trades through another options exchange. An order that is designated by an Options Member as routable will be routed in compliance with applicable trade-through restrictions. Any order entered with a price that would lock or cross a Protected Quotation that is not eligible for either routing or the price adjust process as defined in proposed Rule 21.1(i) will be cancelled. Bulk messages are not eligible for routing.

The proposed routing functionality for MEMX Options is designed to operate much like the routing functionality for the Exchange's equities market, in that the Exchange offers a simple routing service to facilitate compliance with applicable regulations and does not currently offer other complex routing strategies. The Exchange notes that the proposed rules relating to the routing of orders on MEMX Options to away options markets are similar to the approved rules of BZX Options, except that the Exchange proposes to cancel any unexecuted portion of a Market Order after the System has routed to and received response from an away options market, whereas BZX Options offers additional handling instructions that may be chosen with respect to the unexecuted portion of an order after the System has routed to and received response from an away options market, and BZX Options offers various additional routing options, such as routing to a specific destination or at specified price levels.[15]

MEMX Options shall route orders in options via MEMX Execution Services LLC (''MEMX Execution Services''), which serves as the Outbound Router of the Exchange, as defined in Rule 2.11. The function of the Outbound Router will be to route orders in options listed and open for trading on MEMX Options to other options exchanges pursuant to the proposed rules of MEMX Options solely on behalf of MEMX Options. The Outbound Router is subject to regulation as a facility of the Exchange, including the requirement to file proposed rule changes under Section 19 of the Act. Use of MEMX Execution Services or Routing Services (as defined below) to route orders to other market centers is optional. In the event the Exchange is not able to provide order routing services through its affiliated broker-dealer, the Exchange will route orders to other options exchanges in conjunction with one or more routing brokers that are not affiliated with the Exchange (''Routing Services''). Parties that do not desire to use MEMX Execution Services or other Routing Services provided by the Exchange must designate orders as not available for routing.

In connection with the proposed rules regarding routing to away options exchanges, proposed Rule 21.9(f) provides that MEMX Execution Services has, pursuant to Rule 15c3–5 under the Act,[16] implemented certain tests designed to mitigate the financial and regulatory risks associated with providing the Exchange's Users with access to such away options exchanges. Pursuant to the policies and procedures developed by MEMX Execution Services to comply with Rule 15c3–5, if an order or series of orders are deemed to be erroneous or duplicative, would cause the entering User's credit exposure to exceed a preset credit threshold, or are non-compliant with applicable pre-trade regulatory requirements (as defined in Rule 15c3–5), MEMX Execution Services will reject such orders prior to routing and/or seek to cancel any orders that have been routed. This is consistent with the routing implementation of other options exchanges, and the Exchange notes that proposed Rule 21.9(f) is substantively identical to BZX Rule 21.9(f).

Order Priority. The System, like the Exchange's equities facility, shall execute trading interest within the System in price/time priority, meaning it will execute all trading interest at the best price level within the System before executing trading interest at the next best price. Trading interest will be executed with the order clearly established as the first entered into the System at each price level having priority up to the number of contracts specified in the order. Any order entered with a price that would lock or cross a Protected Quotation that is not eligible for either routing or the price adjust process as defined in proposed Rule 21.1(i) will be cancelled. The Exchange notes that the proposed price/time order priority and book processing is substantially similar to that on BZX Options.

Data Feed. The System will include a proprietary data feed which will display without attribution to Users' orders on both the bid and offer side of the market for price levels then within MEMX Options using the minimum price variation applicable to that security.

Risk Controls. The Exchange also proposes to offer to all Users of MEMX Options the ability to establish certain risk control parameters and limits that are intended to assist Users in managing their market risk. The proposed risk controls are set forth in proposed Rules 21.16 and 21.17 and are based, in part, on those of BZX Options, with certain additions and differences described below. The proposed risk controls are designed to offer Users protection from entering orders outside of certain size and price parameters, as well as certain standard or Exchange-established parameters based on order type and market conditions.

The Exchange proposes to offer a Risk Monitor Mechanism described in proposed Rule 21.16 that features passive risk counter functionality, which is similar to the risk monitor mechanism functionality offered by other options exchanges, including BZX Options, as well as active risk counter functionality. Under the proposed Risk Monitor Mechanism, Users may configure risk limits for various parameters, including number of contracts executed (''volume''), notional value of executions (''notional''), number of executions (''count''), number of contracts executed as a percentage of number of contracts outstanding within an Exchange-designated time period or during the trading day (''percentage''), and the number of times the limits on any of the foregoing parameters are reached (''risk trips''). The System will track each of the parameters within an underlying for an EFID (''underlying limit''), across all underlyings for an EFID (''EFID limit''), across all underlyings for a group of EFIDs (''EFID Group'') (''EFID Group limit''), and/or across a customized group of orders designated by the User (''Custom Group Limit''), over a User-established time period (''interval'') and on an absolute basis for a trading day (''absolute limits'').

When the System determines that a specified parameter has reached the User-defined risk limit, depending on the User's instructions and the applicable limit that has been reached, the Risk Monitor Mechanism either: (1) Cancels or rejects such User's orders or quotes in all series of the applicable underlying(s) and cancels or rejects any additional orders or quotes from the User in the applicable underlying(s) until the counting program resets; or (2) suspends all of a User's resting orders or quotes in all series of the applicable underlying(s) and cancels or rejects any additional orders or quotes from the User in the applicable underlying(s) until the Exchange is instructed to

[15] *See* BZX Rule 21.9.

[16] 17 CFR 240.15c3–5.

reinstate such bids and offers. A User may also engage the Risk Monitor Mechanism to cancel resting bids and offers, as well as subsequent orders as set forth in proposed Rule 22.10 (''mass cancellation'') or to suspend all resting bids and offers until the Exchange is instructed to reinstate such bids and offers (''mass suspension'').

The proposed Risk Monitor Mechanism functionality described above is substantially similar to the risk monitor mechanism offered on BZX Options, except that BZX Options does not permit Users to designate a Custom Group Limit to track risk parameters across a customized group of orders, nor does BZX Options permit Users to choose to suspend, rather than cancel or reject, resting orders when a risk limit has been reached or to engage the Risk Monitor Mechanism for mass suspension as an alternative to mass cancellation. The Exchange believes that these proposed additions to the Risk Monitor Mechanism functionality that is currently available on BZX Options would provide Users with greater optionality when managing their risk on MEMX Options.

The proposed Risk Monitor Mechanism functionality described above is similar to the Risk Monitor Mechanism functionality offered by other options exchanges, including BZX Options, in that it provides for the System to track specified risk parameters across designated underlyings and/or order groups until the counting program is reset by the User (such functionality, the ''passive risk counter''). In addition to the Risk Monitor Mechanism's passive risk counter functionality, which is similar to the Risk Monitor Mechanism functionality offered by BZX Options in BZX Rule 21.16, the Exchange also proposes to enable a User to optionally manage their risk limits actively using the Exchange's proposed active risk counter functionality within the Risk Monitor Mechanism. As proposed, for a User using the active risk counter, the System will increment the active risk counter associated with a defined parameter when such parameter increments, and the System will decrement the active risk counter upon positive confirmation from the User via an electronic instruction that the User has acknowledged a change in the active risk counter. A User would also be able to specify the value by which each parameter increments and decrements in the active risk counter. The proposed active risk counter therefore enables a User to interact with the Risk Monitor Mechanism dynamically such that the User may actively acknowledge executions and decrement the counting program by a specified amount as such executions occur (or at any time), rather than waiting until a risk limit is reached or the User otherwise sends a specific instruction to the Exchange to completely reset the counting program.

The following examples illustrate the proposed behavior of the passive risk counter and the active risk counter within the Risk Monitor Mechanism. In each case, assume a User configures a risk limit of 10,000 contracts executed with respect to options contracts on underlying security ABC for a single EFID.

Passive Risk Counter:

- The System executes User's order to purchase 5,000 call options on ABC (''Transaction 1''). The System's counting program would increment to a total of 5,000 executed options contracts on ABC for the User.
- The System then executes User's order to purchase 3,000 call options on ABC (''Transaction 2''). The System's counting program would increment an additional 3,000 executed options contracts for Transaction 2 to a total of 8,000 executed options contracts on ABC for the User.
- The System then executes User's order to purchase 3,000 call options on ABC (''Transaction 3''). The System's counting program would increment an additional 3,000 executed options contracts for Transaction 3 to a total of 11,000 executed options contracts on ABC for the User. As Transaction 3 results in executions in excess of the User's risk limit with respect to the number of options contracts executed, the Risk Monitor Mechanism is triggered, and the System will cancel, reject or suspend, as applicable in accordance with the User's instructions, the User's orders and quotes in all series of options contracts on ABC for the User.
- The User then submits an electronic instruction to the System to reset the counting program, and the counting program is decremented to zero. The System will now accept new orders or quotes from the User in a series of options contracts on ABC.

Active Risk Counter:

- The System executes a transaction to purchase 5,000 call options on ABC (''Transaction 1''). The System's counting program would increment to a total of 5,000 executed options contracts on ABC for the User.
- The User then submits an electronic instruction to the System acknowledging a change in the active risk counter due to Transaction 1. Upon the System's receipt of such instruction, the counting program decrements the active risk counter by 5,000 options contracts for Transaction 1 to a total of zero with respect to the number of executed options contracts on ABC for the User.
- The System then executes two separate transactions to purchase 3,000 call options on ABC per transaction (''Transaction 2'' and ''Transaction 3'' respectively), and the User does not acknowledge a change in the active risk counter due to either of these executions. The System's counting program would increment 3,000 executed options contracts at the time of execution for each of Transaction 2 and Transaction 3, for a total of 6,000 executed options contracts on ABC for the User.
- The User then submits an electronic instruction to the System acknowledging a change in the active risk counter due Transaction 3, but not Transaction 2. Upon the System's receipt of such instruction, the counting program would decrement the active risk counter by the 3,000 executed options contracts for Transaction 3 to a total of 3,000 executed options contracts on ABC for the User.
- The User then executes a transaction to purchase 10,000 call options on ABC (''Transaction 4''). The System's counting program would increment an additional 10,000 executed options contracts for Transaction 4 to a total of 13,000 options contracts on ABC for the User. As Transaction 4 results in executions in excess of the User's risk limit with respect to the number of options contracts executed, the Risk Monitor Mechanism is triggered, and the System will cancel, reject or suspend, as applicable in accordance with the User's instructions, the User's orders and quotes in all series of options contracts on ABC for the User.
- The User then submits an electronic instruction to the System acknowledging a change in the active risk counter due to Transaction 4. Upon the System's receipt of such instruction, the counting program would decrement the active risk counter by the 10,000 executed options contracts for Transaction 4 to a total of 3,000 executed options contracts on ABC for the User. The System will now accept new orders or quotes from the User in a series of options contracts on ABC.

In addition to the Risk Monitor Mechanism functionality described above, the Exchange also proposes to offer additional price protection mechanisms and risk controls that relate to certain standard or Exchange-established parameters based on order type and market conditions, which are

described in proposed Rule 21.17. These additional price protection mechanisms and risk controls are substantially similar to those offered on BZX Options pursuant to BZX Rule 21.17, with slight modifications to align with the Exchange's proposed market opening procedures and available order types and instructions on MEMX Options, except that the Exchange is proposing a simplified version of the drill-through price protection mechanism described in proposed Rule 21.17(d). Whereas the drill-through price protection mechanism offered on BZX Options pursuant to BZX Rule 21.17(d) executes an incoming order to a determined ''Drill-Through Price'' and then displays the remainder of the order on BZX Options at that price for a brief period of time, the Exchange has proposed to simply cancel the remainder of an incoming order after executing the order to the Drill-Through Price.

One Second Exposure Period. Proposed Rule 22.11 would require Options Members to expose their customers' orders on the Exchange for at least one second under certain circumstances. During this one second exposure period, other Options Members will be able to enter orders to trade against the exposed order. In adopting a one second order exposure period, the Exchange is proposing a requirement that is consistent with the rules of other options exchanges.[17] Thus, the exposure period will allow Options Members that are members of other options exchanges to comply with proposed Rule 22.11 without programming separate time parameters into their systems for order entry or compliance purposes. The Exchange believes that market participants are sufficiently automated that a one second exposure period allows an adequate time for market participants to electronically respond to an order. Also, it is possible that market participants might wait until the end of the exposure period, no matter how long, before responding. Thus, the Exchange believes that any longer than one second would not further the protection of investors or market participants, but rather, would potentially increase market risk to investors and other market participants by creating a longer period of time for the exposed order to be subject to market risk.

Options Order Protection and Locked/Crossed Market Plan Rules

The Exchange will participate in the Options Order Protection and Locked/Crossed Market Plan (the ''Plan''), and therefore will be required to comply with the obligations of Participants under the Plan. The Exchange proposes to adopt rules relating to the Plan that are substantially similar to the rules in place on all of the options exchanges that are Participants to the Plan. The Plan essentially applies the Regulation NMS price-protection provisions to the options markets. Similar to Regulation NMS, the Plan requires the Plan Participants to adopt rules ''reasonably designed to prevent Trade-Throughs'', while exempting ISOs from that prohibition. The Plan's definition of an ISO is essentially the same as under Regulation NMS. The remaining exceptions to the trade-through prohibition, discussed more specifically below, either track those under Regulation NMS or correspond to unique aspects of the options market, or both.

The proposed rules in Chapter 27 (Options Order Protection and Locked and Crossed Markets Rules) conform to the requirements of the Plan. Proposed Rule 27.1 sets forth the defined terms for use under the Plan. Proposed Rule 27.2 prohibits trade-throughs and exempts ISOs from that prohibition. Proposed Rule 27.2 also contains additional exceptions to the trade-through prohibition that track the exceptions under Regulation NMS or correspond to unique aspects of the options market, or both.

Proposed Rule 27.3 sets forth the general prohibition against locking/crossing other eligible exchanges as well as certain enumerated exceptions that permit locked markets in limited circumstances; such exceptions have been approved by the Commission for inclusion in the rules of other options exchanges. Specifically, the exceptions to the general prohibition on locking and crossing occur when: (1) The locking or crossing quotation was displayed at a time when the Exchange was experiencing a failure, material delay, or malfunction of its systems or equipment; (2) the locking or crossing quotation was displayed at a time when there is a Crossed Market; or (3) the Options Member simultaneously routed an ISO to execute against the full displayed size of any locked or crossed Protected Bid or Protected Offer.

The Exchange notes that the proposed rules in Chapter 27 (Options Order Protection and Locked and Crossed Markets Rules) are substantively identical to the rules of BZX Options.[18]

Securities Traded on MEMX Options

General Listing Standards. The Exchange proposes to adopt listing standards for options traded on MEMX Options as described in Chapter 19 (Securities Traded on MEMX Options), as well as for index options as described in Chapter 29 (Index Rules), which are substantively identical to the approved rules of BZX Options.[19] The Exchange will join the Options Listings Procedures Plan and will list and trade options already listed on other options exchanges. The Exchange will gradually phase-in its trading of options, beginning with a selection of actively traded options. At least initially, the Exchange does not plan to develop new options products or listing standards.

Conduct and Operational Rules for Options Members

The Exchange proposes to adopt rules for MEMX Options that are substantively identical to the rules of BZX Options regarding: Exercises and deliveries as described in Chapter 23 (Exercises and Deliveries); records, reports and audits as described in Chapter 24 (Records, Reports and Audits); minor rule violations as described in Chapter 25 (Discipline and Summary Suspensions); doing business with the public as described in Chapter 26 (Doing Business With the Public); and margin as described in Chapter 28 (Margin Requirements).[20]

National Market System

MEMX Options will operate as a full and equal participant in the national market system for options trading established under Section 11A of the Exchange Act,[21] just as its equities market participates today. MEMX Options will become a member of the Options Price Reporting Authority (''OPRA''), the Options Linkage Authority (''OLA''), the Options Regulatory Surveillance Authority (''ORSA''), and the Options Listing Procedures Plan (''OLPP''). The Exchange expects to participate in those plans on the same terms currently applicable to current members of those

[17] *See, e.g.,* BZX Rule 22.12; CBOE Rule 5.9; MIAX Options Rule 520(b); BOX Rule IM–7140–3.

[18] *See* BZX Rules, Chapter XXVII.

[19] *See* BZX Rules, Chapters XIX and XXIX. The Exchange notes that it is initially proposing to adopt rules applicable to listing and trading of index options but has not proposed inclusion of references to any specific index options products or indices at this time and therefore has included a placeholder with the rule text ''(Reserved.)'' where such references would otherwise be. To the extent the Exchange does propose to list and trade certain index products in the future, the Exchange will file a proposed rule change with the Commission with respect to such products.

[20] *See* BZX Rules, Chapters XXIII, XXIV, XXV, XXVI and XXVIII.

[21] 15 U.S.C. 78k–1.

plans. The Exchange has contacted the leadership of each options-related national market system plan to begin the membership process.

Regulation

The Exchange will leverage many of the structures it established to operate a national securities exchange in compliance with Section 6 of the Exchange Act.[22] As described in more detail below, there will be three elements of that regulation: (1) The Exchange will join the existing options industry agreements pursuant to Section 17(d) of the Exchange Act,[23] as it did with respect to equities; (2) the Exchange's Regulatory Services Agreement with FINRA will govern many aspects of the regulation and discipline of Members that participate in options trading, just as it does for equities regulation; and (3) the Exchange will perform options listing regulation, as well as authorize Options Members to trade on MEMX Options, and conduct surveillance of options trading as it does today for equities. Section 17(d) of the Exchange Act and the related Exchange Act rules permit SROs to allocate certain regulatory responsibilities to avoid duplicative oversight and regulation. Under Exchange Act Rule 17d–1,[24] the SEC designates one SRO to be the Designated Examining Authority, or DEA, for each broker-dealer that is a member of more than one SRO. The DEA is responsible for the financial aspects of that broker-dealer's regulatory oversight. Because MEMX Options Members also must be members of at least one other SRO, the Exchange would generally not be designated as the DEA for any of its members.

Exchange Act Rule 17d–2 [25] permits SROs to file with the Commission plans under which the SROs allocate among each other the responsibility to receive regulatory reports from, and examine and enforce compliance with specified provisions of the Exchange Act and rules thereunder and SRO rules by, firms that are members of more than one SRO (''common members''). If such a plan is declared effective by the Commission, an SRO that is a party to the plan is relieved of regulatory responsibility as to any common member for whom responsibility is allocated under the plan to another SRO.

All of the options exchanges, FINRA, and NYSE have entered into the Options Sales Practices Agreement, a Rule 17d–2 agreement. Under this Agreement, the examining SROs will examine firms that are common members of the Exchange and the particular examining SRO for compliance with certain provisions of the Exchange Act, certain of the rules and regulations adopted thereunder, certain examining SRO rules, and certain proposed MEMX Options rules. In addition, the proposed MEMX Options rules contemplate participation in this Agreement by requiring that any Options Member also be a member of at least one of the examining SROs.

For those regulatory responsibilities that fall outside the scope of any Rule 17d–2 agreements, the Exchange will retain full regulatory responsibility under the Exchange Act. However, the Exchange has entered into a Regulatory Services Agreement with FINRA, pursuant to which FINRA personnel operate as agents for the Exchange in performing certain of these functions. As is the case with the Exchange's equities market, the Exchange will supervise FINRA and continue to bear ultimate regulatory responsibility for the MEMX Options Exchange.

Consistent with the Exchange's existing regulatory structure, the Exchange's Chief Regulatory Officer shall have general supervision of the regulatory operations of MEMX Options, including responsibility for overseeing the surveillance, examination, and enforcement functions and for administering all regulatory services agreements applicable to MEMX Options. Similarly, the Exchange's existing Regulatory Oversight Committee will be responsible for overseeing the adequacy and effectiveness of Exchange's regulatory and self-regulatory organization responsibilities, including those applicable to MEMX Options.

Finally, as it does with equities, the Exchange will perform automated surveillance of trading on MEMX Options for the purpose of maintaining a fair and orderly market at all times. As it does with its equities trading, the Exchange will monitor MEMX Options to identify unusual trading patterns and determine whether particular trading activity requires further regulatory investigation by FINRA.

In addition, the Exchange will oversee the process for determining and implementing trade halts, identifying and responding to unusual market conditions, and administering the Exchange's process for identifying and remediating ''obvious errors'' by and among its Options Members. The proposed rules in Chapter 20 (Regulation of Trading on MEMX Options) regarding halts, unusual market conditions, extraordinary market volatility, obvious errors, and audit trail are substantively identical to the approved rules of BZX Options, with the exception that Exchange does not propose to include rules permitting certain off-floor transfers of options traded on MEMX Options.[26]

Minor Rule Violation Plan

The Exchange's disciplinary rules, including Exchange Rules applicable to ''minor rule violations,'' are set forth in Chapter 8 of the Exchange's current Rules. Such disciplinary rules will apply to Options Members and their associated persons.

The Commission approved the Exchange's Minor Rule Violation Plan (''MRVP'') in 2020.[27] The Exchange's MRVP specifies those uncontested minor rule violations with sanctions not exceeding $2,500 that would not be subject to the provisions of Rule 19d–1(c)(1) under the Act [28] requiring that an SRO promptly file notice with the Commission of any final disciplinary action taken with respect to any person or organization.[29] The Exchange's MRVP includes the policies and procedures included in Exchange Rule 8.15 (Imposition of Fines for Minor Violation(s) of Rules) and in Exchange Rule 8.15, Interpretations and Policy .01.

The Exchange proposes to amend its MRVP and Exchange Rule 8.15, Interpretation and Policy .01 to include proposed Rule 25.3 (Penalty for Minor Rule Violations).[30] The rules included in proposed Rule 25.3 as appropriate for disposition under the Exchange's MRVP are: (a) Position limit and exercise limit violations; (b) violations regarding the

[22] 15 U.S.C. 78f.

[23] 15 U.S.C. 78q(d).

[24] 17 CFR 240.17d–1.

[25] 17 CFR 240.17d–2.

[26] *See* BZX Rules, Chapter XX.

[27] *See* Release No. 34–89836 (September 11, 2020), 85 FR 58081 (September 17, 2020) (Order Declaring Effective a Minor Rule Violation Plan) (''MRVP Order'').

[28] 17 CFR 240.19d–1(c)(1).

[29] The Commission adopted amendments to paragraph (c) of Rule 19d–1 to allow SROs to submit for Commission approval plans for the abbreviated reporting of minor disciplinary infractions. *See* Release No. 34–21013 (June 1, 1984), 49 FR 23828 (June 8, 1984). Any disciplinary action taken by an SRO against any person for violation of a rule of the SRO which has been designated as a minor rule violation pursuant to such a plan filed with and declared effective by the Commission will not be considered ''final'' for purposes of Section 19(d)(1) of the Act if the sanction imposed consists of a fine not exceeding $2,500 and the sanctioned person has not sought an adjudication, including a hearing, or otherwise exhausted his administrative remedies.

[30] In its proposal to adopt the MRVP, the Exchange requested that, going forward, to the extent that there are any changes to the rules applicable to the Exchange's MRVP, the Exchange requests that the Commission deem such changes to be modifications to the Exchange's MRVP.

failure to accurately report position and account information; (c) Market Maker quoting obligations; (d) violations regarding expiring exercise declarations; (e) violations relating to the failure to respond to the Exchange's requests for the submission of trade data; and (f) violations relating to noncompliance with the Consolidated Audit Trail Compliance Rule requirements. The rules included in proposed Rule 25.3 are the same as the rules included in the MRVPs of other options exchanges.[31]

Upon implementation of this proposal, the Exchange will include the enumerated options trading rule violations in the Exchange's standard quarterly report of actions taken on minor rule violations under the MRVP. The quarterly report includes: The Exchange's internal file number for the case, the name of the individual and/or organization, the nature of the violation, the specific rule provision violated, the fine imposed, the number of times the rule violation has occurred, and the date of disposition. The Exchange's MRVP, as proposed to be amended, is consistent with Sections 6(b)(1), 6(b)(5) and 6(b)(6) of the Act, which require, in part, that an exchange have the capacity to enforce compliance with, and provide appropriate discipline for, violations of the rules of the Commission and of the exchange.[32] In addition, because amended Rule 8.15 will offer procedural rights to a person sanctioned for a violation listed in proposed Rule 25.3, the Exchange will provide a fair procedure for the disciplining of members and associated persons, consistent with Section 6(b)(7) of the Act.[33]

This proposal to include the rules listed in proposed Rule 25.3 in the Exchange's MRVP is consistent with the public interest, the protection of investors, or otherwise in furtherance of the purposes of the Act, as required by Rule 19d–1(c)(2) under the Act,[34] because it should strengthen the Exchange's ability to carry out its oversight and enforcement responsibilities as an SRO in cases where full disciplinary proceedings are unsuitable in view of the minor nature of the particular violation. In requesting the proposed change to the MRVP, the Exchange in no way minimizes the importance of compliance with Exchange Rules and all other rules subject to the imposition of fines under the MRVP. However, the MRVP provides a reasonable means of addressing rule violations that do not rise to the level of requiring formal disciplinary proceedings, while providing greater flexibility in handling certain violations. The Exchange will continue to conduct surveillance with due diligence and make a determination based on its findings, on a case-by-case basis, whether a fine of more or less than the recommended amount is appropriate for a violation under the MRVP or whether a violation requires a formal disciplinary action.

Amendments to Existing Exchange Rules

In addition to the rules of MEMX Options proposed above, the Exchange proposes to amend certain of its existing Exchange Rules that currently apply to the Exchange's equities market in order to reflect the Exchange's proposed operation of MEMX Options.

First, the Exchange proposes to amend paragraph (d) of Interpretations and Policies .01 to Rule 2.5 (Restrictions), which generally requires each Member to register at least two Principals with the Exchange subject to certain exceptions described therein, to provide that such paragraph (d) shall not apply to a Member that solely conducts business on the Exchange as an Options Member, however, Options Members must comply with the registration requirements set forth in proposed Rule 17.2(g). The Exchange notes that proposed Rule 17.2(g), which provides that every Options Member shall have at least one Options Principal and sets forth the Exchange's Options Principal registration requirements, is identical to BZX Rule 17.2(g). In connection with this proposed change, the Exchange also proposes to amend paragraph (i) of Interpretations and Policies .01 to Rule 2.5 to include Options Principal as a registration category and to set forth the Exchange's qualification requirements for an Options Principal, which are the same as those for an Options Principal on BZX Options.

The Exchange also proposes to delete the word ''equities'' in the first sentence of Rule 2.7 (Revocation of Membership or Association with a Member), which currently provides that Members or associated persons of Members may effect approved equities securities transactions on the Exchange's trading facilities only so long as they possess all the qualifications set forth in the Exchange Rules. Thus, such proposed change is intended to make this statement no longer limited to equities securities transactions, as options transactions may also be effected on the Exchange pursuant to this proposal.

Lastly, the Exchange proposes to amend Interpretations and Policies .01 Rule 8.15 (Imposition of Fines for Minor Violation(s) of Rules), which contains the list of Exchange Rule violations and recommended fine schedule pursuant to Rule 8.15, to include a new paragraph (i) referencing proposed Rule 25.3 for the recommended fines for minor rule violations of the Exchange Rules appliable [sic] to MEMX Options, which the Exchange notes are the same as those of BZX Options.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act[35] in general, and furthers the objectives of Section 6(b)(5) of the Act[36] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As described above, the fundamental premise of the proposal is that the Exchange will operate its options market much as it operates its cash equities market today and in a manner similar to that of other options exchanges, with a simplified suite of order types and deterministic functionality leveraging the Exchange's existing robust and resilient technology platform. The Exchange believes MEMX Options will benefit individual investors, options trading firms, and the options market generally by providing an additional competitive dynamic to the options landscape, thereby promoting further initiative and innovation among market centers and market participants. The entry of an innovative, cost competitive market such as MEMX Options will promote competition, spurring existing exchanges to improve their own executions systems and reduce trading costs.

The Exchange proposes to offer a simplified suite of conventional order types and order type modifiers and other instructions that are designed to provide for an efficient, robust, and transparent order matching process. The

[31] *See, e.g.,* BZX Rules, Chapter XXV.

[32] 15 U.S.C. 78f(b)(1), 78f(b)(5) and 78f(b)(6).

[33] 15 U.S.C. 78f(b)(7).

[34] 17 CFR 240.19d–1(c)(2).

[35] 15 U.S.C. 78f(b).

[36] 15 U.S.C. 78f(b)(5).

basis for a majority of the proposed rules of MEMX Options are the approved rules of other options exchanges, primarily BZX Options, which have already been found consistent with the Exchange Act. Therefore, the Exchange does not believe that any of the proposed order types and order type functionality raise any new or novel issues that have not been previously considered by the Commission.

In few instances where the Exchange proposes functionality that differs from that of other options exchanges, it has done so to simplify and/or to improve upon an existing process. For instance, the Exchange believes the proposed operation of the Exchange's Risk Monitor Mechanism described in Rule 21.16, including the proposed functionality in addition to that provided under BZX Rule 21.16, removes impediments to and perfects the mechanism of a free and open market and a national market system by offering Users additional ways to establish and monitor risk parameters consistent with their overall approach to risk management. Specifically, the following additional proposed features with respect to its Risk Monitor Mechanism would provide Users with greater optionality when managing their risk on MEMX Options: (i) The ability to designate a Custom Group Limit to track risk parameters across a customized group of orders, (ii) the ability to suspend, rather than cancel or reject, resting orders when a risk limit has been reached, (iii) the ability to engage the Risk Monitor Mechanism for mass suspension as an alternative to mass cancellation, and (iv) the ability to utilize the proposed active risk counter to actively acknowledge executions, rather than waiting until a risk limit is reached or the counting program is completely reset. Additionally, the Exchange believes proposed Rule 21.17, which contains standard and Exchange-determined risk controls based on order type and market conditions that are the same as other options exchanges, as well as a simplified version of the drill-through price protection mechanism, removes impediments to and perfects the mechanism of a free and open market and a national market system by imposing risk controls that are designed to prevent orders from executing at prices inconsistent with the current market.

The Exchange further believes that the functionality that it proposes to offer is consistent with Section 6(b)(5) of the Act because the System is designed to be efficient and its operation transparent, thereby facilitating transactions in securities, removing impediments to and perfecting the mechanisms of a free and open national market system. As described above, the Exchange's proposed rules, including the proposed Order Types and Handling Instructions, opening procedures, routing services, and order matching process are designed to provide a simplified suite of conventional features and to comply with all applicable regulatory requirements, including the obligations of the Options Order Protection and Locked/Crossed Market Plan.

The Exchange believes that the proposed rules of MEMX Options, as well as the proposed method of monitoring for compliance with and enforcing such rules is also consistent with the Exchange Act, particularly Sections 6(b)(1), 6(b)(5) and 6(b)(6) of the Exchange Act, which require, in part, that an exchange have the capacity to enforce compliance with, and provide appropriate discipline for, violations of the rules of the Commission and of the exchange. The Exchange has proposed to adopt rules necessary to regulate Options Members that are nearly identical to the approved rules of other options exchanges, as described above. The Exchange proposes to regulate activity on MEMX Options in the same way it regulates activity on its equities market, specifically through various Exchange specific functions, an RSA with FINRA, as well as participation in industry plans, including plans pursuant to Rule 17d–2 under the Exchange Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in an intensely competitive global marketplace for transaction services. Relying on its array of services and benefits, the Exchange competes for the privilege of providing market services to broker-dealers. The Exchange's ability to compete in this environment is based in large part on the quality of its trading systems, the overall quality of its market and its attractiveness to the largest number of investors, as measured by speed, likelihood and cost of executions, as well as spreads, fairness, and transparency.

Consolidation amongst U.S. options exchanges has led to concentration of ownership by certain exchange groups, thereby diminishing the competitive landscape among options exchanges. This proposal will enhance competition by allowing the Exchange to leverage its existing robust technology platform to provide a resilient, deterministic, and transparent execution platform for options. The proposed rule change will insert an additional competitive dynamic to the options landscape by allowing the Exchange to compete with existing options exchanges and will promote further initiative and innovation among market centers and market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 90 days of the date of publication of this notice in the **Federal Register**, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.[37]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–MEMX–2022–10 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MEMX–2022–10. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/*

[37] In its filing, MEMX consented to an extension of time for Commission action to ninety (90) days after the date of publication of the proposal.

rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street, NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MEMX–2022–10, and should be submitted on or before May 31, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[38]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09958 Filed 5–9–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–497, OMB Control No. 3235–0555]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 6h–1

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 6h–1 (17 CFR 240.6h–1) under the Securities Exchange Act of 1934 (''Act'') (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Section 6(h) of the Act (15 U.S.C. 78f(h)) requires national securities exchanges and national securities associations that trade security futures products to establish listing standards that, among other things, require that: (i) Trading in such products not be readily susceptible to price manipulation; and (ii) the market on which the security futures product trades has in place procedures to coordinate trading halts with the listing market for the security or securities underlying the security futures product. Rule 6h–1 implements these statutory requirements and requires that (1) the final settlement price for each cash-settled security futures product fairly reflect the opening price of the underlying security or securities, and (2) the exchanges and associations trading security futures products halt trading in any security futures product for as long as trading in the underlying security for trading of a security futures product based on a single security, or trading in 50% or more of the underlying securities for trading of a security futures product based on a narrow-based security index, is halted on the listing market.

It is estimated that approximately 1 respondent will incur an average burden of 10 hours per year to comply with this rule, for a total burden of 10 hours. At an average internal cost per hour of approximately $428, the resultant total internal cost of compliance for the respondents is $4,280 per year (1 respondent × 10 hours/respondent × $428/hour).

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by July 11, 2022.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: May 4, 2022.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09952 Filed 5–9–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94851; File No. SR–PEARL–2022–15]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt Exchange Rule 532, Order Price Protection Mechanisms and Risk Controls

May 4, 2022.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 21, 2022 MIAX PEARL, LLC (''MIAX Pearl'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt new Exchange Rule 532, Order Price Protection Mechanisms and Risk Controls, and a new Max Put Price Protection feature in new proposed Rule 532.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/pearl* at MIAX PEARL's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for

[38] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt new Exchange Rule 532, Order Price Protection Mechanisms and Risk Controls. The Exchange proposes to adopt a new Managed Protection Override feature, and a new Max Put Price Protection feature in new proposed Rule 532.

Proposal

Max Put Price Protection (''MPPP'')

The Exchange proposes to adopt a new price protection for put [3] options by establishing a maximum price at which a put option may trade.[4] To determine the maximum price the Exchange will add a pre-set value of $0.10 to the strike price of the put option. Buy orders from an Electronic Exchange Member (''EEM'') [5] that are priced through the maximum trading price limit will trade up to, and including, the maximum trading price limit, and will then be placed on the Book [6] and managed to the appropriate trading price limit as described in Rule 515(d)(2), or cancelled if the Managed Protection Override (''MPO'') (as described below) is enabled. Sell orders from an EEM that are priced higher than the maximum trading price limit will be rejected.

Buy orders from a Market Maker (''MM'') [7] that are priced through the maximum trading price limit will trade up to, and including, the maximum trading price limit, then will be placed on the Book and managed to the appropriate trading price limit as described in Rule 515(d)(2). Sell orders from a Market Maker that are priced higher than the maximum trading price limit will be displayed.

Example Max Put Price Protection for a Buy Market Order

An order to buy 10 XYZ Jan 5 Put @ market [8] is received from an EEM.

The current market is:

PBBO [9] 0.50 (10) × 5.50 (10)

The price protection is:

Put Price Variance (PPV) = $0.10
Max Put Price Protection = (Strike + PPV) = $5.10

The Max Put Price Protection establishes the maximum trading price limit at which an order can trade. Because the buy order is priced through the Max Put Price Protection of $5.10, the order is subject to management pursuant to 515(d)(2) and is posted to the Book at $5.10.

PBBO 5.10 (10) × 5.50 (10)

Example Max Put Price Protection for a Sell Limit Order

An order to sell 10 XYZ Jan 5 Put @ $5.25 is received from an EEM.

The current market is:

PBBO 0.50 (10) × 5.50 (10)

The price protection is:

Put Price Variance (PPV) = $0.10
Put Option = XYZ Jan 5 Put
Max Put Price Protection = (Strike + PPV) = $5.10

Because the sell order is priced higher than the Max Put Price Protection of $5.10, the order is rejected.

For the purposes of the Max Put Price Protection, the Exchange treats an order to sell a put option priced above the maximum trading price limit received from Electronic Exchange Members differently than a similar order received from a Market Maker. Members that are Market Makers have a heightened obligation on the Exchange and are obligated to maintain a two-sided market in those option series in which the Market Maker is registered to trade.[10] Further, Market Makers are required to submit continuous bids and offers for the options series in their appointed classes for a certain percentage of time in each trading session.[11] As such, the Exchange treats Market Maker orders differently than EEM orders, and will not reject an order to sell a put option from a Market Maker that is priced higher than the maximum trading price limit.

Managed Protection Override (''MPO'')

The Exchange proposes to adopt a new Managed Protection Override feature which will work in conjunction with the Max Put Price Protection. Members must contact the Exchange's Help Desk [12] to enable the Managed Protection Override feature. When the Max Put Price Protection is triggered, and if the Managed Protection Override feature has been enabled, the order subject to the Max Put Price Protection will be cancelled. The Managed Protection Override is currently only available for the Max Put Price Protection proposed herein.

The Exchange believes that offering Members the option to have their orders either managed by the Exchange or cancelled when the Max Put Price Protection is triggered gives Members greater flexibility and control over their orders while retaining the risk protection functionality. If the Managed Protection Override is enabled the Exchange will return the unexecuted order to the Member for further analysis and evaluation. If the Managed Protection Override is not enabled the Exchange will manage the unexecuted order on behalf of the Member.

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act [13] in general, and furthers the objectives of Section 6(b)(5) of the Act [14] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in, securities, to remove impediments to and perfect the

[3] The term ''put'' means an option contract under which the holder of the option has the right, in accordance to the terms and provisions of the option, to sell to the Clearing Corporation the number of units of the underlying security covered by the option contract. *See* Exchange Rule 100.

[4] The Exchange notes its affiliate Exchange, the MIAX Options Exchange, recently adopted this protection. *See* Securities Exchange Act Release No. 94353 (March 3, 2022), 87 FR 13339 (March 9, 2022) (SR–MIAX–2021–58).

[5] The term ''Electronic Exchange Member'' or ''EEM'' means the holder of a Trading Permit who is a Member representing as agent Public Customer Orders or Non-Customer Orders on the Exchange and those non-Market Maker Members conducting proprietary trading. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[6] The term ''Book'' means the electronic book of buy and sell orders and quotes maintained by the System. *See* Exchange Rule 100.

[7] The term ''Market Maker'' or ''MM'' means a Member registered with the Exchange for the purposes of making markets in option contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI or the MIAX Pearl Rulebook. *See* Exchange Rule 100.

[8] A market order is an order to buy or sell a stated number of option contracts at the best price available at the time of execution. A Market Maker may not submit a market order. *See* Exchange Rule 516(b).

[9] The term ''PBBO'' means the best bid or offer on MIAX Pearl. *See* Exchange Rule 100.

[10] *See* Exchange Rule 604(a)(1).

[11] *See* Exchange Rule 605.

[12] The term ''Help Desk'' means the Exchange's control room consisting of Exchange staff authorized to make certain trading determinations on behalf of the Exchange. The Help Desk shall report to and be supervised by a senior executive officer of the Exchange. *See* Exchange Rule 100.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

Max Put Price Protection

The Exchange believes that the Max Put Price Protection feature promotes just and equitable principles of trade, removes impediments to and perfects the mechanism of a free and open market and a national market system and, in general, protects investors and the public interest by providing a risk protection mechanism to prevent trades from occurring at potentially unwanted or erroneous prices. The Exchange believes that the Max Put Price Protection feature promotes a fair and orderly market by mitigating the potential risks associated with orders trading at potentially erroneous prices.

The Exchange believes that its proposal to accept and display a Market Maker order to sell a put that is priced higher than the maximum trading price limit promotes a free and open market and national market system as Market Makers on the Exchange have heightened obligations on the Exchange that Electronic Exchange Members do not, that requires Market Makers to submit continuous bids and offers in the series to which they are appointed in order to enhance the depth, liquidity, and competitiveness of the market.[15]

Managed Protection Override

The Exchange believes that the Managed Protection Override feature promotes just and equitable principles of trade, removes impediments to and perfects the mechanism of a free and open market and a national market system and, in general, protects investors and the public interest by providing a mechanism by which Members may determine the way their orders are handled when a risk protection is triggered. The Exchange believes that it has an effective way to manage orders on the Exchange so that they do not execute at potentially erroneous prices, however the Exchange believes that giving Members the option to have their orders cancelled if a risk protection is triggered protects investors and the public interest. When the Exchange cancels an order, a Member can make a decision on what to do with that order based on the then current market conditions and may choose to re-submit the order at the same or different limit price. Specifically, the Exchange believes the proposed change will remove impediments to and perfect the mechanism of a free and open market by providing market participants with the option to either manage their own orders or have the Exchange manage their orders when a price protection is triggered which will promote fair and orderly markets, increase overall market confidence, and promote the protection of investors.

The Exchange believes that offering Members the option to have orders either managed by the Exchange or cancelled when the Max Put Price risk protection is triggered gives Members greater flexibility and control over their orders to buy puts while retaining the risk protection functionality. If the Managed Protection Override is enabled the Exchange will return the unexecuted order to the Member for further analysis and evaluation. If the Managed Protection Override is not enabled the Exchange will manage the unexecuted order on behalf of the Member.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Specifically, the Exchange does not believe that the proposed changes will impose any burden on intra-market competition as the rules of the Exchange apply equally to all MIAX Pearl Members. The Max Put Price Protection is applicable to all MIAX Pearl Members that submit an order to buy a put option. Additionally, any MIAX Pearl Member may elect to enable the Managed Protection Override functionality to allow the Exchange to cancel their order when the Max Put Price Protection risk protection is triggered.

The Exchange does not believe that its proposal to provide dissimilar treatment for sell put orders priced above the maximum trading price limit submitted by EEMs and MMs will impose any burden on intra-market competition as Market Makers have heightened obligations on the Exchange and are required to submit continuous bids and offers in the series to which they are appointed.

In addition, the Exchange does not believe the proposal will impose any burden on inter-market competition as the proposal is intended to protect investors by providing additional price protection functionality. The Exchange's proposal may promote inter-market competition as the Exchange's proposal adds additional price protection features and functionality that may attract additional order flow to the Exchange, thereby promoting inter-market competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act[16] and Rule 19b–4(f)(6)[17] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–PEARL–2022–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–PEARL–2022–15. This file number should be included on the

[15] *See supra* notes 10 and 11.

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–PEARL–2022–15, and should be submitted on or before May 31, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09961 Filed 5–9–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34578; File No. 812–15333]

Voya Russia Fund, a Series of Voya Mutual Funds, and Voya Investments, LLC; Notice of Application and Temporary Order

May 4, 2022.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application and a temporary order under Section 22(e)(3) of the Investment Company Act of 1940 (the ''Act'').

SUMMARY OF APPLICATION: Applicants request a temporary order to permit Voya Russia Fund (the ''Fund''), a series of Voya Mutual Funds (the ''Trust''), to suspend the right of redemption of its outstanding redeemable securities and postpone the date of payment of redemption proceeds with respect to redemption orders received but not yet paid.

APPLICANTS: The Trust, on behalf of the Fund, and Voya Investments, LLC, the Fund's investment adviser (''Adviser'' and together with the Trust, the ''Applicants'').

FILING DATE: The application was filed on May 4, 2022.

HEARING OR NOTIFICATION OF HEARING: Interested persons may request a hearing by emailing to the Commission's Secretary at *Secretarys-Office@sec.gov* and serving Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on May 31, 2022, and should be accompanied by proof of service on Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary at *Secretarys-Office@sec.gov*.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Timothy W. Diggins, Esq. and Elizabeth J. Reza, Esq., Ropes & Gray LLP, Prudential Tower, 800 Boylston Street, Boston, MA 02199–3600, with copies to Huey P. Falgout, Jr., Esq., Voya Investments, LLC, 7337 East Doubletree Ranch Road, Suite 100, Scottsdale, Arizona 85258.

FOR FURTHER INFORMATION CONTACT: Christopher D. Carlson, Senior Counsel, Kaitlin Bottock, Branch Chief, or Nadya Roytblat, Assistant Chief Counsel, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' application, dated May 4, 2022, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at *https://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

Background

1. The Trust is registered under the Act as an open-end series management investment company. Adviser is the investment adviser to the Fund, a series of the Trust. Adviser is registered as an investment adviser under the Investment Advisers Act of 1940.

2. Applicants state that the request for relief arises from the effect of geopolitical affairs on transactions in the Russian equity markets and on the relevant markets for Russian equity securities generally, and on related clearance and payment systems. As a result of these geopolitical affairs, virtually all of the Fund's direct and indirect holdings of Russian equity securities have become illiquid and are fair valued at zero ($0.00).

3. If the order requested in the Application is granted, the Fund will distribute in liquidation all of its liquid assets to shareholders, less a reserve in an amount estimated to meet the costs of the liquidation and the continued limited operation of the Fund through its final termination. Following that distribution, the Fund will have no assets of value (other than the amount so held in reserve), and the Fund's positions in Russian securities will not be transferable by the Fund. If some or all of those Russian securities were at some point before the Fund's final termination determined to have a non-zero value, it is possible that they would continue to not be transferable at that time.

4. Applicants believe the requested relief will permit the Fund to liquidate its holdings in the manner described above without the risk that it might be required to meet redemption requests submitted potentially out of the reserve or otherwise when the Fund would have no or few assets to meet the redemption requests. In addition, applicants state that suspension of redemptions prior to the initial distribution in liquidation will ensure that shareholders submitting such redemption requests will participate in the liquidation and also will be entitled to share both in the May 2022 liquidating distribution and any subsequent liquidating distribution.

Relief Requested

1. Applicants request an order pursuant to Section 22(e) of the Act to suspend the right of redemption with respect to shares of the Fund effective

[18] 17 CFR 200.30–3(a)(12).

May 4, 2022, and postpone the date of payment of redemption proceeds with respect to redemption orders received on or after April 27, 2022 but not yet paid as of May 4, 2022, for more than seven days after the tender of securities to the Fund, until the Fund completes the liquidation of its portfolio and distributes all its assets to the shareholders, or until the Commission rescinds the order granted herein. Applicants believe that the relief requested is appropriate for the protection of shareholders of the Fund.

Applicants' Legal Analysis

1. Section 22(e)(1) of the Act provides that a registered investment company may not suspend the right of redemption or postpone the date of payment or satisfaction upon redemption of any redeemable security in accordance with its terms for more than seven days after the tender of such security to the company or its designated agent except for any period during which the New York Stock Exchange (''NYSE'') is closed other than customary week-end and holiday closings, or during which trading on the NYSE is restricted.

2. Section 22(e)(3) of the Act provides that redemptions may be suspended by a registered investment company for such other periods as the Commission may by order permit for the protection of security holders of the registered investment company.

3. Applicants submit that granting the requested relief would be for the protection of the shareholders of the Fund, as provided in Section 22(e)(3) of the Act. Applicants assert that, in requesting an order by the Commission, the Applicants' goal is to ensure that the Fund's shareholders will be treated appropriately in view of the otherwise detrimental effect on the Fund of the illiquidity of the Fund's investments and the ongoing uncertainty surrounding the relevant markets for the Russian equity securities held by the Fund. The requested relief is intended to permit an orderly liquidation of the Fund's portfolio and ensure that all of the Fund's shareholders are protected in the process.

Applicants' Conditions

Applicants agree that any order of the Commission granting the requested relief will be subject to the following conditions:

1. The Board, including a majority of the independent Trustees, will adopt or has adopted the Plan of Liquidation for the orderly liquidation of Fund assets and distribution of appropriate payments to Fund shareholders.

2. Pending liquidating distributions, the Fund will invest proceeds of cash dispositions of portfolio securities solely in U.S. government securities, money market funds that are registered under the 1940 Act and comply with the requirements of Rule 2a–7 under that Act, cash equivalents, securities eligible for purchase by a registered money market fund meeting the requirements of Rule 2a–7 under the 1940 Act with legal maturities not in excess of 90 days and, if determined to be necessary to protect the value of a portfolio position in a rights offering or other dilutive transaction, additional securities of the affected issuer.

3. The Fund's assets will be distributed to the Fund's shareholders solely in accordance with the Plan of Liquidation.

4. The Fund and the Adviser will make and keep true, accurate and current all appropriate records, including but not limited to those surrounding the events leading to the requested relief, the Plan of Liquidation, the sale of Fund portfolio securities, the distribution of Fund assets, and communications with shareholders (including any complaints from shareholders and responses thereto).

5. The Fund and the Adviser will promptly make available to Commission staff all files, books, records and personnel, as requested, relating to the Fund.

6. The Fund and the Adviser will provide periodic reporting to Commission staff regarding their activities carried out pursuant to the Plan of Liquidation.

7. The Adviser, its affiliates, and its and their associated persons will not receive any fee for managing the Fund.

8. The Fund will be in liquidation and will not be engaged and does not propose to engage in any business activities other than those necessary for the protection of its assets, the protection of shareholders and the winding-up of its affairs, as contemplated by the Plan of Liquidation.

9. The Fund and the Adviser will appropriately convey accurate and timely information to shareholders of the Fund, before or promptly following the effective date of the liquidation, with regard to the status of the Fund and its liquidation (including posting such information on the Fund's website), and will thereafter from time to time do so to reflect material developments relating to the Fund or its status, including, without limitation, information concerning the dates and amounts of distributions, and press releases and periodic reports, and will maintain a toll-free number to respond to shareholder inquiries.

10. The Fund and the Adviser shall consult with Commission staff prior to making any material amendments to the Plan of Liquidation.

Commission Finding

Based on the representations and conditions in the application, the Commission permits the temporary suspension of the right of redemption for the protection of the Fund's security holders. Under the circumstances described in the application, which require immediate action to protect the Fund's security holders, the Commission concludes that it is not practicable to give notice or an opportunity to request a hearing before issuing the order.

Accordingly, in the matter of Voya Russia Fund, a series of Voya Mutual Funds, and Voya Investments, LLC (File No. 812–15333),

It is ordered, pursuant to Section 22(e)(3) of the Act, that the requested relief from Section 22(e) of the Act is granted with respect to the Fund until it has liquidated, or until the Commission rescinds the order granted herein. This order shall be in effect as of May 4, 2022, with suspension of redemption rights as requested by the Applicants to be effective as of May 4, 2022 and the postponement of payment of redemption proceeds to apply to redemption orders received on or after April 27, 2022 but not yet paid as of May 4, 2022.

By the Commission.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09946 Filed 5–9–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94843; File No. SR–NYSEArca–2022–25]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change To Modify Rule 7.31–E To Add Subparagraph (f)(4) Regarding Directed Orders

May 4, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on April 20, 2022, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify Rule 7.31–E to add subparagraph (f)(4) regarding Directed Orders and make other conforming changes. The proposed change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify Rule 7.31–E (Orders and Modifiers) to add new subparagraph (f)(4) to provide for Directed Orders and to make other conforming changes to its Rules in connection with the addition of this new order type on the Exchange. The Directed Order, as further defined below, would be an order sent to the Exchange to be routed directly to an alternative trading system (''ATS'') specified by an ETP Holder.

The Exchange proposes to add Rule 7.31–E(f)(4), which would define a Directed Order as a Limit Order with instructions to route on arrival at its limit price to a specified ATS with which the Exchange maintains an electronic linkage. Proposed Rule 7.31–E(f)(4) would further provide that Directed Orders would be available for all securities eligible to trade on the Exchange. Proposed Rule 7.31–E(f)(4) would also provide that a Directed Order would not be assigned a working time or interact with interest on the NYSE Arca Book. The Exchange also proposes to provide in Rule 7.31–E(f)(4) that the ATS to which a Directed Order is routed would be responsible for validating whether the order is eligible to be accepted, and if such ATS determines to reject the order, the order would be cancelled.

Proposed Rule 7.31–E(f)(4)(A) would provide that a Directed Order must be designated for the Exchange's Core Trading Session, as defined in Rule 7.34–E(a)(2).[4]

Proposed Rule 7.31–E(f)(4)(A) would further provide that a Directed Order must be designated with a Time in Force modifier of IOC[5] or Day[6] and would be routed to the specified ATS with such modifier. The Exchange proposes that a Directed Order designated IOC would be traded in whole or in part on the ATS to which it is routed after receipt of the order, and any untraded quantity would be cancelled. The Exchange proposes that a Directed Order designated Day would expire at the end of the Core Trading Session on the day it is entered. Proposed Rule 7.31–E(f)(1)(A) would also provide that a Directed Order may not be designated with any other modifiers defined in Rule 7.31–E.

Proposed Rule 7.31–E(f)(4)(B) would provide that a Directed Order in a security that is having its initial listing on the Exchange would be rejected if received before the IPO Auction concludes.

Proposed Rule 7.31–E(f)(4)(C) would provide that, during a trading halt or pause, an incoming Directed Order would be rejected.

Proposed Rule 7.31–E(f)(4)(D) would provide that a request to cancel a Directed Order designated Day would be routed to the ATS to which the order was routed.

The Exchange also proposes a conforming change to Rule 7.19–E (Pre-Trade Risk Controls). The Exchange proposes to modify Rule 7.19–E(a)(5), which sets forth the definition of Gross Credit Risk Limit and currently provides that unexecuted orders in the NYSE Arca Book, orders routed on arrival pursuant to Rule 7.37–E(a)(1), and executed orders are included for purposes of calculating the Gross Credit Risk Limit. The Exchange proposes to modify Rule 7.19–E(a)(5) to specify that orders routed on arrival pursuant to Rule 7.31–E(f)(4) would also be included for purposes of the Gross Credit Risk Limit calculation.

The Exchange believes that the proposed rule change would facilitate additional trading opportunities by offering ETP Holders the ability to designate orders submitted to the Exchange to be routed to an ATS of their choosing for execution. The Exchange believes the proposed change would encourage ETP Holders to utilize the Exchange as a venue for order entry and further believes that the proposed change could create efficiencies for ETP Holders by enabling them to send orders that they wish to route to an alternate destination through the Exchange, thereby enabling them to leverage order entry protocols and specifications already configured for their interactions with the Exchange. The Exchange notes that the Directed Order, as proposed, would operate similarly to the Primary Only Order already offered by the Exchange, which is an order that is routed directly to the primary listing market on arrival, without being assigned a working time or interacting with interest on the NYSE Arca Book.[7] The Exchange also believes that the Directed Order would offer ETP Holders functionality akin to order types and routing options that currently exist on other equities exchanges.[8]

[4] Because the Exchange proposes that Directed Orders may only be designated for the Core Trading Session, the Exchange also proposes conforming changes to Rule 7.34–E (Trading Sessions). Specifically, the Exchange proposes to modify Rule 7.34–E(c)(1)(E) to provide that Directed Orders designated for the Early Trading Session would be rejected and Rule 7.34–E(c)(3)(C) to provide that Directed Orders designated for the Late Trading Session would be rejected.

[5] *See* Rule 7.31–E(b)(2), which provides that a Limit Order may be designated with an Immediate-or-Cancel (''IOC'') modifier.

[6] *See* Rule 7.31–E(b)(1), which provides that orders may be designated with a Day modifier, and that an order to buy or sell designated Day, if not traded, will expire at the end of the designated session on the day on which it was entered.

[7] *See* Rule 7.31–E(f)(1). NYSE Arca also offers variations of the Primary Only Order, including the Primary Only Until 9:45 Order, which is a Limit or Inside Limit Order that, on arrival and until 9:45 a.m. Eastern Time, routes to the primary listing market, and the Primary Only Until 3:55 Order, which is a Limit or Inside Limit Order entered on the Exchange until 3:55 p.m. Eastern Time, after which time the order is cancelled on the Exchange and routed to the primary listing market. *See* Rules 7.31–E(f)(2) and (f)(3). The Exchange's affiliated exchanges NYSE American LLC (''NYSE American''), NYSE Chicago, Inc. (''NYSE Chicago''), and NYSE National, Inc. (''NYSE National'') (collectively, the ''Affiliated Exchanges'') also offer the Primary Only Order and variations thereof. *See* NYSE American Rules 7.31E(f)(1)–(f)(3); NYSE Chicago Rules 7.31(f)(1)–(f)(3); NYSE National Rules 7.31(f)(1)–(f)(3).

[8] *See, e.g.,* Nasdaq Stock Market LLC (''Nasdaq''), Equity 4, Equity Trading Rules, Rule 4758(a)(ix) (defining the Nasdaq Directed Order as an order designed to use a routing strategy under which the order is directed to an automated trading center other than Nasdaq, as directed by the entering party, without checking the Nasdaq Book); Cboe EDGX Exchange, Inc. (''EDGX'') Rules 11.8(c)(7)

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date by Trader Update.[9] Subject to effectiveness of this proposed rule change, the Exchange anticipates that the proposed change will be implemented in the second quarter of 2022.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934,[10] in general, and furthers the objectives of Section 6(b)(5),[11] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market and promote just and equitable principles of trade because the Directed Order would offer ETP Holders access to additional trading opportunities by permitting them to designate orders submitted to the Exchange to be routed directly to a specified ATS for execution. The Exchange further believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market by offering ETP Holders the option to send orders that they wish to route to an alternate destination for execution through the Exchange, which would create efficiencies to the extent ETP Holders are able to leverage existing protocols and specifications. Finally, the Exchange notes that the proposed functionality is not novel, as both the Exchange and other exchanges offer their members functionality whereby an exchange routes orders on behalf of a member to a specified trading center without such order interacting with the exchange's book.[12]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rules governing Directed Orders would promote competition because they would provide for an order type on the Exchange that would facilitate additional trading opportunities for market participants. The Exchange further believes that the proposed rules would allow it to offer ETP Holders functionality similar to order types and routing options that exist on other equities exchanges, thereby enabling the Exchange to compete with such exchanges.[13]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEARCA–2022–25 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2022–25. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All

(defining the Routing/Directed ISO order type as an ISO that bypasses the EDGX system and is immediately routed by EDGX to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe EDGA Exchange, Inc. (''EDGA'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGA system and is immediately routed by EDGA to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe BZX Exchange, Inc. (''BZX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BZX system and be sent to a specified away trading center); Cboe BYX Exchange, Inc. (''BYX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BYX system and be sent to a specified away trading center). The Exchange also believes that the Directed Order would provide functionality similar to the C–LNK routing strategy formerly offered by EDGA, in which C–LNK orders bypassed EDGA's local book and routed directly to a specified Single Dealer Platform destination. *See* Securities Exchange Act Release No. 82904 (March 20, 2018), 83 FR 12995 (March 26, 2018) (SR–CboeEDGA–2018–004) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Expand an Offering Known a Cboe Connect To Provide Connectivity to Single-Dealer Platforms Connected to the Exchange's Network and To Propose a Per Share Executed Fee for Such Service).

[9] The Exchange will also provide information regarding the ATS(s) to which a Directed Order may be designated to route by Trader Update.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] *See* notes 7 & 8, *supra.*

[13] *See* note 8, *supra.*

submissions should refer to File Number SR–NYSEARCA–2022–25 and should be submitted on or before May 31, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09956 Filed 5–9–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94850; File No. SR–MSRB–2022–02]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Filing of a Proposed Rule Change Consisting of Amendments to MSRB Rule G–19 Regarding Regulation Best Interest for Certain Municipal Securities Activities of Bank Dealers and MSRB Rule G–48 Regarding Quantitative Suitability for Institutional Sophisticated Municipal Market Professionals

May 4, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 29, 2022, the Municipal Securities Rulemaking Board (''MSRB or ''Board'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the MSRB. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The MSRB filed with the Commission a proposed rule change consisting of amendments to: (i) MSRB Rule G–19, on suitability of recommendations and transactions, and (ii) MSRB Rule G–48, on transactions with sophisticated municipal market professionals (''SMMPs'')[3] (collectively, the ''proposed rule change''). The proposed rule change would align MSRB Rule G–19 to the Commission's Rule 15*l*–1 under the Exchange Act (''Regulation Best Interest'')[4] for certain municipal securities activities of bank dealers[5] (the ''Best Interest Amendments''). In addition, the proposed rule change would amend MSRB Rule G–48 to modify the quantitative suitability obligation of brokers, dealers, and municipal securities dealers (collectively, ''dealers'' and, individually, each a ''dealer'') by eliminating the quantitative suitability obligation for recommendations in circumstances where a dealer does not have actual control or de facto control over the account of an Institutional SMMP (the ''Institutional SMMP Amendment'').[6]

Subject to Commission approval, the respective compliance dates for the amendments to MSRB rules included in the proposed rule change will be announced in a regulatory notice published by the MSRB on its website within 30 days of the publication of the Commission's approval order in the **Federal Register**. Such compliance date for the Best Interest Amendments will be no earlier than one year from the MSRB's publication of the regulatory notice announcing it.[7] Such compliance date for the Institutional SMMP Amendment will be no earlier than 30 days from the MSRB's publication of the regulatory notice announcing it.

The text of the proposed rule change is available on the MSRB's website at *www.msrb.org/Rules-and-Interpretations/SEC-Filings/2022-Filings.aspx,* at the MSRB's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the MSRB included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The MSRB has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The proposed rule change consists of the Best Interest Amendments to MSRB Rule G–19 and the proposed Institutional SMMP Amendment to MSRB Rule G–48 for the respective purposes further described below.

Background and Purpose of the Best Interest Amendments

The proposed Best Interest Amendments would amend MSRB Rule G–19 to extend the obligations of Regulation Best Interest to Bank Dealers when making recommendations to retail customers of municipal securities transactions or investment strategies involving municipal securities (collectively, ''retail municipal recommendations'' and, individually, each a ''retail municipal recommendation''). The Best Interest Amendments are intended to improve investor protection in the municipal securities market by ensuring that retail customers are afforded investor protections under Regulation Best Interest, regardless of whether a retail municipal recommendation received by a retail customer is made by a Broker-Dealer or a Bank Dealer.[8]

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[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Under MSRB Rule D–15, on the term sophisticated municipal market professional, ''[t]he term 'sophisticated municipal market professional' or 'SMMP' is generally defined by three essential requirements: the nature of the customer; a determination of sophistication by the broker, dealer or municipal securities dealer [ ]; and an affirmation by the customer; as specified [therein].'' *See* MSRB Rule D–15. *See also* related discussion under *Background and Purpose of the Institutional SMMP Amendment—Background on MSRB Rule D–15 and SMMP Affirmation Requirements* near note 37 *infra.*

[4] 17 CFR 240.15*l*–1; *see also* Exchange Act Release No. 86031 (June 5, 2019), 84 FR 33318 (July 12, 2019) (File No. S7–07–18) (''Regulation Best Interest Adopting Release'').

[5] Consistent with MSRB Rule D–8, on the term bank dealer, the term ''bank dealer'' as used herein means ''a municipal securities dealer which is a bank or a separately identifiable department or division of a bank as defined in rule G–1 of the Board.'' Such references in this proposed rule shall be collectively to ''Bank Dealers'' or individually to a ''Bank Dealer.'' *See also* MSRB Rule D–11, on the term associated persons (indicating that the term bank dealer as used in MSRB rules shall generally refer to the associated persons of a bank dealer unless the context otherwise requires or a rule of the Board otherwise specifically provides).

[6] The term ''Institutional SMMP'' is used here as defined below under the discussion *Background and Purpose of the Institutional SMMP Amendment.* The Institutional SMMP definition used herein would not encompass any natural person customers who qualify as ''retail customers'' under the definitions of Regulation Best Interest, such as certain natural persons with significant total assets, who might otherwise meet the status requirements of an SMMP. *See* note 20 *infra* and related discussion under *Background and Purpose of the Institutional SMMP Amendment.*

[7] This one-year minimum timeframe is roughly equivalent to the timeframe provided by the Commission when it adopted Regulation Best Interest. *See* Regulation Best Interest Adopting Release, 84 FR at 33318, 33400 (setting an effective date of September 10, 2019 and a compliance date of June 30, 2020).

[8] The term ''Broker-Dealer'' is used here as defined below under the following discussion *Background on the Commission's Regulation Best Interest.*

Background on the Commission's Regulation Best Interest

On June 5, 2019, the SEC adopted Regulation Best Interest, which established a new standard of conduct for broker-dealers, and the natural persons who are associated persons of such broker-dealers (collectively, ''Broker-Dealers'' and, individually, each a ''Broker-Dealer''), when making a recommendation to a retail customer of any securities transaction or investment strategy involving securities.[9] As defined in Regulation Best Interest, the term ''retail customer'' generally refers to any natural person, or the legal representative of such person, who receives and uses a recommendation from a Broker-Dealer primarily for personal, family, or household purposes.[10] Regulation Best Interest enhanced the Broker-Dealer standard of conduct beyond existing suitability obligations, such as those required by MSRB Rule G–19, on suitability, for such retail customers and aligned the applicable standard of conduct with the reasonable expectations of retail customers.[11] In this regard, Regulation Best Interest imposes the following ''general obligation'' on Broker-Dealers, stating a broker, dealer, or a natural person who is an associated person of a broker or dealer, when making a recommendation of any securities transaction or investment strategy involving securities (including account recommendations) to a retail customer, shall act in the best interest of the retail customer at the time the recommendation is made, without placing the financial or other interest of the broker, dealer, or natural person who is an associated person of a broker or dealer making the recommendation ahead of the interest of the retail customer.[12]

Discussion of Regulation Best Interest's Current Applicability to Bank Dealers

By its terms, Regulation Best Interest does not apply to retail municipal recommendations made by Bank Dealers, because Bank Dealers in exempted securities have an exception from Broker-Dealer status under the Act and Regulation Best Interest applies only to Broker-Dealers. As a result, Bank Dealers presently are not required to comply with Regulation Best Interest and, therefore, retail investors may not benefit from its enhanced standard of conduct when receiving recommendations from Bank Dealers.[13]

Application of Regulation Best Interest to Bank Dealers

The proposed Best Interest Amendments would amend MSRB Rule G–19 to require a Bank Dealer to comply with Regulation Best Interest to the same extent as if it were a Broker-Dealer when making a retail municipal recommendation. Consequently, a Bank Dealer would have to act in the best interest of the retail customer at the time a retail municipal recommendation is made, without placing the financial or other interests of the Bank Dealer ahead of the interest of the retail customer. Correspondingly, the Bank Dealer would have to comply with the Commission's component obligations of Regulation Best Interest to the same extent as if it were a Broker-Dealer, including Regulation Best Interest's Disclosure Obligation,[14] Care Obligation,[15] Conflict-of-Interest Obligation,[16] and Compliance Obligation.[17] Under the proposed Best Interest Amendments, the component obligations of Regulation Best Interest would apply to those municipal securities activities associated with a retail municipal recommendation within the overall context of a Bank Dealer business model. The MSRB believes that any SEC guidance with respect to the understanding and application of Regulation Best Interest would be equally applicable to Bank Dealers.

Application of the Disclosure Obligation to Bank Dealers

Consistent with Regulation Best Interest's Disclosure Obligation, the proposed Best Interest Amendments would require a Bank Dealer, prior to or at the time of the retail municipal recommendation, to provide to its retail customer, in writing, full and fair disclosure of: (a) All material facts relating to the scope and terms of the relationship with the retail customer, including: (i) That the Bank Dealer is acting as a municipal securities dealer with respect to the retail municipal recommendation; (ii) The material fees and costs that apply to the retail customer's transactions, holdings, and accounts; and (iii) The type and scope of services provided to the retail customer, including any material limitations on the securities or investment strategies involving securities that may be recommended to the retail customer; [18] and (b) All material facts relating to conflicts of interest that are associated with the retail municipal recommendation.

[9] *See, generally,* Regulation Best Interest Adopting Release (citation at note 4 *supra*). In response, on May 1, 2020, the MSRB filed a proposed rule change with the Commission to harmonize Regulation Best Interest with certain MSRB rules applicable to related municipal securities activities of Broker-Dealers. *See* Exchange Act Release No. 88828 (May 6, 2020), 85 FR 28082, File No. SR–MSRB–2020–02 (hereinafter, the ''Broker-Dealer Harmonization Filing''), available at *https://msrb.org/-/media/Files/SEC-Filings/2020/MSRB-2020-02-Notice.ashx*?. The Commission approved these proposed amendments on June 25, 2020. *See* Exchange Act Release No. 89154 (June 25, 2020), 85 FR 39613 (July 1, 2020), File No. SR–MSRB–2020–02, available at *https://msrb.org/-/media/Files/SEC-Filings/2020/MSRB-2020-02-Federal-Register.ashx*?.

[10] 17 CFR 240.15*l*–1(b)(1) (''Retail customer means a natural person, or the legal representative of such natural person, who (i) [r]eceives a recommendation of any securities transaction or investment strategy involving securities from a broker, dealer, or a natural person who is an associated person of a broker or dealer; and (ii) [u]ses the recommendation primarily for personal, family, or household purposes.'') For discussion of what it means for a retail customer to ''use'' a recommendation, *see* the SEC staff's *Frequently Asked Questions on Regulation Best Interest,* available at *https://www.sec.gov/tm/faq-regulation-best-interest.*

[11] Regulation Best Interest Adopting Release, 84 FR at 33319.

[12] 17 CFR 240.15*l*–1(a)(1). Regulation Best Interest provides that this general obligation is satisfied only if a Broker-Dealer complies with four component obligations: (i) An obligation to make certain prescribed disclosures, before or at the time of the recommendation, about the recommendation and the relationship between the retail customer and the Broker-Dealer (the ''Disclosure Obligation'') (*see* 17 CFR 240.15*l*–1(a)(2)(i)); (ii) an obligation to exercise reasonable diligence, care, and skill in making a recommendation (the ''Care Obligation'') (*see* 17 CFR 240.15*l*–1(a)(2)(ii)); (iii) an obligation to establish, maintain, and enforce written policies and procedures reasonably designed to address conflicts of interest (the ''Conflict-of-Interest Obligation'') (*see* 17 CFR 240.15*l*–1(a)(2)(iii)); and (iv) an obligation to establish, maintain, and enforce written policies and procedures reasonably designed to achieve compliance with Regulation Best Interest (the ''Compliance Obligation'') (*see* 17 CFR 240.15*l*–1(a)(2)(iv)).

[13] *See* Broker-Dealer Harmonization Filing, 85 FR at 28083, n. 5 (discussing how Bank Dealers are not subject to Regulation Best Interest by the terms of the SEC's rules and indicating the Board's intent to issue a request for comment regarding extending the requirements of Regulation Best Interest to Bank Dealers). Notably, all Bank Dealer recommendations, including retail municipal recommendations, are presently subject to the longstanding suitability obligations provided by MSRB rules, including MSRB Rule G–19 and, when applicable, MSRB Rule G–48.

[14] 17 CFR 240.15*l*–1(a)(2)(i).

[15] 17 CFR 240.15*l*–1(a)(2)(ii).

[16] 17 CFR 240.15*l*–1(a)(2)(iii).

[17] 17 CFR 240.15*l*–1(a)(2)(iv).

[18] For example, if the applicable legal charter of a Bank Dealer only permits a Bank Dealer to conduct municipal securities activities or, in fact, a Bank Dealer's business model is limited to municipal securities activities, then the Bank Dealer generally would be required to accurately disclose the fact that it only engages in transactions involving municipal securities and, therefore, will only make recommendations to a retail customer regarding transactions involving municipal securities. *See* also note 19 *infra* (discussing the Compliance Obligation pursuant to the Best Interest Amendments for Bank Dealers who do not engage in any retail municipal recommendations).

Application of the Care Obligation to Bank Dealers

Consistent with Regulation Best Interest's Care Obligation, the proposed Best Interest Amendments would require a Bank Dealer to exercise reasonable diligence, care, and skill to: (a) Understand the potential risks, rewards, and costs associated with any retail municipal recommendation, and have a reasonable basis to believe that a retail municipal recommendation could be in the best interest of at least some retail customers; (b) Have a reasonable basis to believe that the retail municipal recommendation is in the best interest of a particular retail customer, based on that retail customer's investment profile and the potential risks, rewards, and costs associated with the recommendation, and does not place the financial or other interest of the Bank Dealer ahead of the interest of the retail customer; (c) Have a reasonable basis to believe that a series of retail municipal recommendations, even if in the retail customer's best interest when viewed in isolation, is not excessive and is in the retail customer's best interest when taken together in light of the retail customer's investment profile and does not place the financial or other interest of the Bank Dealer ahead of the interest of the retail customer.

Application of the Conflict-of-Interest Obligation to Bank Dealers

Consistent with Regulation Best Interest's Conflict-of-Interest Obligation, the proposed Best Interest Amendments would require a Bank Dealer to establish, maintain, and enforce written policies and procedures reasonably designed to: (a) Identify and at a minimum disclose, in accordance with its Disclosure Obligation, or eliminate, all conflicts of interest associated with such retail municipal recommendations; (b) Identify and mitigate any conflicts of interest associated with such retail municipal recommendations that create an incentive for a natural person who is an associated person of the Bank Dealer to place the interests of the Bank Dealer or such associated person ahead of the interest of the retail customer; (c)(i) Identify and disclose any material limitations placed on the securities or investment strategies involving securities that may be recommended to a retail customer and any conflicts of interest associated with such limitations, in accordance with its Disclosure Obligation, and (ii) Prevent such limitations and associated conflicts of interest from causing the Bank Dealer to make retail municipal recommendations that place the interest of the Bank Dealer ahead of the interest of the retail customer; and (d) Identify and eliminate any sales contests, sales quotas, bonuses, and non-cash compensation that are based on the sales of specific municipal securities or specific types of municipal securities within a limited period of time.

Application of the Compliance Obligation to Bank Dealers

Consistent with Regulation Best Interest's Compliance Obligation, the proposed Best Interest Amendments would require a Bank Dealer to establish, maintain, and enforce written policies and procedures reasonably designed to achieve compliance with Regulation Best Interest.[19]

Purpose and Intent of the Best Interest Amendments

The MSRB is proposing the Best Interest Amendments to MSRB Rule G–19 for purposes of enhancing the standard of investor protection in the municipal securities market and enhancing fairness and efficiency in the municipal securities market by promoting regulatory parity among Bank Dealers and Broker-Dealers. Specific to enhancing the standard of investor protection, the MSRB believes that all retail customers receiving a retail municipal recommendation should benefit from the enhanced investor protections afforded by Regulation Best Interest, regardless of whether such a retail customer is a customer of a Broker-Dealer or a Bank Dealer. Currently, retail customers of Bank Dealers are not afforded the protections of Regulation Best Interest when receiving a retail municipal recommendation from a Bank Dealer. The proposed Best Interest Amendments would require a Bank Dealer to comply with the enhanced standard of conduct required by Regulation Best Interest and, thereby, improve overall investor protection in the municipal securities market.

Specific to promoting regulatory parity, the MSRB believes that the proposed Best Interest Amendments would establish a uniform regulatory standard in the municipal securities market by requiring the same standard of conduct for Bank Dealers and Broker-Dealers when making retail municipal recommendations. This uniform standard would enhance the fairness and efficiency of the municipal securities market by ensuring Bank Dealers have regulatory obligations and burdens when engaging in retail municipal recommendations that are equivalent to the regulatory obligations and burdens of Broker-Dealers when engaging in the same municipal securities activities. This uniformity would better ensure that Bank Dealers do not have a competitive advantage in the municipal securities market by operation of a less burdensome regulatory standard of conduct and, thereby, mitigate the potential for regulatory arbitrage.

Background and Purpose of the Institutional SMMP Amendment

The proposed Institutional SMMP Amendment would amend MSRB Rule G–48 to modify the current obligation to perform a quantitative suitability analysis for recommendations where the dealer does not have actual control or de facto control over the account of an SMMP who is not a retail customer under Regulation Best Interest (collectively, ''Institutional SMMPs'' and, individually, each an ''Institutional SMMP'').[20]

Similar to the reduced customer-specific suitability obligations currently afforded to Institutional SMMPs under MSRB Rule G–48(c), the MSRB believes that dealers transacting with Institutional SMMPs should have similarly reduced quantitative-suitability obligations in instances where the dealer does not have actual control or de facto control over the account of an Institutional SMMP. This modification would effectively revert the quantitative suitability standard for Institutional SMMPs back to the longstanding standard that was in place under MSRB rules prior to June 30, 2020.[21] The proposed Institutional

[19] If a Bank Dealer's business model is such that it and its associated persons are not permitted to make any retail municipal recommendations, then a Bank Dealer may opt not to establish policies and procedures outlining the affirmative regulatory obligations pursuant to the Disclosure Obligation, Care Obligation, and Conflict of Interest Obligation. However, it would be prudent for a Bank Dealer to have policies and procedures that make clear that, prior to permitting the making of any such retail municipal recommendations, the Bank Dealer would need to establish policies and procedures reasonably designed to ensure compliance with the Best Interest Amendments to MSRB Rule G–19.

[20] *See supra* note 10 for the applicable definition of ''retail customer'' and related citation. Any customer meeting such definition of retail customer pursuant to Regulation Best Interest would not be considered an Institutional SMMP for the purposes of the proposed Institutional SMMP Amendment and its modification to MSRB Rule G–48. For purposes of MSRB rules, such a customer meeting the definition of a ''retail customer'' would receive the protections afforded by Regulation Best Interest.

[21] *See* Broker-Dealer Harmonization Filing, 85 FR at 28082, n. 4. The MSRB notes that it has had a long held prohibition against ''churning,'' and the MSRB formally ''recast'' this prohibition as quantitative suitability through an amendment to MSRB Rule G–19 approved by the SEC in 2014. *See* Exchange Act Release No. 71665 (Mar. 7, 2014), 79

SMMP Amendment is intended to improve the efficiency of the municipal securities market without eroding investor protection by aligning the compliance burden associated with certain recommendations made by dealers to the reasonable expectations and capabilities of Institutional SMMPs—who by their nature are more sophisticated, non-natural-person customers and must affirmatively indicate their capacity to (i) exercise independent judgment and (ii) access material information.[22]

Background on MSRB Rule G–19's Quantitative Suitability Requirements

MSRB Rule G–19 sets the MSRB's baseline investor protection standards regarding the suitability of recommendations made by dealers to their customers of purchases, sales, or exchanges of municipal securities that are not subject to Regulation Best Interest. Among other requirements, Supplementary Material .05 of MSRB Rule G–19 enumerates three components of a dealer's suitability analysis when recommending a transaction or investment strategy involving a municipal security or municipal securities to a non-retail customer (*i.e.,* a recommendation that is not subject to Regulation Best Interest).[23] As further defined in the text of the rule, MSRB Rule G–19 provides that a dealer's suitability obligation is composed of (i) reasonable-basis suitability, (ii) customer-specific suitability, and (iii) quantitative suitability. Most relevant to the proposed Institutional SMMP Amendment of this proposed rule change, quantitative suitability requires a dealer to have a reasonable basis for believing that a series of recommended transactions, even if suitable when viewed in isolation, are not excessive and unsuitable for the customer when taken together in light of the customer's investment profile, as delineated in MSRB Rule G–19.[24] No single test defines excessive activity, but factors such as the turnover rate, the cost-equity ratio, and the use of in-and-out trading in a customer's account may provide a basis for a finding that a dealer has violated the quantitative suitability obligation.[25]

Pursuant to the amendments effectuated by the Broker-Dealer Harmonization Filing, discussed above and effective as of June 30, 2020, the quantitative suitability obligation of MSRB Rule G–19 no longer incorporates an element of control in relation to a customer's account.[26]As a result, dealers are currently obligated to conduct a quantitative suitability analysis under MSRB Rule G–19 when making recommendations to Institutional SMMPs, even in instances where the dealer does not have actual control or de facto control over the account. The obligation applies notwithstanding the fact that Institutional SMMPs self-identify under MSRB Rule G–48 and MSRB Rule D–15 as having the willingness and requisite investment sophistication to, for example, independently evaluate the recommendations of a dealer and the quality of a dealer's execution, as further discussed below.[27]

Background on MSRB Rule G–48 and Modified Regulatory Obligations

MSRB Rule G–48 provides for modified dealer regulatory obligations under MSRB rules when dealing with certain customers that meet the definition of a Sophisticated Municipal Market Participant [28] (*i.e.,* an SMMP). More specifically, when transacting with an SMMP customer, Rule G–48 modifies aspects of a dealer's baseline regulatory obligations in terms of: (i) Time of trade disclosures,[29] (ii) transaction pricing,[30] (iii) bona fide quotations,[31] (iv) best execution,[32] and (vi) suitability.[33] The modified regulatory obligations afforded to SMMPs under MSRB rules are intended to account for the distinct capabilities of certain sophisticated, non-retail customers and the varied types of dealer-customer relationships occurring in the municipal securities market.[34]

Most relevant to the proposed Institutional SMMP Amendment, Rule G–48(c) currently modifies the suitability requirements of MSRB Rule G–19 by eliminating the requirement for dealers to conduct a customer-specific suitability analysis for recommendations made to an Institutional SMMP.[35] The operative provision of MSRB Rule G–48 provides that, ''[w]hen making a recommendation subject to Rule G–19 and not Regulation Best Interest, Rule 15l–1 under the Act, a broker, dealer, or municipal securities dealer shall not have any obligation under Rule G–19 to perform a customer-specific suitability analysis.'' [36] This

FR 2432 (Mar. 13, 2014), File No. SR–MSRB–2013–07 (discussing the then-existing MSRB prohibition on churning and a proposed rule change to recast this prohibition using the phrase ''quantitative suitability''), available at *http://www.msrb.org/~/media/Files/SEC-Filings/2013/MSRB-2013-07-Fed-Reg-Approval.ashx?la=en&hash=AEDA0B5509630E25473E9F6F3A3F9C34.*

[22] *See* MSRB Rule G–48(c). *See also* related discussion *infra* under *Background and Purpose of the Institutional SMMP Amendment—Background on MSRB Rule D–15 and SMMP Affirmation Requirements.*

[23] *See* the Broker-Dealer Harmonization Filing, 85 FR at 28084. The Broker-Dealer Harmonization Filing amended MSRB Rule G–19 to provide that the rule does not apply to recommendations subject to Regulation Best Interest.

[24] MSRB Rule G–19, Supplementary Material .05(c).

[25] *Id.*

[26] In other words, as of June 30, 2020, if the obligations of MSRB Rule G–19 attach to a dealer's recommendation, then the investor protections regarding quantitative suitability apply regardless of whether the dealer making the recommendation exercises any actual control or de facto control over the customer's account. The Broker-Dealer Harmonization Filing amended this language of Supplementary Material .05(c) to eliminate such control requirements, effectively extending the requirements of quantitative suitability to any customer account. *See* Broker-Dealer Harmonization Filing, 85 FR at 28084. June 30, 2020 was the compliance date for the amendments enacted by the Broker-Dealer Harmonization Filing. *See* Broker-Dealer Harmonization Filing, 85 FR at 28082, n. 4. Pursuant to the Broker-Dealer Harmonization Filing, the MSRB also notes that this quantitative suitability obligation applies uniformly to any dealer (*i.e.,* the same regulatory obligations apply to both Broker-Dealers and Bank Dealers).

[27] *See* MSRB Rule D–15(c) (requiring Institutional SMMPs to ''affirmatively indicate,'' among other things, that it is exercising independent judgment in evaluating (A) the recommendations of the dealer and (B) the quality of execution of the customer's transactions by the dealer).

[28] *See* discussion under *Background and Purpose of the Institutional SMMP Amendment—Background on MSRB Rule D–15 and SMMP Affirmation Requirements* near note 37 *infra* (discussing the definition of Sophisticated Municipal Market Participant under MSRB Rule D–15).

[29] MSRB Rule G–48(a) (''The broker, dealer, or municipal securities dealer shall not have any obligation under Rule G–47 to ensure disclosure of material information that is reasonably accessible to the market.'')

[30] MSRB Rule G–48(b).

[31] MSRB Rule G–48(d) (''The broker, dealer, or municipal securities dealer disseminating an SMMP's 'quotation' as defined in Rule G–13, which is labeled as such, shall apply the same standards regarding quotations described in Rule G–13(b) as if such quotations were made by another broker, dealer, or municipal securities dealer.'')

[32] MSRB Rule G–48(e) (''The broker, dealer, or municipal securities dealer shall not have any obligation under Rule G–18 to use reasonable diligence to ascertain the best market for the subject security and buy or sell in that market so that the resultant price to the SMMP is as favorable as possible under prevailing market conditions.'')

[33] MSRB Rule G–48(c).

[34] *See, e.g.,* Exchange Act Release No. 67064 (May 25, 2012), 77 FR 32704 (June 1, 2012), File No. SR–MSRB–2012–05 (May 25, 2012) (approving an MSRB proposed rule change to relax certain qualifications for a dealer to afford a customer SMMP status in light of market developments regarding the increased availability of municipal securities market information and the desire of certain institutional customers to access alternative trading systems).

[35] *Id.* The amendments to MSRB Rule G–48 enacted by the Broker-Dealer Harmonization Filing carved out recommendations to customers that are subject to Regulation Best Interest from the rule's modified standards. *See* Broker-Dealer Harmonization Filing, 85 FR at 28084–85.

[36] MSRB Rule G–48(c).

relaxed customer-specific suitability obligation is generally aligned with the ''independent judgment'' affirmations a customer seeking SMMP status makes under MSRB Rule D–15. The proposed Institutional SMMP Amendment would likewise relax the quantitative suitability obligation for similar reasons, as further described in the following sections.[37]

Background on MSRB Rule D–15 and SMMP Affirmation Requirements

MSRB Rule G–48 incorporates the definition of SMMP under MSRB Rule D–15 for purposes of defining which customers do (or do not) qualify as an SMMP for purposes of Rule G–48 and, therefore, MSRB Rule D–15 establishes the scope of potential customers who might qualify for MSRB Rule G–48's modified obligations. The SMMP definition of MSRB Rule D–15 enumerates three definitional components, which separately address: (i) The minimum qualifying traits and characteristics of an SMMP customer; [38] (ii) that a dealer must develop a reasonable basis for determining whether a customer has the requisite level of expertise and sophistication to be deemed an SMMP customer (the ''SMMP Reasonable Basis Determination''); [39] and (iii) what affirmations a customer must communicate to the dealer regarding its own investment judgment and access to information in order to be appropriately deemed an SMMP customer (the ''SMMP Customer Affirmations'').[40] In terms of the SMMP Customer Affirmations, MSRB Rule D–15(c) provides that the customer must affirmatively indicate to the dealer that (i) it is exercising independent judgment in evaluating the recommendations of the dealer; the quality of execution of the customer's transactions by the dealer; and the transaction price for non-recommended secondary market agency transactions as to which the dealer's services have been explicitly limited to providing anonymity, communication, order matching and/or clearance functions and the dealer does not exercise discretion as to how or when the transactions are executed; [41] and (ii) it has timely access to material information that is available publicly through established industry sources as defined in MSRB Rule G–47(b)(i) and MSRB Rule G–47(b)(ii) (*i.e.,* ''material information'' from ''established industry sources,'' such as EMMA website information and rating agency reports).[42]

Thus, an institutional customer who self-identifies as an SMMP has freely affirmed to a dealer its willingness to be treated as a sophisticated customer with the capacity and resources to exercise its own independent judgment. In this way, the SMMP Customer Affirmations are designed to ensure that any customer treated as an SMMP has affirmatively and knowingly provided the grounds on which a dealer may afford such SMMP customer lesser protections under certain MSRB rules. As an additional investor protection safeguard beyond the requirement for SMMP Customer Affirmations, the SMMP Reasonable Basis Determination also requires a dealer to have a reasonable basis to believe that an SMMP customer is capable of evaluating investment risks and market value independently, both in general and with regard to particular transactions and investment strategies in municipal securities.[43] In this way, the SMMP Reasonable Basis Determination further ensures that an Institutional SMMP does in fact possess a more sophisticated understanding of the municipal securities market. Importantly, the proposed Institutional SMMP Amendment would not alter the SMMP Customer Affirmations, the SMMP Reasonable Basis Determination, nor any of the other definitional elements of MSRB Rule D–15.

Purpose and Intent of the Institutional SMMP Amendment to MSRB Rule G–48

The proposed Institutional SMMP Amendment would amend MSRB Rule G–48 to modify the quantitative suitability obligations of dealers when effecting transactions for their Institutional SMMPs. The proposed Institutional SMMP Amendment would require a dealer to conduct a quantitative suitability analysis only in situations where the dealer has actual control or de facto control over an Institutional SMMP's account.[44] As stated above, the proposed amendments to MSRB Rule G–48 would narrowly reinstate the scope of suitability protections afforded to Institutional SMMPs in effect prior to the amendments effectuated by the Broker-Dealer Harmonization Filing and so should be a familiar regulatory concept to dealers and Institutional SMMPs alike.[45] More importantly, because each Institutional SMMP must self-identify as an SMMP by making the SMMP Customer Affirmations, as well as must fulfill the requirements associated with a dealer's SMMP Reasonable Basis Determination, the MSRB believes that the proposed Institutional SMMP Amendment will ease a regulatory burden on dealers that effectively replicates the sort of analysis an Institutional SMMP is willing and capable of performing itself. As a result, the proposed Institutional SMMP Amendment would align the compliance burden associated with certain recommendations made by dealers to the reasonable expectations and capabilities of Institutional SMMPs.

While the investor protection benefits associated with requiring dealers to perform a potentially duplicative suitability analysis can be appropriate

[37] *See* Exchange Act Release No. 71665 (Mar. 7, 2014), 79 FR 14321 (Mar. 13, 2014), File No. SR–MSRB–2013–07 (Sept. 17, 2013) (codifying the relaxed customer-specific suitability obligation for recommendations made to SMMPs in MSRB Rule G–48 and the actual control or de facto control requirement, thereafter eliminated in 2020 as described herein, for the applicability of quantitative suitability to recommendations made to customers in MSRB Rule G–19).

[38] MSRB Rule D–15(a). A customer is only eligible to be treated as an SMMP if the customer is: (i) A bank, savings and loan association, insurance company, or registered investment company, (ii) a registered investment advisor, or (iii) a person or entity with total assets of at least $50 million.

[39] MSRB Rule D–15(b). A customer is only eligible to be treated as an SMMP if the dealer has developed a reasonable basis to believe that the customer is capable of evaluating investment risks and market value independently, both in general and with regard to particular transactions and investment strategies in municipal securities. In addition, Supplementary Material .01 of MSRB Rule D–15 states that, as part of the reasonable-basis analysis, the dealer should consider the amount and type of municipal securities owned or under management by the customer.

[40] MSRB Rule D–15(c).

[41] *See* MSRB Rule D–15(c)(1) (''The customer must affirmatively indicate that it: (1) is exercising independent judgment in evaluating: (A) the recommendations of the dealer; (B) the quality of execution of the customer's transactions by the dealer; and (C) the transaction price for non-recommended secondary market agency transactions as to which (i) the dealer's services have been explicitly limited to providing anonymity, communication, order matching and/or clearance functions and (ii) the dealer does not exercise discretion as to how or when the transactions are executed . . .'').

[42] *See* MSRB Rule D–15(c)(2) (''The customer must affirmatively indicate that it . . . (2) has timely access to material information that is available publicly through established industry sources as defined in Rule G–47(b)(i) and (ii).'')

[43] *See* MSRB Rule D–15(b) and Rule D–15 Supplementary Material .01.

[44] Where a dealer exercises actual control or de facto control over an Institutional SMMP's account, the dealer would still be required to perform a quantitative suitability analysis in accordance with Supplementary Material .05 of MSRB Rule G–19. Relatedly, if an Institutional SMMP limitedly provides its customer affirmation on a trade-by-trade basis, then the dealer would be required to comply with all aspects of MSRB Rule G–19, including both the quantitative suitability requirement and the customer-specific suitability requirement, for those recommendations for which the Institutional SMMP did not provide the applicable customer affirmation. *See* Supplementary Material .02 of MSRB Rule D–15 (discussing trade-by-trade affirmations).

[45] *See supra* note 21 and related discussion.

in other circumstances,[46] the MSRB believes that the compliance burden associated with performing a quantitative suitability analysis on recommendations made to Institutional SMMPs outweighs the potential marginal investor protection benefits. In this way, the proposed Institutional SMMP Amendment would promote efficiency in the municipal securities market by eliminating a regulatory burden on dealers that generally provides a duplicative or unneeded analyses in supplement of an Institutional SMMPs' own independent and informed judgment, and, consequently, the proposed Institutional SMMP Amendment would allow dealers to redirect the resources associated with this regulatory burden to other more productive market activities.

2. Statutory Basis

The MSRB believes that the proposed rule change is consistent with Section 15B(b)(2) of the Act,[47] which provides that the Board shall propose and adopt rules to effect the purposes of this title with respect to transactions in municipal securities effected by brokers, dealers, and municipal securities dealers and advice provided to or on behalf of municipal entities or obligated persons by brokers, dealers, municipal securities dealers, and municipal advisors with respect to municipal financial products, the issuance of municipal securities, and solicitations of municipal entities or obligated persons undertaken by brokers, dealers, municipal securities dealers, and municipal advisors.[48]

Section 15B(b)(2)(C) of the Act[49] provides that the MSRB's rules shall be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in municipal securities and municipal financial products, to remove impediments to and perfect the mechanism of a free and open market in municipal securities and municipal financial products, and, in general, to protect investors, municipal entities, obligated persons, and the public interest.[50] The MSRB believes the proposed rule change is consistent with Section 15B(b)(2)(C) of the Act[51] for the following reasons.

Statutory Basis for the Best Interest Amendments

The proposed Best Interest Amendments are consistent with Section 15B(b)(2)(C) of the Act[52] because the amendments would: Foster cooperation and coordination with regulators; prevent fraudulent and manipulative acts and practices; protect investors; remove impediments to and perfect the mechanism of a free and open market in municipal securities; and promote capital formation in the municipal securities market.

Fostering Cooperation and Coordination With Regulators

The proposed Best Interest Amendments would foster cooperation and coordination with regulators by more tightly aligning the suitability obligations of MSRB Rule G–19 with the suitability obligations of Regulation Best Interest. By providing a uniform standard for all types of dealers, this alignment of the regulatory scheme applicable to retail municipal recommendations will foster greater cooperation and coordination among the MSRB and the SEC, as well as greater cooperation and coordination among the authorities that examine Broker-Dealers and Bank Dealers for compliance with MSRB rules.

Protecting Investors and Preventing Fraudulent and Manipulative Act and Practices

The proposed Best Interest Amendments would protect investors and prevent fraudulent and manipulative acts and practices by extending the enhanced standards of conduct required by Regulation Best Interest to the retail municipal recommendations of Bank Dealers. As noted by the Commission in the adopting release for Regulation Best Interest, Regulation Best Interest enhances the broker-dealer standard of conduct beyond existing suitability obligations, and aligns the standard of conduct with retail customers' reasonable expectations by requiring broker-dealers, among other things, to: Act in the best interest of the retail customer at the time the recommendation is made, without placing the financial or other interest of the broker-dealer ahead of the interests of the retail customer; and address conflicts of interest by establishing, maintaining, and enforcing policies and procedures reasonably designed to identify and fully and fairly disclose material facts about conflicts of interest, and in instances where we have determined that disclosure is insufficient to reasonably address the conflict, to mitigate or, in certain instances, eliminate the conflict.[53]

In addition, the Commission stated the enhancements contained in Regulation Best Interest are designed to improve investor protection by enhancing the quality of broker-dealer recommendations to retail customers and reducing the potential harm to retail customers that may be caused by conflicts of interest.[54] For the same reasons, the MSRB believes that extending Regulation Best Interest to the retail municipal recommendations of Bank Dealers would prevent potential fraudulent and manipulative acts and practices and promote the protection of the retail customers of Bank Dealers.

Removing Impediments and Perfecting the Mechanisms of a Free and Open Market

The proposed Best Interest Amendments would remove impediments to and perfect the mechanism of a free and open market in municipal securities by applying a uniform regulatory standard for retail municipal recommendations that would promote parity regarding the regulatory obligations of Broker-Dealers and Bank Dealers and, thereby, reduce potential confusion among market participants as to which standard of conduct applies.

Promoting Capital Formation

The proposed Best Interest Amendments would not have a deleterious effect on capital formation in the municipal securities market and would have the potential to improve capital formation for the following reasons. Similar to the Commission's reasoning in its adoption of Regulation Best Interest,[55] the enhanced obligations

[46] For example, the MSRB believes that the obligation to perform quantitative suitability analyses under MSRB rules remains appropriate, regardless of the potential for such duplication, in circumstances of recommendations made to retail customers; non-retail, institutional customers who fail to meet the characteristics of an SMMP; and/or non-retail customers who have declined to make the affirmations necessary to be appropriately deemed an SMMP.

[47] 15 U.S.C. 78*o*–4(b)(2).

[48] *Id.*

[49] 15 U.S.C. 78*o*–4(b)(2)(C).

[50] *Id.*

[51] *Id.*

[52] *Id.*

[53] Regulation Best Interest Adopting Release, 84 FR at 33318.

[54] Regulation Best Interest Adopting Release, 84 FR at 33321.

[55] Regulation Best Interest Adopting Release, 84 FR at 33462 (''The possibility that Regulation Best Interest may increase the efficiency of the recommendations provided by the associated persons of the broker-dealer may enhance the attractiveness of broker-dealer services for those investors who currently do not invest through broker-dealers . . . If retail customers are more

Continued

of Regulation Best Interest may increase the efficiency of retail municipal recommendations and increase the attractiveness of Bank Dealer services for those retail customers who do not invest with a Bank Dealer because recommendations made by bank dealers are not currently subject to the additional standards of investor protection afforded by Regulation Best Interest. Additionally, by adopting a uniform regulatory standard for retail municipal recommendations across all dealers (*i.e.,* across Bank Dealers and Broker-Dealers), the overall attractiveness of the municipal securities activities of dealers may improve. Consequently, if more retail customers are more willing to participate in municipal securities activities, then the proposed Best Interest Amendments would promote capital formation in the municipal securities market.

Statutory Basis for the Institutional SMMP Amendment

The proposed Institutional SMMP Amendment is consistent with Section 15B(b)(2)(C)[56] of the Act because the amendment would facilitate transactions in municipal securities and remove impediments to and perfect the mechanism of a free and open market in municipal securities, while not compromising investor protection.

The proposed Institutional SMMP Amendment would facilitate transactions in municipal securities and remove impediments to and perfect the mechanism of a free and open market in municipal securities by reducing a compliance burden on dealers. The modification of a dealer's suitability obligations to eliminate the current requirement to perform a quantitative suitability analysis for recommendations in circumstances where the dealer does not have actual control or de facto control over an Institutional SMMP's account will eliminate what could potentially be duplicative analyses undertaken by dealers on behalf of Institutional SMMPs—analyses which Institutional SMMPs have already affirmed their capacity and expertise to conduct for themselves, and which the Institutional SMMPs presumably have taken upon themselves to perform. In this regard, the proposed Institutional SMMP Amendment will remove an impediment to the mechanisms of a free and open market in municipal securities and promote greater efficiency. By eliminating this regulatory burden, the proposed Institutional SMMP Amendment would allow dealers to redirect the resources associated with this regulatory burden to other more productive market activities. As a separate, but related benefit, the MSRB believes that the Institutional SMMP Amendment would allow dealers to more efficiently serve those Institutional SMMPs who may be seeking relatively greater transaction activity and/or are more comfortable taking on the risks associated with more frequent transaction activity.

The MSRB believes that the proposed Institutional SMMP Amendment to MSRB Rule G–48 will not compromise investor protections. The MSRB believes that allowing dealers to make recommendations to their Institutional SMMP customers without the burden of performing a quantitative suitability analysis is consistent with the SMMP Customer Affirmations and dealers' SMMP Reasonable Basis Determination. More specifically, the SMMP Customer Affirmations ensure that an Institutional SMMP itself believes that it has the requisite knowledge and judgment to be afforded SMMP status; and, as an additional safeguard to investor protection, the SMMP Reasonable Basis Determination separately ensures that the dealer also has a reasonable basis to conclude that an Institutional SMMP has the knowledge and sophistication to be treated as a SMMP based on supplemental factors beyond just the SMMP Customer Affirmations. If either definitional prong is not met, a dealer is not permitted to afford an institutional customer the status of a SMMP. Therefore, the MSRB believes that the proposed Institutional SMMP Amendment is generally consistent with an Institutional SMMP's more sophisticated understanding of (i) the commercial nature of its relationship with a dealer and (ii) the lesser regulatory standards of conduct governing the SMMP-dealer relationship.

In addition, the proposed Institutional SMMP Amendment would incorporate the concepts of actual control or de facto control. Reinstating these control elements would help address potential scenarios in which the ability of an Institutional SMMP to exercise independent judgment is undermined or circumvented, such as when a dealer may not have formal discretionary authority over an Institutional SMMP's account, but nevertheless exercises de facto control over the account to, for example, engage in churning activity in clear contravention of an Institutional SMMP's investment interests.[57] The MSRB believes that incorporating the actual control or de facto control elements maintains baseline investor protections for Institutional SMMPs in such scenarios of greater dealer impropriety or intentional wrongdoing.

The MSRB also notes that new institutional customers, who otherwise would qualify as SMMPs but desire the additional investor protections afforded by quantitative suitability under MSRB Rule G–19, can decline to provide the required affirmations under MSRB Rule D–15.[58] Similarly, existing Institutional SMMPs could withdraw their SMMP status and obtain the suitability protections afforded by MSRB Rule G–19. This ability to self-identify as an Institutional SMMP will ensure that those institutional customers who desire additional investor protection can secure them under MSRB rules, and thus, require the dealers to undertake a quantitative suitability analysis.

Accordingly, the MSRB believes that the proposed Institutional SMMP Amendment would maintain essential safeguards for investor protection and, overall, not compromise investor protections inconsistent with Section 15B(b)(2)(C)[59] of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

Section 15B(b)(2)(C) of the Act[60] requires that MSRB rules not be designed to impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act. The MSRB considered the economic impact associated with the proposed rule change, including a comparison to reasonable alternative regulatory approaches, relative to the baseline.[61] The MSRB believes the proposed rule changes would relieve a burden on competition and do not impose any

willing to participate in the securities markets through broker-dealers, Regulation Best Interest would have a positive effect on capital formation.'')

[56] 15 U.S.C. 78*o*–4(b)(2)(C).

[57] *See, e.g., Harry Gliksman,* 54 SEC. 471, 475 (1999) (upholding a NASD finding that a registered representative violated his suitability obligations by recommending frequent and short-term securities transactions even though the registered representative did not have written discretionary authority).

[58] *See* related discussion *supra* under *Background and Purpose of the Institutional SMMP Amendment—Background on MSRB Rule D–15 and SMMP Affirmation Requirements. See also* MSRB Rule D–15(c)(1)–(2).

[59] 15 U.S.C. 78*o*–4(b)(2)(C).

[60] *Id.*

[61] *See* Policy on the Use of Economic Analysis in MSRB Rulemaking, available at *http://msrb.org/Rules-and-Interpretations/Economic-Analysis-Policy.aspx.* In evaluating whether there was a burden on competition, the Board was guided by its principles that required the Board to consider costs and benefits of a rule change, its impact on capital formation and the main reasonable alternative regulatory approach.

burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act.

Necessity of Rule Change

Best Interest Amendments

As previously mentioned, the retail municipal recommendations made by Bank Dealers currently are outside the scope of Regulation Best Interest,[62] and the municipal securities activities of Bank Dealers continue to be subject to the existing investor protection obligations of MSRB rules, including MSRB Rule G–19. The proposed Best Interest Amendments to MSRB Rule G–19 would require each Bank Dealer to comply with the requirements of Regulation Best Interest to the same extent as a Broker-Dealer must. The proposed Best Interest Amendments are necessary because they would increase investor protection in the municipal securities market by creating regulatory uniformity in the market between the municipal securities activities of Bank Dealers and those of Broker-Dealers, each of whom may provide retail municipal recommendations. Similar to the Broker-Dealer Harmonization Filing for Broker-Dealers in 2020, the MSRB believes another benefit of the proposed Best Interest Amendments is that the amendments would reduce agency costs and information asymmetry between Bank Dealers and retail customers.[63]

The MSRB addresses reasonable alternatives where applicable when considering the costs, benefits, and impact of a proposed amendment. The MSRB believes the only reasonable alternative for evaluation is the option of leaving in place the current regulatory state in which a Bank Dealer's retail municipal recommendations are not subject to the requirements of Regulation Best Interest, while a Broker-Dealer's retail municipal recommendations are subject to the full requirements of Regulation Best Interest, even though the activities of both groups of dealers are similar. As shown below, the MSRB believes that maintaining the status quo would preserve a regulatory imbalance and therefore competitive imbalance in this regard between Bank Dealers and Broker-Dealers engaged in the same activity, as well as deprive certain retail customers of the investor protections afforded by Regulation Best Interest. In this way, maintaining the status quo would maintain a discrepancy in the investor protections afforded to the retail customers receiving retail municipal recommendations from Bank Dealers as compared to the investor protections afforded to retail customers receiving retail municipal recommendations from Broker-Dealers and, thereby, maintain a competitive imbalance in terms of the compliance burdens of Bank Dealers versus Broker-Dealers.

Institutional SMMP Amendment

The purpose of amending MSRB Rule G–48 is to reinstate the requirement that a dealer have actual control or de facto control with respect to Institutional SMMP accounts to trigger a dealer's quantitative suitability obligation. A prior rule provision, applying the quantitative suitability obligation only when a dealer had actual control or de facto control over the account, was removed as part of the Broker-Dealer Harmonization Filing; and, as a result, dealers currently have an obligation to conduct a quantitative suitability analysis for transactions with Institutional SMMP customers whether or not the dealer has actual control or de facto control over the Institutional SMMP's account. The proposed Institutional SMMP Amendment to MSRB Rule G–48 will clarify that the quantitative suitability requirement of MSRB Rule G–19 is only applicable to natural person SMMPs but not to Institutional SMMPs. Since the proposed Institutional SMMP Amendment reinstates a previous requirement in the MSRB's suitability rule, the MSRB considered the alternative of placing the reinstated requirement in MSRB Rule G–19 for all institutional entities but decided that MSRB Rule G–48 is a more appropriate place to incorporate the reinstated standard, as Institutional SMMPs are by their nature sophisticated entities that have freely affirmed and self-identified their capacity to independently evaluate dealers' recommendations.

Benefits, Costs and Effect on Competition

Best Interest Amendments

The proposed Best Interest Amendments to MSRB Rule G–19 would help create a uniform standard of investor protection for retail municipal recommendations. The proposed Best Interest Amendments to MSRB Rule G–19 would obligate a Bank Dealer to comply with Regulation Best Interest to the same extent as a Broker-Dealer making retail municipal recommendations. In this regard, the MSRB believes the effects of the proposed Best Interest Amendments would be similar and comparable to the effects resulting from when Broker-Dealers were first required to comply with Regulation Best Interest, though at a much smaller scale concerning only retail municipal recommendations.[64] Therefore, the MSRB believes that the SEC's estimates of the burdens on competition and benefits of applying Regulation Best Interest to Broker-Dealers is a reasonable reference point for analyzing burdens on competition and benefits of applying Regulation Best Interest to Bank Dealers' retail municipal recommendations. The MSRB therefore built upon the findings of the SEC's multiyear in-depth analysis for its analysis of the proposed Best Interest Amendments.

Notably, in the Regulation Best Interest Adopting Release, the SEC emphasized that it is ''difficult to quantify such benefits and costs with meaningful precision'' for Broker-Dealers and, particularly over long time periods, the quantification may be insufficiently precise and inherently speculative,[65] mainly due to the following factors, among others, (i) a lack of data on the extent to which Broker-Dealers with different business practices engage in disclosure and conflict mitigation activities to comply with existing requirements, and therefore how costly it would be to comply with the proposed requirements; [66] (ii) Regulation Best Interest provides Broker-Dealers flexibility in how to comply with the obligations and, as a result, there could be multiple ways in which Broker-Dealers will satisfy their obligations; [67] and (iii) Regulation Best Interest may affect Broker-Dealers differently depending on their business model (*e.g.,* full-service Broker-Dealer, Broker-Dealer that uses independent contractors,

[62] Regulation Best Interest applies to ''a broker, dealer or a natural person who is an associated person of a broker or dealer,'' which does not apply Bank Dealers. *See* 17 CFR 240.15*l*–1(a)(1).

[63] The SEC describes this reduction in agency cost, in the Regulation Best Interest Adopting Release, as ''the difference between the net benefit to the retail customer from accepting a less than efficient recommendation about a securities transaction or investment strategy, where the associated person or Broker-Dealer puts its interests ahead of the interests of the retail customer, and the net benefit the retail customer might expect from a similar securities transaction or investment strategy that is efficient for him or her.'' *See* Regulation Best Interest Adopting Release, 84 FR at 33403.

[64] *See* Regulation Best Interest Adopting Release, 84 FR at 33403.

[65] *Id.* The MSRB is not aware of any post-implementation study or other analysis that provides data on the costs and benefits of adopting Regulation Best Interest.

[66] *See* Regulation Best Interest Adopting Release, 84 FR at 33434.

[67] *Id.*

insurance-affiliated Broker-Dealer) and size.[68]

The SEC further cautioned that the associated costs for each individual Broker-Dealer firm could not be anticipated because of the wide variation in size and scope of business practices across firms as well as the many unknown factors associated with the principles-based nature of the Regulation Best Interest.[69] The MSRB believes the same difficulties and complexities experienced by the SEC in attempting to analyze the economic effects of applying Regulation Best Interest to Broker-Dealers also applies to the MSRB's attempt to provide a meaningful quantitative estimate of the impact of the proposed Best Interest Amendments on Bank Dealers.[70]

While acknowledging these challenges, the MSRB attempted to determine the scope of activity that would be subject to the proposed Best Interest Amendments, which is summarized in *Table 1* below. The summary table provides an estimate of the number of Bank Dealers likely to be affected by the proposed Best Interest Amendments. The Bank Dealers were included in that table based on their market share of retail-sized dealer-to-customer trades in calendar year 2020 (*i.e.,* dealer-to-customer trades with a par value of $100,000 or less).[71] Among the over 1,200 dealers registered with the MSRB, only 21 firms are registered as Bank Dealers. Those 21 Bank Dealers conducted only 1.6% of all retail-sized dealer-to-customer trades in municipal securities in 2020.[72] Even among the 21 Bank Dealers, nearly all of this activity was concentrated in a small number of firms, with the top seven most-active Bank Dealers conducting the vast majority of all retail-sized customer trades in 2020 (about 99.5%). The remaining number of registered Bank Dealers were significantly less active in executing retail-sized trades with customers during that same period, with six Bank Dealers not executing any retail-sized customer trades over the course of the entire year and the remaining eight Bank Dealers altogether averaging a little over one retail-sized customer trade per day.

TABLE 1—MARKET SHARE OF MUNICIPAL SECURITIES RETAIL-SIZED CUSTOMER TRADES BY DEALERS JANUARY 2020–DECEMBER 2020

Type of dealers	Number of retail-sized customer trades	Market share of retail-sized customer trades (%)
Non-Bank Dealers	3,865,880	98.4
Top Seven Bank Dealers	61,140	1.6
All Fourteen Other Bank Dealers	325	0.0

Source: MSRB analysis with data obtained from the MSRB's Real-Time Transaction Reporting System (RTRS) and the MSRB's registration database.

In developing these numbers, the MSRB believes they are likely overly inclusive of potential retail activity, because there is a high probability the numbers capture more trades than would be subject to the requirements of the proposed Best Interest Amendments. Nevertheless, the MSRB believes the numbers are a reasonable estimate for the purpose of this economic analysis and are conservative to the extent that they are more likely to over-estimate the potential burden on Bank Dealers than underestimate it. In terms of the limitations of this data, dealer-to-customer trades with a par value of $100,000 or less are not always conducted with investors who would meet the definition of a retail customer under Regulation Best Interest, as representatives acting on behalf of non-retail customers potentially execute trades with a par value of $100,000 or less (*i.e.,* small institutional trades). Conversely, retail investors may execute trades above $100,000 par value (*i.e.,* large retail trades); however, the MSRB believes large retail trades occur less frequently and, thus, do not fully offset the more frequent occurrences of sub-$100,000 par value non-retail trades.[73]

Additionally, the MSRB acknowledges that the number of trades is not a reasonable proxy for the number of retail municipal recommendations. That is, the fact that a Bank Dealer executes a trade with an investor who meets the definition of a retail customer under Regulation Best Interest does not necessarily mean that the Bank Dealer has made a ''recommendation'' to such retail customer for purposes of Regulation Best Interest. The Bank Dealer may have, for example, executed a non-recommended trade at the customer's request. Hence, the MSRB believes that some unknown number of these retail-sized trades would not be subject to the proposed Best Interest Amendments (*i.e.,* the trades would not be subject to Regulation Best Interest).

Benefits

The MSRB believes extending the requirements of Regulation Best Interest to Bank Dealers would reduce or eliminate a regulatory imbalance between Bank Dealers, on the one hand,

[68] *Id.*

[69] *Id.*

[70] The MSRB sought public comment to solicit data to use in a quantitative analysis relating to the proposed changes in its Request for Comments. While commenters did provide some specifics on the scope of Bank Dealers' activities that would be subject to the proposed Best Interest Amendments, the MSRB did not receive any quantitative estimate of the impact of the proposed Best Interest Amendments on Bank Dealers. In addition, the MSRB is not aware of any post-implementation study that provides data on the costs and benefits of adopting Regulation Best Interest.

[71] The MSRB does not have access to reliable data to determine the precise number of Bank Dealers who provide (or may provide) recommendations to investors who meet the definition of a retail customer. To develop a reasonable proxy, the MSRB analyzed market data to determine the number of retail-sized trades (par value at $100,000 or less in this case). In the absence of more specific data about a trade, total par size of $100,000 or less is commonly used in the municipal securities market as an indicator of a retail activity. Data were obtained from the MSRB's Real-Time Transaction Reporting System (RTRS) and the MSRB's registration database.

[72] These figures are provided by an MSRB analysis with data obtained from MSRB's Real-Time Transaction Reporting System (RTRS) combined with existing registration data.

[73] For example, one commenter, the Capital Markets Group of Commerce Bank (''CMG'') based in Kansas City, MO, stated that ''For CMG, retail customers comprise approximately 9% of CMG's total open account customer base. Further, only a portion of these retail accounts actually executed transactions in the last 12 months, comprising approximately 3% of CMG's total customers. . . .'' *See* letter from Erik Swanson, Managing Director, and Joseph Reece, Chief Compliance Officer, Capital Markets Group of Commerce Bank (''Commerce Bank''), not dated (the ''Commerce Bank Letter'') in response to MSRB Notice 2021–06 (March 4, 2021).

and Broker-Dealers, on the other, as the terms of Regulation Best Interest do not currently apply to Bank Dealers. The proposed Best Interest Amendments would both close a regulatory gap and also mitigate certain market risks and inefficiencies associated with a potentially lower compliance standard.[74] Therefore, the proposed Best Interest Amendments would protect retail customers seeking investment recommendations and transacting in municipal securities, regardless of whether they are customers of a Broker-Dealer or a Bank Dealer. The MSRB believes retail customers receiving retail municipal recommendations should benefit from a uniform standard of enhanced investor protections, which would not be dependent upon the type of dealer entity making the retail municipal recommendation.

As to the overall merit of the proposed new requirements, they are intended to reduce Bank-Dealer retail customer agency costs by lessening conflicts of interest that currently exist between Bank Dealers and retail customers and reduce information asymmetries limiting the ability of retail customers to assess the efficiency of recommendations from Bank Dealers.[75]

Costs

If the proposed Best Interest Amendments were enacted, the MSRB believes Bank Dealers would experience initial costs associated with establishing the revised policies and procedures to comply with the requirements of Regulation Best Interest, as well as the costs of ongoing compliance. The initial setup costs likely would be proportionately higher for smaller and less active Bank Dealers with fewer retail municipal recommendations than for the larger and more active Bank Dealers with more retail municipal recommendations, while the ongoing costs would likely be proportionate with each Bank Dealer's retail business activities. Additionally, Bank Dealers with an affiliated Broker-Dealer that is subject to Regulation Best Interest likely would not experience as much initial set-up costs as other Bank Dealers because they can leverage established policies and procedures from their Broker-Dealers affiliates presumably in compliance with Regulation Best Interest.

The MSRB believes the average per-firm total costs (initial and ongoing) would be substantially lower for a Bank Dealer providing retail municipal recommendations that are *only* related to municipal securities, as compared to the overall costs associated with a Broker-Dealer providing recommendations to retail customers of securities transactions or investment strategies involving securities related to many different types of securities. On average, there are many more retail-sized trades in other types of securities—for example, equities, corporate bonds, treasury and agency securities, options, convertible bonds, mutual funds, and exchange-traded funds—than in municipal securities alone.[76] A Broker-Dealer subject to Regulation Best Interest incurs compliance costs any time it provides a recommendation to its retail customers on any security, while a Bank Dealer would only incur cost when it provides a retail municipal recommendation. As a result, the MSRB believes the average per-Bank Dealer total costs would not approach the per-Broker-Dealer level, as estimated by the SEC in relation to Regulation Best Interest. *Table 2* provides an illustration of potential costs to be expected for a Bank Dealer with an average number of retail-sized trades in municipal securities as a result of the proposed rule change. Using the SEC's estimates of initial cost and ongoing cost for 2,766 Broker-Dealers, the MSRB estimated the portion of the costs attributable to municipal securities only for a Broker-Dealer with an average number of retail-sized trades in municipal securities, with the assumption that the same Broker-Dealer would incur only 35% of the initial cost and one percent of the ongoing cost if the Broker-Dealer only provided recommendations on municipal securities to retail customers.[77] The MSRB then applied the cost estimates to an average Bank Dealer.

TABLE 2—ESTIMATED INITIAL SETUP AND ONGOING COMPLIANCE COSTS FOR AN AVERAGE BANK DEALER

	Initial cost	Ongoing cost	Number of retail-sized customer trades
SEC Estimate			
Average Broker-Dealer (Non-Bank Dealer)	$2,153,290	$855,897	
Average Broker-Dealer Trading Municipal Bonds Only	753,651	8,559	5,523
Apply SEC Estimate to Average Bank Dealer Trading Municipal Bonds	753,651	4,590	2,962

Source: MSRB analysis with data obtained from the MSRB's Real-Time Transaction Reporting System (RTRS), MSRB's registration data and SEC's estimates of costs and benefits of applying Regulation Best Interest to Broker-Dealers.[78]

[74] As one potential example, where a Bank Dealer and a Broker-Dealer are both subsidiary entities of a common parent holding company, the MSRB is concerned that the parent holding company may attempt to take advantage of any regulatory imbalance by utilizing a regulatory arbitraging strategy to move retail customer accounts to the subsidiary with the lowest compliance standard, and, thus, Broker-Dealers may relocate retail customers accounts to affiliated Bank Dealers to avoid compliance with Regulation Best Interest.

[75] For a detailed discussion of the economic theory behind agency costs, please refer to the Regulation Best Interest Adopting Release, 84 FR at 33400–41.

[76] Based on the MSRB's estimate, there were approximately five million retail-sized customer trades in municipal securities in 2018, compared to 6.8 million retail-sized customer trades in corporate bonds, 132.5 million retail-sized customer trades in treasury securities and 4.4 billion retail-sized customer trades in equities, which include exchange-traded funds.

[77] The MSRB's analysis focuses on four securities that have substantial retail customer trades: Municipal securities, corporate bonds, treasury securities and equities, which include exchange-traded funds. To be conservative, all other securities, such as stock options, federal agency securities, mortgage-backed securities, asset-backed securities, mutual funds, etc., are assumed to have no retail trades. For the initial cost, the MSRB assumes a cost saving of 65% when establishing policies and procedures for one security only, municipal bonds, as opposed to for four securities, accounting for some fixed costs when working on a single security product. For the ongoing cost, the MSRB estimated the number of retail-sized customer trades for municipal securities that are likely based on a Broker-Dealer's recommendation relative to comparable retail-sized customer trades for corporate bonds, treasury securities and equities (including exchange-traded funds), and derived that the proportion for municipal securities would be less than one percent of the total. Conservatively, one percent is used for estimating the ongoing costs related to municipal securities. Data were obtained from the MSRB's Real-Time Transaction Reporting System (RTRS), MSRB's registration database, and SEC's estimates of costs and benefits of applying Regulation Best Interest to Broker-Dealers.

[78] *See* Regulation Best Interest Adopting Release, 84 FR at 33318.

Effect on Competition, Efficiency, and Capital Formation [79]

The MSRB believes that, if the proposed Best Interest Amendments were adopted, there is a possibility some Bank Dealers that rarely execute retail-sized customer trades, assuming those trades represent retail municipal recommendations, may choose to forgo retail business entirely to avoid the costs of compliance with proposed Best Interest Amendments and Regulation Best Interest, or more narrowly, stop providing retail municipal recommendations to limit the costs of compliance. Therefore, some Bank Dealers may be impacted by the proposed Regulation Best Interest Amendments by deciding to forego retail municipal recommendations or retail customer business altogether, though the broader impact on competition in the municipal securities market is expected to be minor given these Bank Dealers' relatively minor presence in executing retail-sized trades for municipal securities currently; accordingly, even if those Bank Dealers choose to relinquish their retail business, there should not be any significant reduction in the supply of services to retail investors. On the other hand, the MSRB does not expect a significant alteration to the competitive landscape from retail investors' perspective if the proposed Best Interest Amendments were adopted, as retail investors rarely use Bank Dealers for retail trading. Moreover, for those retail investors who do choose Bank Dealers to conduct retail activities, their activities are concentrated in a small number of Bank Dealers who are less likely to withdraw from the retail business as a result of the burdens created by the proposed Best Interest Amendments.

The MSRB believes requiring Bank Dealers to comply with the requirements of Regulation Best Interest, when making retail municipal recommendations, would improve market efficiency by imposing the same requirements on Bank Dealers when making such recommendations as on Broker-Dealers under Regulation Best Interest. The harmonization of MSRB rule requirements for Bank Dealers with SEC requirements for Broker-Dealers would create consistency for firms who have both Broker-Dealer and Bank Dealer subsidiaries, and, thus, would increase efficiency in terms of firms' compliance burdens. It also may encourage competition for retail customers among Bank Dealers (and between Bank Dealers and Broker-Dealers in some instances) to the extent that the disclosure of fees and conflicts of interest would increase transparency and facilitate more comparability across Bank Dealers and Broker-Dealers among retail investors, and, therefore, would further inform customers' decisions of whether to utilize a Bank Dealer versus a Broker-Dealer for transactions in municipal securities. In addition, the MSRB believes investors should benefit from receiving the same type of information from Bank Dealers and Broker-Dealers in relation to an investment recommendation. Therefore, as stated above, because of the creation of consistent regulatory requirements across Bank Dealers and Broker-Dealers for their retail municipal recommendations and the greater competition fostered by this consistency among firms serving retail customers, the MSRB believes that the proposed Best Interest Amendments would facilitate capital formation.

Institutional SMMP Amendment

The MSRB proposal to amend MSRB Rule G–48 would reinstate a previously existing actual control or de facto control standard for Institutional SMMP accounts for purposes of dealers' quantitative suitability obligations.

Benefits

The proposed Institutional SMMP Amendment to MSRB Rule G–48 would reduce the compliance burden for all dealers, including Bank Dealers and Broker-Dealers, by eliminating the requirements to undertake a quantitative suitability analysis for Institutional SMMPs when a dealer does not have actual control or de facto control over the customer's accounts. The requirement is not necessary because of the sophistication and differing needs of Institutional SMMPs who have knowingly declined to have such requirements apply to them, as described herein.

Costs

The MSRB believes the proposed Institutional SMMP Amendment to MSRB Rule G–48 to modify the quantitative suitability obligation of a dealer in the limited circumstances provided under the proposed Institutional SMMP Amendment would have minimal costs associated, particularly since the intent was to reinstate an exemption from quantitative suitability previously enacted for all recommendations through MSRB Rule G–19. One potential one-time cost would be for all dealers, including Bank Dealers and Broker-Dealers, to update their policies and procedures. Because of the recent existence of the same actual control or de facto control standard that would be reestablished by the proposed Institutional SMMP Amendment, the MSRB believes this one-time change should be familiar to firms and the cost of compliance implementation will be reduced in this regard. Moreover, to the degree that dealers are likely to reintroduce the same standards in their policies and procedures as previously existed, the cost of implementation would be minimized.

In addition, one impetus of the Broker-Dealer Harmonization Filing was to harmonize the rule with Regulation Best Interest and FINRA Rule 2111 and to reduce inconsistency on suitability requirements between FINRA's rules and MSRB's rules. By amending MSRB Rule G–48 to provide a narrow exemption from the application of quantitative suitability, this rule would not be fully harmonized with FINRA Rule 2111, and, thus, would establish two standards for accounts across the corporate and municipal securities markets. The MSRB believes that this lack of harmonization is justified in this instance for all the reasons stated herein,[80] including the fact that Institutional SMMPs are by their nature sophisticated entities that have affirmed and self-identified their capacity to independently evaluate dealers' recommendations of municipal securities transactions.

Effect on Competition, Efficiency, and Capital Formation

The MSRB believes the proposed Institutional SMMP Amendment to MSRB Rule G–48 would improve the operational efficiency of the municipal securities market by reintroducing the element of actual control or de facto control with respect to Institutional SMMP accounts that would trigger a dealer's quantitative suitability obligation, as dealers would have one fewer compliance burden. The MSRB does not expect that the proposed Institutional SMMP Amendment to MSRB Rule G–48 would harm competition in the municipal securities market, because the proposed Institutional SMMP Amendment would be applicable to all dealers and,

[79] Capital formation is defined by the SEC on their website ''What we do,'' available at *https://www.sec.gov/about/what-we-do#section2*. It refers to companies and entrepreneurs accessing America's capital markets to help them create jobs, develop innovations and technology, and provide financial opportunities for those who invest in them. *Id.*

[80] *See* related discussion *supra* under *Purpose and Intent of the Institutional SMMP Amendment to MSRB Rule G–48.*

therefore, any of the benefits and burdens created by the proposed Institutional SMMP Amendments would be evenly applied to all such firms transacting with Institutional SMMP customers and, thereby, avoid discriminatory impacts among dealer firms.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

On March 4, 2021, the Board published a request for comment seeking public feedback on requiring Bank Dealers to comply with Regulation Best Interest when making a retail municipal recommendation (the ''Request for Comments'').[81] The Board received five comments letters in response to the Request for Comments.[82] Each of these will be addressed below. The comment letters addressing the proposed Best Interest Amendments will be discussed separately from the one comment letter addressing the proposed Institutional SMMP Amendment.

Discussion of Comments Related to the Best Interest Amendments

The MSRB received four comment letters addressing the proposed Best Interest Amendments in response to its Request for Comments. Comments submitted by SIFMA and the Securities Association were supportive of the proposed Best Interest Amendments, while the comments submitted by the Bankers Association and Commerce Bank expressed concerns about the proposed Best Interest Amendments, generally, in terms of the consequences of the potential compliance burden in relation to Bank Dealers' limited retail customer activity, as further discussed below.

Support for a Uniform Regulatory Standard

SIFMA cited the goal of achieving regulatory parity among regulated entities as the reason for being in favor of the proposed rule change.[83] Specifically, the SIFMA Bank Dealer Letter stated that ''SIFMA supports the proposed amendment to extend Regulation Best Interest to bank dealers, as defined in the notice'' and that ''we believe that regulatory parity among regulated entities, which this amendment achieves, is a worthwhile goal.'' [84] The Securities Association cited a reduction in regulatory confusion and establishing Regulation Best Interest as the standard for Broker-Dealers and Bank Dealers as the reasons for being in favor of the proposed rule change.[85] The Securities Association stated that adopting Regulation Best Interest for bank dealers will ''reduce regulatory confusion for municipal dealers and further establish [Regulation Best Interest] as the national standard for broker-dealers and bank dealers.'' [86] Further, the Securities Association stated that ''[it] appreciates the work by the MSRB in the Proposal to align their rules with the SEC and Financial Industry Regulatory Authority's (FINRA) when possible so that broker-dealers are not subjected to multiple standards.'' [87] As discussed above, the Board agrees with the commenters that the proposed Best Interest Amendments would benefit the municipal securities market through more uniform regulatory standards.

Concerns Regarding Bank Dealer's Compliance Burden and Effects on Competition

Among other topics in the Request for Comments, the Board sought public input on the potential burdens associated with the proposed Best Interest Amendments and, in particular, if requiring Bank Dealers to comply with Regulation Best Interest would disincentivize Bank Dealers from engaging in certain municipal securities activities with retail customers.[88] Commerce Bank and the Bankers Association offered comments. The Bankers Association commented that, while its members have long supported the notion that financial professionals offering investment advice to retail customers should be subject to a best interest standard, the Bankers Association urged the Board to consider the compliance costs imposed by such a rule on Bank Dealers in relation to their limited amount of retail customer activity.[89] The Bankers Association continued, stating that, ultimately, Bank Dealers in municipal securities do not have a significant retail customer base to warrant a new regulatory compliance regime in this manner.[90]

Echoing this concern regarding the potential compliance burden of the proposed Best Interest Amendments, Commerce Bank responded that they would assess the additional compliance costs that come with compliance with Regulation Best Interest and consider the elimination of providing recommendations for securities or strategies to retail customers.[91] Commerce Bank also expressed concern that the compliance burden of the proposed Best Interest Amendments may cause it to eliminate or become uncompetitive in relation to certain underwriting activities, particularly for services provided to issuers utilizing retail order periods.[92]

While the Board believes that commenters' concerns regarding the potential compliance burden for Bank Dealers associated with the proposed Best Interest Amendments are valid, the Board also believes that the potential investor protection benefits associated with the proposed Best Interest Amendments outweigh these potential compliance burdens for Bank Dealers. The Bankers Association Letter and the Commerce Bank Letter articulated concerns regarding the potential compliance burden associated with the proposed Best Interest Amendments,[93] but these commenters did not specifically address why Bank Dealers face compliance burdens that are materially different from those faced by

[81] MSRB Notice 2021–06 (March 4, 2021).

[82] Letter from Justin M. Underwood, Executive Director, American Bankers Association (''Bankers Association''), dated June 2, 2021 (the ''Bankers Association Letter''); Letter from Christopher A. Iacovella, Chief Executive Officer, American Securities Association (''Securities Association''), dated May 27, 2021 (the ''Securities Association Letter''); the Commerce Bank Letter; Letter from Leslie M. Norwood, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association (''SIFMA''), dated June 2, 2021 (the ''SIFMA Bank Dealer Letter''); and Letter from Leslie M. Norwood, Managing Director and Associate General Counsel, SIFMA, dated June 2, 2021 (the ''SIFMA SMMP Letter'').

[83] SIFMA Bank Dealer Letter at 2.

[84] SIFMA Bank Dealer Letter at 1–2.

[85] Securities Association Letter at 1.

[86] *Id.* at 1.

[87] *Id.* at 2.

[88] Request for Comments at 7.

[89] Bankers Association Letter at 2

[90] *Id.*

[91] Commerce Bank Letter at 2.

[92] Commerce Bank Letter at 3 (''Assuming the amendments are approved as adopted and bank dealers begin to move away from providing services to retail customers, bank dealers that underwrite municipal bonds would need controls in place to ensure underwriting or related commitments are appropriate for any retail order periods required by an issuer. The potential impact may be a smaller number of underwriting firms available or willing to work with smaller issuers and public entities in the market, limiting the number of competitors available for either competitive or negotiated deals.'') In addition to the reasons discussed below, the MSRB observes that analogous concerns regarding such dampening effects of Regulation Best Interest's requirements on the competition for underwriting activities equally apply to Broker-Dealers. Yet, the Commission ultimately found that Regulation Best Interest would not have a deleterious effect on capital formation. *See, generally,* Regulation Best Interest Adopting Release, 84 FR at 33461 *et seq.*

[93] *See, respectively,* Bankers Association Letter at 2 and Commerce Bank Letter at 2 (noting that retail accounts account for approximately 9% of their total open accounts and only a portion of these accounts transacted in the previous twelve months).

Broker-Dealers, who are already required to adhere to the enhanced suitability standards required by Regulation Best Interest. Consequently, the MSRB is unaware of any material distinctions between the municipal securities activities of Bank Dealers and Broker-Dealers that would persuade the MSRB to propose a non-uniform regulatory scheme of lesser investor protections for the retail municipal recommendations of Bank Dealers.

Moreover, in developing the proposed Best Interest Amendments, the MSRB observed that Regulation Best Interest did not adopt de minimis thresholds or other standards to exclude smaller regulated entities with lesser amounts of retail customer activity from Regulation Best Interest's baseline compliance burdens.[94] Relatedly, the Commission concluded that the final version of its Regulation Best Interest appropriately balanced the concerns of various commenters from larger and smaller entities.[95] Similar to the Commission's determination, the MSRB believes that the proposed Best Interest Amendments are written to balance the interests of commenters, including the various types and sizes of dealer entities, to best achieve the important goals of enhancing retail investor protection and decision making, while preserving, to the extent possible, retail investor access (in terms of choice and cost) to differing types of municipal security investment services and municipal security products.

Relatedly, the MSRB observes that the Commission determined that Regulation Best Interest would not have a deleterious effect on capital formation.[96] More specifically, the Commission concluded that (i) the possibility that Regulation Best Interest may increase the efficiency of the recommendations provided by the associated persons of the broker-dealer may enhance the attractiveness of broker-dealer services for those investors who currently do not invest through broker-dealers,[97] and (ii) if retail customers are more willing to participate in the securities markets through broker-dealers, Regulation Best Interest would have a positive effect on capital formation.[98]

For similar reasons, the MSRB believes that the proposed Best Interest Amendments would not hinder capital formation in the municipal securities market, as suggested by the Commerce Bank Letter, such as in instances where there is less underwriter competition for small municipal issuers or municipal issuers who seek to utilize retail order periods. To the degree that retail municipal recommendations are subject to a uniform regulatory standard across Bank Dealers and Broker-Dealers, the MSRB believes that the proposed Best Interest Amendments may increase the efficiency of retail municipal recommendations and enhance the attractiveness of dealer's municipal security services. This uniform regulatory standard could draw more retail customers to the primary offering of municipal securities with retail order periods and, in this respect, incrementally reduce issuer borrowing costs.

Discussion of Comments Related to the Institutional SMMP Amendment

The Board did not seek separate comment on the proposed Institutional SMMP Amendment but did receive the SIFMA SMMP Letter as part of the Request for Comments, which was generally supportive of the proposed Institutional SMMP Amendment. SIFMA stated in the SMMP Letter that its members ''feel strongly that the Quantitative Suitability Requirement in Rule G–19 should be clarified, and interpreted as applicable only to natural person SMMPs, but not to institutional SMMPs. Extending the Quantitative Suitability Requirement to all SMMPs would be unduly costly and burdensome.'' [99] As discussed above, the Board agrees with the commenter that requiring a dealer to undertake a quantitative suitability analysis, when an institutional customer has already affirmatively opted out of receiving such an analysis, is an unnecessarily burdensome requirement to place on dealer's recommendations to Institutional SMMPs.

SIFMA cited the MSRB's ''history of treating SMMPs differently from non-SMMPs, based on a reasoned recognition of the differences between these two investor classes and the relative protections that should be afforded to both.'' [100] The Board agrees that in limited circumstances it is appropriate for certain investor classes to be afforded different protections under MSRB rules, as different classes can have differing levels of sophistication, differing risk tolerances, and differing investment goals. As noted above, the SMMP concept and the modified regulatory obligations afforded to SMMPs under MSRB rules are intended to account for the distinct capabilities of certain self-identifying, sophisticated, non-retail customers, as well as the varied types of dealer-customer relationships occurring in the municipal securities markets. Thus, the MSRB believes it is appropriate to afford Institutional SMMPS more finely tailored protections, and that the proposed Institutional SMMP Amendment would not erode the overall protections afforded to Institutional SMMPs.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period of up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–MSRB–2022–02 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–MSRB–2022–02. This file

[94] *See, generally*, Regulation Best Interest Adopting Release, 84 FR at 33485 *et seq* (discussing impact on ''Small Entities Subject to the Rule'').

[95] Regulation Best Interest Adopting Release, 84 FR at 33323 (''After careful consideration of the comments and additional information we have received, we believe that Regulation Best Interest, as modified, appropriately balances the concerns of the various commenters in a way that will best achieve the Commission's important goals of enhancing retail investor protection and decision making, while preserving, to the extent possible, retail investor access (in terms of choice and cost) to differing types of investment services and products.'')

[96] *See, generally*, Regulation Best Interest Adopting Release, 84 FR at 33461 *et seq*.

[97] Regulation Best Interest Adopting Release, 84 FR at 33462.

[98] *Id*.

[99] SIFMA SMMP Letter at 2.

[100] SIFMA SMMP Letter at 3.

number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the MSRB. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MSRB–2022–02 and should be submitted on or before May 31, 2022.

For the Commission, pursuant to delegated authority.[101]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09960 Filed 5–9–22; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice 11725]

U.S. Advisory Commission on Public Diplomacy Notice of Meeting

The U.S. Advisory Commission on Public Diplomacy (ACPD) will hold a virtual public meeting on Wednesday, June 1, 2022, from 12:00 p.m. until 1:15 p.m., to preview the April 2022 special report, *Exploring U.S. Public Diplomacy's Domestic Dimensions: Purviews, Publics, and Policies, https://www.state.gov/exploring-u-s-public-diplomacys-domestic-dimensions-purviews-publics-and-policies-2022/.* The meeting will feature a panel of city diplomacy professionals who will discuss the relationship between city diplomacy and domestic public diplomacy.

This meeting is open to the public, including the media and members and staff of governmental and non-governmental organizations. To obtain the web conference link and password, please register here: *https://www.eventbrite.com/e/domestic-public-diplomacy-city-diplomacy-perspectives-tickets-328956657217.* To request reasonable accommodation, please email ACPD Program Assistant Kristy Zamary at *ZamaryKK@state.gov.* Please send any request for reasonable accommodation no later than May 20, 2022. Requests received after that date will be considered but might not be possible to fulfill. Attendees should plan to enter the web conference waiting room by 11:50 a.m. to allow for a prompt start.

Since 1948, the ACPD has been charged with appraising activities intended to understand, inform, and influence foreign publics and to increase the understanding of, and support for, these same activities. The ACPD conducts research that provides honest assessments of public diplomacy efforts, and disseminates findings through reports, white papers, and other publications. It also holds public symposiums that generate informed discussions on public diplomacy issues and events. The Commission reports to the President, Secretary of State, and Congress and is supported by the Office of the Under Secretary of State for Public Diplomacy and Public Affairs.

For more information on the U.S. Advisory Commission on Public Diplomacy, please visit *https://www.state.gov/bureaus-offices/under-secretary-for-public-diplomacy-and-public-affairs/united-states-advisory-commission-on-public-diplomacy/,* or contact Executive Director Vivian S. Walker at *WalkerVS@state.gov* or Senior Advisor Deneyse Kirkpatrick at *kirkpatrickda2@state.gov.*

Vivian S. Walker,

Executive Director, U.S. Advisory Commission on Public Diplomacy, Department of State.

[FR Doc. 2022–09993 Filed 5–9–22; 8:45 am]

BILLING CODE 4710–45–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 391 (Sub–No. 11X)]

Red River Valley & Western Railroad Company—Abandonment Exemption—Cass County, N.D.

Red River Valley & Western Railroad Company (RRVW) has filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exemption Abandonments* to abandon an approximately 2.29-mile rail line extending from milepost 9.36 to milepost 11.65 (at Horace, N.D.) in Cass County, N.D. (the Line). The Line traverses U.S. Postal Service Zip Code 58047.

RRVW has certified that: (1) No local traffic has moved over the Line for at least two years; (2) there is no overhead traffic on the Line that has been, or would need to be, rerouted as a result of the proposed abandonment; (3) no formal complaint filed by a user of rail service on the Line (or by state or local government on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board (Board) or has been decided in favor of a complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7(b) and 1105.8(c) (notice of environmental and historic reports), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to government agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received,[1] this exemption will be effective on June 9, 2022, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[2] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2), and interim trail use/rail banking requests under 49 CFR 1152.29 must be filed by

[101] 17 CFR 200.30–3(a)(12).

[1] Persons interested in submitting an OFA must first file a formal expression of intent to file an offer, indicating the type of financial assistance they wish to provide (*i.e.,* subsidy or purchase) and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(2)(i).

[2] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

May 20, 2022.[3] Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by May 31, 2022.

All pleadings, referring to Docket No. AB 391 (Sub-No. 11X), must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on RRVW's representative, William A. Mullins, Baker & Miller PLLC, 2401 Pennsylvania Avenue NW, Suite 300, Washington, DC 20037.

If the verified notice contains false or misleading information, the exemption is void ab initio.

RRVW has filed a combined environmental and historic report that addresses the potential effects, if any, of the abandonment on the environment and historic resources. OEA will issue a Draft Environmental Assessment (Draft EA) by May 13, 2022. The Draft EA will be available to interested persons on the Board's website, by writing to OEA, or by calling OEA at (202) 245–0294. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339. Comments on environmental or historic preservation matters must be filed within 15 days after the Draft EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), RRVW shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the Line. If consummation has not been effected by RRVW's filing of a notice of consummation by May 10, 2023, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available at *www.stb.gov.*

Decided: May 4, 2022.

By the Board, Valerie O. Quinn, Acting Director, Office of Proceedings.

Regena Smith-Bernard,

Clearance Clerk.

[FR Doc. 2022–10014 Filed 5–9–22; 8:45 am]

BILLING CODE 4915–01–P

[3] Filing fees for OFAs and trail use requests can be found at 49 CFR 1002.2(f)(25) and (27), respectively.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FRA–2022–0620]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Pilot Certification and Qualification Requirements for Air Carrier Operations

AGENCY: Federal Aviation Administration (FAA), Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves FAA review of Airline Transport Pilot (ATP) Certification Training Program (CTP) submittals to determine that the program complies with the applicable requirements. It also involves FAA review of an institution of higher education's application for the authority to certify its graduates meet the minimum regulatory requirements.

DATES: Written comments should be submitted by July 11, 2022.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Sandra Ray, Federal Aviation Administration, Voluntary Programs and Rulemaking Section AFS–260, 1187 Thorn Run Road, Suite 200, Coraopolis, PA 15108.

By fax: 412–239–3063.

FOR FURTHER INFORMATION CONTACT: Sandra L. Ray by email at: *Sandra.ray@faa.gov*; phone: 412–329–3088.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0755.

Title: Pilot Certification and Qualification Requirements for Air Carrier Operations.

Form Numbers: None.

Type of Review: Renewal of an information collection.

Background: FAA aviation safety inspectors review the Airline Transport Pilot (ATP) Certification Training Program (CTP) submittals to determine that the program complies with the applicable requirements of 14 CFR 61.156. The programs that comply with the minimum requirements receive approval to begin offering the course to applicants for an ATP certificate with a multiengine class rating or an ATP certificate obtained concurrently with an airplane type rating. FAA aviation inspectors also review an institution of higher education's application for the authority to certify its graduates meet the minimum requirements of 14 CFR 61.160. The institutions of higher education that receive a letter of authorization for their degree program(s) are authorized to place a certifying statement on a graduates' transcript indicating he or she is eligible for a restricted privileges ATP certificate.

Respondents: Varies per requirement.

Frequency: Varies per requirement.

Estimated Average Burden per Response: Varies per requirement.

Estimated Total Annual Burden: 1,301 Hours.

Issued in Washington, DC, on May 5, 2022.

Sandra L. Ray,

Aviation Safety Inspector, AFS–260.

[FR Doc. 2022–10004 Filed 5–9–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2010–0054]

Alaska Railroad Corporation's Request To Field Test Its Positive Train Control System

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of availability and request for comments.

SUMMARY: This document provides the public with notice that, on April 25, 2022, the Alaska Railroad Corporation (ARRC) submitted a request to field test new functionality to improve the safety critical nature of existing functions, such as mandatory directive conveyance and confirmation, and conditional authorities, and a safety server that is being added in ARRC's PTC Office

Segment to provide safety oversight of these new functions with the intent of improving the safety and efficiency of rail operations. FRA is publishing this notice and inviting public comment on the railroad's field test request.

DATES: FRA will consider comments received by July 11, 2022. FRA may consider comments received after that date to the extent practicable and without delaying implementation of valuable or necessary modifications to a PTC system.

ADDRESSES:

Comments: Comments may be submitted by going to *https://www.regulations.gov* and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and the applicable docket number. The relevant PTC docket number for this host railroad is Docket No. FRA–2010–0054. For convenience, all active PTC dockets are hyperlinked on FRA's website at *https://railroads.dot.gov/train-control/ptc/ptc-annual-and-quarterly-reports.* All comments received will be posted without change to *https://www.regulations.gov;* this includes any personal information.

FOR FURTHER INFORMATION CONTACT: Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816–516–7168, email: *Gabe.Neal@dot.gov.*

SUPPLEMENTARY INFORMATION: On December 11, 2020, FRA certified ARRC's Interoperable Electronic Train Management System (I–ETMS) PTC system under Title 49 Code of Federal Regulations (CFR) Section 236.1015 and Title 49 United States Code (U.S.C.) 20157(h). Pursuant to 49 CFR 236.1035, a railroad must obtain FRA's approval before field testing an uncertified PTC system, or a product of an uncertified PTC system, or any regression testing of a certified PTC system on the general rail system. *See* 49 CFR 236.1035(a).

Interested parties are invited to comment on ARRC's field test request by submitting written comments or data. During FRA's review of this railroad's field test request, FRA will consider any comments or data submitted within the timeline specified in this notice and to the extent practicable, without delaying implementation of valuable or necessary modifications to a PTC system. Under 49 CFR 236.1035, FRA maintains the authority to approve, approve with conditions, or deny a railroad's field test request at FRA's sole discretion.

Privacy Act Notice

In accordance with 49 CFR 211.3, FRA solicits comments from the public to better inform its decisions. DOT posts these comments, without edit, including any personal information the commenter provides, to *https://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See *https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov.* To facilitate comment tracking, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. If you wish to provide comments containing proprietary or confidential information, please contact FRA for alternate submission instructions.

Issued in Washington, DC.

Carolyn R. Hayward-Williams,

Director, Office of Railroad Systems and Technology.

[FR Doc. 2022–09943 Filed 5–9–22; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2022–0044]

Agency Information Collection Activities; Notice and Request for Comment; Field Study of Heavy Vehicle Crash Avoidance Systems

ACTION: Notice and request for public comment on an extension of a currently approved information collection.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) invites public comments about our intention to request approval from the Office of Management and Budget (OMB) for an extension of a currently approved information collection. Before a federal agency may collect certain information from the public, it must receive approval from OMB. Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections. This document describes a collection of information for which NHTSA intends to seek OMB extension approval, titled ''Heavy Vehicle Crash Avoidance Systems'' and identified by OMB Control Number 2127–0741, which is currently approved through August 31, 2022. This project has been delayed due to COVID–19 shutdowns and precautions. The extension is necessary to continue the current data collection to completion. This extension request updates the burden hours to reflect the numbers of respondents that are needed to complete the study, updates to time estimates for responses, and mean hourly rates. Additionally, this notice provides clarification on the burden hours and the costs to the public.

DATES: Comments must be submitted on or before July 11, 2022.

ADDRESSES: You may submit comments using any of the following methods:

- *Electronic submissions:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* Docket Management, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building, Room W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. Telephone (202) 366–9322.

Instructions: Each submission must include the Agency name and Docket number identified at the beginning of this document. Note that all comments received will be posted without change to *http://www.regulation.gov,* including any personal information provided. Please see the Privacy heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://www.dot.gov/privacy.html.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov,* or the street address listed above. Follow the online instructions for accessing the dockets via the internet.

FOR FURTHER INFORMATION CONTACT: Jenny Zhang, Office of Vehicle Safety Research, National Highway Traffic Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, Telephone: 202–366–3973; email address *jenny.zhang@dot.gov.* Please identify the relevant collection of

information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) how to enhance the quality, utility, and clarity of the information to be collected; (d) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In compliance with these requirements, NHTSA asks for public comments on the extension of the following collection of information for which the agency is seeking approval from OMB.

Title: Field Study of Heavy Vehicle Crash Avoidance Systems.

Type of Request: Extension of a currently approved information collection.

OMB Control Number: 2127–0741.

Form Number: None.

Type of Review Requested: Regular.

Requested Expiration Date of Approval: Three years from date of approval.

Summary of the Collection of Information: The National Highway Traffic Safety Administration (NHTSA) is gathering information regarding drivers' naturalistic driving experiences and opinions about crash avoidance systems (CAS) consisting of Lane Departure Warning, Forward Collision Warning, Impact Alert, and Automatic Emergency Braking for heavy vehicles.

CAS technology has been advancing rapidly since the conclusion of the previous study, with products for heavy commercial vehicles becoming commercially available. These systems present opportunities for improving driver awareness and behavior, improving drivers' responses to potential collisions, and mitigating or preventing collisions when drivers do not respond. The newest generation of CAS technology includes several new features, such as multiple sensors, improvements to radar algorithms, and new features such as full braking in response to static objects or pedestrians. However, it is unknown if this newest generation of products has been able to reduce the prevalence of false or nuisance alerts observed in the previous study, if there are any issues with new types of alerts that have been added since previous studies, or whether driver have negative perceptions of the technology due to these issues. As these technologies become more popular with fleets, it is important to understand their real-world performance and any unintended consequences that may arise from them.

Data collection began in August 2021 after COVID delays and a shortage of chips necessary for use in the data acquisition system necessary for the naturalistic driving portion of the study. As of December 31, 2021, one respondent has completed the study, three are in the field study portion, and one has completed the informed consent document and pre-field study surveys but still needs to go through the installation portion of stage one and stages two to three of the study. Information in this extension requests refers to the respondents and burden associated with completing the study.

Description of the Need for the Information and Proposed Use of the Information: The collection of information consists of: An informed consent for participation, a demographic questionnaire, an initial CAS technology questionnaire, and a post-study CAS technology questionnaire.

The information to be collected will be used as follows:

- *Informed Consent* is collected from respondents who agree to participate in the study; the informed consent has been approved by an Institutional Review Board.
- *Demographic questionnaire* is used to obtain demographic information so that potential analysis may account for participants from various groups (*e.g.,* age, self-identified gender, driving experience, and experience with CAS technology).
- *Initial CAS technology questionnaire* is used to get information about drivers' beliefs and attitudes towards the CAS technology installed on the commercial vehicle they use for their job prior to data collection. This questionnaire assesses perceived usability of the systems in terms of acceptance and satisfaction, as well as willingness to have this technology in their vehicle.
- *Final CAS technology questionnaire* is used to get information about drivers' beliefs and attitudes towards the CAS technology installed on the commercial vehicle they use for their job at the end of data collection. These questionnaires will also be used to assess perceived distraction potential of the systems in terms of acceptance and satisfaction, as well as willingness to have this technology in their vehicle. Each driver will complete a post-study questionnaire once, after the completion of his or her data collection. The post-study survey will gauge how drivers' attitudes and preferences may have changed over the course of participation.
- Each participating driver will have a data acquisition system (DAS) installed in their vehicle for approximately three months while they perform their normal work duties. This system will collect video of the driver and forward roadway, telemetry and vehicle network data related to driving, and activations of the vehicle's CAS.

Respondents: Respondents for this study are drawn from a convenience sample from trucking fleets across the United States. Drivers are recruited from fleets that have signed agreements with the research team and have trucks that are outfitted with CAS technologies. Recruitment will attempt to balance the number of vehicles using particular brands of CAS technology but will be subject to fleet availability and scheduling constraints. Requirements of drivers involved in the study do not extend beyond employment requirements for each fleet.

Estimated Number of Respondents: 170 remaining respondents for initial phases of the study; anticipating some drop-out, the end-goal number of remaining respondents is 149.

Estimated Number of Responses: 170 for the consent form (one per respondent); 170 for the Demographic Questionnaire (one per respondent); 170 for the Initial CAS Questionnaire (one per respondent); 149 for the Final CAS Questionnaire (one per respondent) that completes the study.

Estimated Total Annual Burden: 123.6 hours total.

Estimated Frequency: The Informed Consent Form, Demographic Questionnaire, and Initial CAS Technology Questionnaire are completed once at the start of participation and data collection. The

Final CAS Technology Questionnaire is completed once at the completion of participation, approximately three months later.

TABLE 1—BURDEN CALCULATIONS AND ESTIMATED OPPORTUNITY COST

Instrument	Number of respondents	Estimated time for completion	Total estimated burden hours †	Hourly wage	Estimated total opportunity cost
Stage One:					
Informed Consent Form	170	20	57 hours	$23.42	$1,334.94
Demographic Questionnaire	170	5	15 hours	23.42	351.30
Initial CAS Technology Questionnaire	170	25	71 hours	23.42	1,662.82
Stage Two:					
Naturalistic Driving Study	171	N/A	N/A	N/A	N/A
Stage Three:					
Final CAS Technology Questionnaire	149	25	63 hours	23.42	1,475.46
Total Burden Remaining			206 hours		4,824.52
Months Remaining			20		
Annual Burden Remaining			123.6 hours		2,894.71

The above table reflects the annual burden hours to be 123.6 to complete data collection. While the table reflects opportunity costs, this is not a burden incurred by the public for this information collection. The annual burden cost to respondents is zero.

The previous notice estimated total burden hours for this study to be 193.5 total. The total number of burden hours to complete data collection is now 206 based on updates to the time for the Informed Consent and the Demographic Questionnaire. Opportunity costs have been updated to reflect current average hourly wages; however, this is not a burden to respondents for the information collection.

Due to COVID–19 shutdowns and precautions, data collection efforts were suspended. NHTSA anticipates additional time beyond the August 31, 2022, expiration date of the currently approved collection to complete this effort. The federal government began this study at $2,581,075 in contract expenses and has added expenses due to the time delays and resulting changes in technology. The total cost expected at this time is $2,954,970 with an annualized cost to the federal government over the expected study time-to-completion of $402,950.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility, and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995, 44. U.S.C. Chapter 35, as amended; 5 CFR part 1320; and 49 CFR 1.95.

Issued in Washington DC.

Cem Hatipoglu,

Associate Administrator for Vehicle Safety Research.

[FR Doc. 2022–10012 Filed 5–9–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket ID Number: DOT–OST–2010–0054]

Notice of Submission of Proposed Information Collection to OMB Agency Request for Reinstatement of Previously Approved Collections: Nondiscrimination on the Basis of Disability in Air Travel: Reporting Requirements for Disability-Related Complaints

AGENCY: Office of the Secretary (OST), Department of Transportation (Department or DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the *Paperwork Reduction Act of 1995* (44 U.S.C. Chapter 35, as amended), this notice announces the DOT's intention to reinstate an Office of Management and Budget (OMB) Control Number 2105–0551, ''Reporting Requirements for Disability-Related Complaints.'' The information collection is related to a requirement in the Code of Federal Regulations (CFR) for carriers to report annually to the Department the number of disability-related complaints they receive.

DATES: Interested persons are invited to submit comments regarding this proposal. Written comments should be submitted by July 11, 2022.

ADDRESSES: You may file comments identified by the docket number DOT–OST–2010–0054 by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for submitting comments. (You may access comments received for this notice at *http://www.regulations.gov* by searching docket DOT–OST–2010–0054.)
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building Ground Floor Room W12–140, Washington, DC 20590–0001;
- *Hand delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

Instructions: You must include the agency name and docket number DOT–OST–2010–0054 at the beginning of your comment. All comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

Privacy Act: Anyone is able to search the electronic form of all comments received in any of DOT's dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register**

published on April 11, 2000 (65 FR 19477–78).

FOR FURTHER INFORMATION CONTACT: John Wood, Office of Aviation Consumer Protection, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, Telephone Number (202) 366–9342 (voice), (202) 366–7152 (fax), *john.wood@dot.gov* (email). Arrangements to receive this document in an alternative format may be made by contacting the above-named individual.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2105–0551.

Title: Reporting Requirements for Disability-Related Complaints.

Type of Request: Reinstatement of information collections.

Background: The Department requires U.S. and foreign air carriers operating to, from and within the United States that conduct passenger-carrying service with at least one large aircraft to record complaints that they receive alleging inadequate accessibility or discrimination on the basis of disability. The carriers must also categorize these complaints according to the type of disability and nature of complaint, prepare a summary report annually of the complaints received during the preceding calendar year, submit the report to the Department's Office of Aviation Consumer Protection, and retain copies of correspondence and records of action taken on the reported complaints for three years. Carriers are also required to submit their annual report via the World Wide Web except if the carrier can demonstrate an undue burden by doing so and receives permission from the Department to submit it in an alternative manners. The first required report covered disability-related complaints received by carriers during calendar year 2004, was due to the Department on January 31, 2005. Carriers have since submitted subsequent reports by the last Monday in January for the prior calendar year.

DOT is publishing this notice to announce its intent to seek reinstatement of the previously approved information collections described above under OMB Control Number 2105–0551. OMB authorization of the information collections expired on April 30, 2022.

The Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to monetary penalty for failing to comply with a collection of information if the collection of information does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

For each of these information collections, the title, a description of the respondents, and an estimate of the annual recordkeeping and periodic reporting burden are set forth below.[1]

(1) Requirement to record and categorize complaints received.

Respondents: U.S. air carriers and foreign air carriers operating to and from the United States that conduct passenger-carrying service with at least one large aircraft.

Number of Respondents: 176 (the average of the total number of respondents that reported for Calendar Years (CYs) 2018, 2019, and 2021).

Estimated Annual Burden on Respondents: 0–2,431 hours (145,905 minutes) a year for each respondent (estimated time to record and categorize each complaint (15 minutes) multiplied by the lowest number of complaints and the average of the highest number of complaints received during CYs 2018, 2019, and 2021 (0–9,727)).

Estimated Total Annual Burden: 7,854 hours (471,255 minutes) for all respondents (time to record and categorize each complaint (15 minutes) multiplied by the average total number of complaints received during CYs 2018, 2019, and 2021 (31,417) for all respondents).

Frequency: 0–9,727 complaints (The range of the lowest number of complaints and an average of the highest number of complaints received by any respondent during CYs 2018, 2019, and 2021).

(2) Requirement to prepare and submit annual report.

Respondents: U.S. air carriers and foreign air carriers operating to and from the United States that conduct passenger-carrying service with at least one large aircraft.

Number of Respondents: 176 (the average of the total number of respondents that reported for CYs 2018, 2019, and 2021).

Estimated Annual Burden on Respondents: 30 minutes a year per each respondent.

Estimated Total Annual Burden: 88 hours (5,280 minutes) for all respondents (estimate annual burden [30 minutes] multiplied by the total number of respondents (176)).

Frequency: 1 report to DOT per year for each respondent.

(3) Requirement to retain correspondences and records of action taken on all disability-related complaints.

Respondents: U.S. air carriers and foreign air carriers operating to and from the United States that conduct passenger-carrying service with at least one large aircraft.

Number of Respondents: 176 (the average of the total number of respondents that reported for CYs 2018, 2019, and 2021).

Estimated Annual Burden on Respondents: 0–811 hours (0–48,635 minutes) for each respondent (the estimated time it will take for each respondent to retain or save the correspondences and records of action taken on disability-related complaints (5 minutes) multiplied by the lowest number of complaints and the average of the highest number of complaints received per respondent during CYs 2018, 2019, and 2021 (0–9,727)).

Estimated Total Annual Burden: 2,618 hours (157,085 minutes) for all respondents (time to retain or save the correspondences and records of action taken on disability-related complaints (5 minutes) multiplied by the average total number of complaints received during CYs 2018, 2019, and 2021 (31,417) for all respondents.

Frequency: 0–9,727 complaints per year for each respondent (The range of the lowest number of complaints and an average of the highest number of complaints received by any respondent during CYs 2018, 2019, and 2021).

Comments Invited

We invite comments on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will

[1] DOT did not use calendar year 2020 data for its estimates because airline operations were not representative of a typical year due to the unprecedented impact of COVID–19 on air transportation that year.

also become a matter of public record on the docket.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 59 CFR 1.48.

Issued in Washington, DC, on May 4, 2022.

Blane Abaineh Workie,

Assistant General Counsel, Office of Aviation Consumer Protection.

[FR Doc. 2022–09942 Filed 5–9–22; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Disclosure of Returns and Return Information to Designee of Taxpayer

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning disclosure of returns and return information to designee of taxpayer.

DATES: Written comments should be received on or before July 11, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *omb.unit@irs.gov.* Include OMB control number 1545–1816 or Disclosure of Returns and Return Information to Designee of Taxpayer, in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis at (202) 317–5751, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington DC 20224, or through the internet, at *Kerry.L.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Disclosure of Returns and Return Information to Designee of Taxpayer.

OMB Number: 1545–1816.

Regulation Project Number: TD 9054, as amended by TD 9618.

Abstract: Under section 6103(a), returns and return information are confidential unless disclosure is otherwise authorized by the Code. Section 6103(c), as amended in 1996 by section 1207 of the Taxpayer Bill of Rights II, Public Law 104–168 (110 Stat. 1452), authorizes the IRS to disclose returns and return information to such person or persons as the taxpayer may designate in a request for or consent to disclosure, or to any other person at the taxpayer's request to the extent necessary to comply with a request for information or assistance made by the taxpayer to such other person. Disclosure is permitted subject to such requirements and conditions as may be prescribed by regulations. With the amendment in 1996, Congress eliminated the longstanding requirement that disclosures to designees of the taxpayer must be pursuant to the written request or consent of the taxpayer.

Current Actions: There are no changes to the regulation that would affect burden. However, the agency is updating the estimated number of responses based on recent collection data.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, business or other not-for-profit institutions, farms, and Federal, state, local or tribal governments.

Estimated Number of Respondents: 9,000.

Estimated Time per Respondent: 12 minutes.

Estimated Total Annual Burden Hours: 1,800 hours.

The following paragraph applies to all the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 3, 2022.

Kerry L. Dennis,

Tax Analyst.

[FR Doc. 2022–09976 Filed 5–9–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Emergency Submission for OMB Review; Comment Request; Capital Projects Fund Compliance Reporting

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance utilizing emergency review procedures in accordance with the Paperwork Reduction Act of 1995. Emergency review and approval of this collection has been requested from OMB by April 30, 2022. The public is invited to submit comments on this request.

DATES: Written comments must be received on or before May 25, 2022.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, by the following method:

- *Federal E-rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Refer to Docket Number TREAS–DO–2022–0011 and the specific Office of Management and Budget (OMB) control number 1505–NEW.

FOR FURTHER INFORMATION CONTACT: For questions related to this program, please contact Jeremy Turret by emailing *Jeremy.Turret@treasury.gov,* or calling 202–622–4256. Additionally, you can view the information collection requests at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Title: Coronavirus Capital Projects Fund.

OMB Control Number: 1505–XXXX.

Type of Review: New Collection.

Description: Section 604 of the Social Security Act (the ''Act''), as added by section 9901 of the American Rescue Plan Act of 2021, Public Law 117–2 (Mar. 11, 2021) established the Coronavirus Capital Projects Fund (''CPF''). The CPF provides $10 billion in funding for the U.S. Department of the Treasury (''Treasury'') to make payments according to a statutory formula to States (defined to include each of the 50 states, the District of Columbia, and Puerto Rico), seven territories and freely associated states (the United States Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau), and Tribal governments [1] to carry out critical capital projects directly enabling work, education, and health monitoring, including remote options, in response to the public health emergency with respect to the Coronavirus Disease (COVID–19).

The current information collection will be used to solicit information related to quarterly project and expenditure reports and annual performance reports. Both information collections are described generally in the Compliance and Reporting Guidance. The Compliance and Reporting Guidance provides recipients with information needed to fulfill their reporting requirements and compliance obligations. Treasury will also prepare an IT portal user guide with specific instructions on entering data into the reporting web-based portal.

The initial Project and Expenditure Report must be submitted by States, territories, and freely associated states on July 31, 2022,[2] with subsequent reports being due quarterly for the duration of the period of performance. The Project and Expenditure Report contains a set of standardized questions to ascertain the recipient's use of funds received as of the date of reporting, as well as the status of individual projects. Treasury will make the data submitted by recipients publicly available.

The first interim Performance Report must be submitted by States, territories, and freely associated states on January 31, 2023, with subsequent reports being due annually on July 31 for the duration of the period of performance. The Performance Report will contain detailed performance data corresponding to the ''Programs'' specified previously in a recipient's Grant Plan. This will include information on efforts to improve equity and engage communities. The Performance Report is largely freely written text, and while there are certain data and topics that recipients must cover in the Performance Report, it is mostly free-form written content. Recipients are required to publish the Performance Report on their website and provide the reports to Treasury. Treasury will make the Performance Reports and associated data submitted by recipients publicly available.

Forms: Compliance and Reporting Guidance for States, Territories, and Freely Associated States

Affected Public: State, Territorial, and Freely Associated State Governments.

Estimated Number of Respondents: 59.

Frequency of Response: 4 times per year for Progress and Expenditure reports; 1 time per year for Performance Reports.

Estimated Total Number of Annual Responses: 295.

Estimated Time per Response: 62 hours for Project and Expenditure Reports. 80 hours for Performance Reports.

Estimated Total Annual Burden Hours: 19,352.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services required to provide information.

(Authority: 44 U.S.C. 3501 *et seq.*)

Molly Stasko,

Treasury PRA Clearance Officer.

[FR Doc. 2022–09953 Filed 5–9–22; 8:45 am]

BILLING CODE 4810–AK–P

[1] An eligible Tribal government is the recognized governing body of any Indian or Alaska Native tribe, band, nation, pueblo, village, community, component band, or component reservation, individually identified (including parenthetically) in the list published most recently as of the date of enactment of this Act pursuant to section 104 of the Federally Recognized Indian Tribe List Act of 1994 (25 U.S.C. 5131). The State of Hawaii, for exclusive use of the Department of Hawaiian Home Lands and the Native Hawaiian Education Programs to assist Native Hawaiians, is also eligible to apply for funding under this funding category.

[2] State, territory, and freely associated state recipients that have not received any payments by June 15, 2022, will be exempted from the report due on July 31, 2022.

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0894]

Agency Information Collection Activity Under OMB Review: Program of Comprehensive Assistance for Family Caregivers (PCAFC) Decision Appeal Forms

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Health Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–0894.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0894'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–3521.

Title: Program of Comprehensive Assistance for Family Caregivers (PCAFC) Decision Appeal Forms, VA Forms 10–306 and 10–307.

OMB Control Number: 2900–0894.

Type of Review: Extension of a currently approved collection.

Abstract: The Caregivers and Veterans Omnibus Health Services Act of 2010 (Pub. L. 111–163) established 38 U.S.C. 1720G, which directed the Department

of Veterans Affairs (VA) to establish a Program of Comprehensive Assistance for Family Caregivers (PCAFC) and a Program of General Caregiver Support Services (PGCSS). Both programs are managed by VA's Caregiver Support Program (CSP) Office. On June 06, 2018, the President signed into law the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018 or the VA MISSION Act 2018 (Pub. L. 115–182). The VA MISSION Act of 2018 fundamentally transformed elements of the Department of Veterans Affairs' (VA) healthcare system to include expanding the PCAFC to Family Caregivers of eligible Veterans of all eras in a phased approach, established new benefits for Primary Family Caregivers of eligible Veterans, and made other changes affecting program eligibility and VA's evaluation of PCAFC applications. The statutory authority for PCAFC and PGCSS is codified at 38 U.S.C. 1720G. VA's regulations implementing PCAFC and PGCSS are in 38 CFR part 71.

Since program inception, Veterans and caregivers who disagree with a PCAFC decision were afforded the right to appeal through the Veterans Health Administration (VHA) Clinical Appeals Process. A recent Court ruling has changed the appeal and review options now available to individuals who have received a PCAFC decision and disagree with that decision. On April 19, 2021, in the case of *Jeremy Beaudette & Maya Beaudette* v. *Denis McDonough, Secretary of Veterans Affairs,* the U.S. Court of Appeals for Veterans Claims ruled in favor of petitioners seeking review by the Board of Veterans' Appeals (BVA or Board) of decisions under the PCAFC. The Court also certified, as a class, claimants who received an adverse benefits decision under PCAFC, exhausted the administrative review process within VHA (the VHA Clinical Appeals Process), and have not been afforded the right to appeal to the Board. As a result of the Court's ruling, BVA review is now available to individuals who have received a decision under the PCAFC since the program began in May 2011. Consequently, VA has expanded options available to Veterans and caregivers who seek review of or to appeal a PCAFC decision.

The options now include a separate appeals process (legacy) that must be used to appeal to the Board regarding PCAFC decisions issued before February 19, 2019. This legacy process is implemented through use of VA Forms 10–306 and 10–307.

VA Form 10–306, Request for Information—Because individuals now have additional options for appealing and seeking review of previous PCAFC decisions, dating back to May 2011, this form allows Veterans and caregivers to request information about past PCAFC decisions to determine whether they wish to pursue an appeal to the Board or request review.

VA Form 10–307, Notice of Disagreement—This form was developed because VA Form 21–0958, which previously was used to initiate an appeal to the Board of benefits decisions dated before February 19, 2019, is no longer an approved information collection. VA Form 10–307, Notice of Disagreement, is now used for legacy appeals of PCAFC decisions and is specific to individuals who wish to appeal a PCAFC decision that was issued prior to February 19, 2019.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at: 87 FR 42 on March 3, 2022, pages 12223 and 12224.

Affected Public: Individuals or Households.

Estimated Annual Burden: 88,270 total hours.

a. 10–306—45,500 hours.

b. 10–307—42,770 hours.

Estimated Average Burden per Respondent: 45 total minutes.

a. 10–306—15 minutes.

b. 10–307—30 minutes.

Frequency of Response: Once annually.

Estimated Number of Respondents: 267,540 total.

a. 10–306—182,000.

b. 10–307—85,540.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–09973 Filed 5–9–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0682]

Agency Information Collection Activity Under OMB Review: Advertising, Sales, Enrollment Materials, and Candidate Handbooks

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–0682.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0682'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 CFR 21.4252(h).

Title: Advertising, Sales, Enrollment Materials, and Candidate Handbooks.

OMB Control Number: 2900–0682.

Type of Review: Revision of a currently approved collection.

Abstract: The statute prohibits approval of the enrollment of a Veteran in a course if the educational institution uses advertising, sales, or enrollment practices that are erroneous, deceptive, or misleading either by actual statement, omission, or intimation. The advertising, sales and enrollment materials are reviewed to determine if the institution is in compliance with guidelines for approval.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information

unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 87 FR 30 on February 14, 2022, page 8341.

Affected Public: Individuals or Households.

Estimated Annual Burden: 5,525 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: Annually.

Estimated Number of Respondents: 5,525.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–10032 Filed 5–9–22; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 482, et al.
Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 482, 485, and 495

[CMS–1771–P]

RIN 0938–AU84

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would: Revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals; make changes relating to Medicare graduate medical education (GME) for teaching hospitals; update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs). In additon it would establish new requirements and revise existing requirements for eligible hospitals and critical access hospitals (CAHs) participating in the Medicare Promoting Interoperability Program; provide estimated and newly established performance standards for the Hospital Value-Based Purchasing (VBP) Program; and propose updated policies for the Hospital Readmissions Reduction Program, Hospital Inpatient Quality Reporting (IQR) Program, Hospital VBP Program, Hospital-Acquired Condition (HAC) Reduction Program, PPS-Exempt Cancer Hospital Reporting (PCHQR) Program, and the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). It would also revise the hospital and critical access hospital (CAH) conditions of participation (CoPs) for infection prevention and control and antibiotic stewardship programs; and codify and clarify policies related to the costs incurred for qualified and non-qualified deferred compensation plans. Lastly, this proposed rule would provide updates on the Rural Community Hospital Demonstration Program and the Frontier Community Health Integration Project.

DATES: To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section, no later than 5 p.m. EDT on June 17, 2022.

ADDRESSES: In commenting, please refer to file code CMS–1771–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may (and we encourage you to) submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the instructions under the ''submit a comment'' tab.

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1771–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1771–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Donald Thompson, (410) 786–4487, and Michele Hudson, (410) 786–4487, Operating Prospective Payment, MS–DRG Relative Weights, Wage Index, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH) Payment Adjustment, Sole Community Hospitals (SCHs), Medicare-Dependent Small Rural Hospital (MDH) Program, Low-Volume Hospital Payment Adjustment, and Critical Access Hospital (CAH) Issues.

Emily Lipkin, (410) 786–3633 and Jim Mildenberger, (410) 786–4551, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Allison Pompey, (410) 786–2348, New Technology Add-On Payments and New COVID–19 Treatments Add-on Payments Issues.

Mady Hue, *marilu.hue@cms.hhs.gov,* and Andrea Hazeley, *andrea.hazeley@cms.hhs.gov,* MS–DRG Classifications Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

Jeris Smith, *jeris.smith@cms.hhs.gov,* Frontier Community Health Integration Project Demonstration Issues.

Sophia Chan, *sophia.chan@cms.hhs.gov,* Hospital Readmissions Reduction Program—Administration Issues.

Jennifer Robinson, *jennifer.robinson@cms.hhs.gov,* Hospital Readmissions Reduction Program—Measures Issues.

Jennifer Tate, *jennifer.tate@cms.hhs.gov,* Hospital-Acquired Condition Reduction Program—Administration Issues.

Yuling Li, *yuling.li@cms.hhs.gov,* Hospital-Acquired Condition Reduction Program—Measures Issues.

Julia Venanzi, *julia.venanzi@cms.hhs.gov,* Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs—Administration Issues.

Melissa Hager, *melissa.hager@cms.hhs.gov,* Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues.

Elizabeth Goldstein, (410) 786–6665, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Ora Dawedeit, *ora.dawedeit@cms.hhs.gov,* PPS-Exempt Cancer Hospital Quality Reporting—Administration Issues.

Leah Domino, *leah.domino@cms.hhs.gov,* PPS-Exempt Cancer Hospital Quality Reporting Program—Measure Issues.

Christy Hughes, *christy.hughes@cms.hhs.gov,* Long-Term Care Hospital Quality Reporting Program—Data Reporting Issues.

Elizabeth Holland, *elizabeth.holland@cms.hhs.gov,* Medicare Promoting Interoperability Program.

CAPT Scott Cooper, USPHS, (410) 786–9465, and Dawn Linn, *dawn.linn@cms.hhs.gov,* Conditions of Participation Pandemic Reporting Requirements for Hospitals and Critical Access Hospitals.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov/.* Follow the search instructions on that website to view public comments.

Tables Available Through the Internet on the CMS Website

The IPPS tables for this fiscal year (FY) 2023 proposed rule are available through the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Click on the link on the left side of the screen titled ''FY 2023 IPPS Proposed rule Home Page'' or ''Acute Inpatient—Files for Download.'' The LTCH PPS tables for this FY 2023 proposed rule are available through the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1771–P. For further details on the contents of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this FY 2023 IPPS/LTCH PPS proposed rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites, as previously identified, should contact Michael Treitel at (410) 786–4552.

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- C. Response to Comments

Addendum—Schedule of Standardized Amounts, Update Factors, and Rate-of-

Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2022 and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2022

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This FY 2023 IPPS/LTCH PPS proposed rule would make payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it would make payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). This proposed rule also would make policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs. In this FY 2023 proposed rule, we are proposing to implement a permanent policy to cap wage index decreases as well as continuing policies to address wage index disparities impacting low wage index hospitals. We also are proposing to make changes relating to Medicare graduate medical education (GME) for teaching hospitals and new technology add-on payments.

We are proposing to establish new requirements and revise existing requirements for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

We are proposing updated policies for the Hospital Readmissions Reduction Program, Hospital Inpatient Quality Reporting (IQR) Program, Hospital Value-Based Purchasing (VBP) Program, Hospital-Acquired Condition (HAC) Reduction Program, Long Term Care Hospital Quality Reporting Program (LTCH QRP), and the PPS-Exempt Cancer Hospital Reporting (PCHQR) Program. We are also requesting feedback across programs on health impacts due to climate change and on overarching principles in measuring healthcare quality disparities in hospital quality programs and value-based purchasing programs. We are also seeking feedback on advancing the Trusted Exchange Framework and Common Agreement (TEFCA). Additionally, due to the impact of the COVID–19 PHE on measure data used in our value-based purchasing programs, we are proposing to suppress several measures in the Hospital VBP Program and HAC Reduction Program. In addition to these measure suppressions for the Hospital VBP Program, we are proposing to implement a special scoring methodology for FY 2023 that results in each hospital receiving a value-based incentive payment amount that matches their 2 percent reduction to the base operating DRG payment amount. Similarly, we are also proposing to suppress all six measures in the HAC Reduction Program for the FY 2023 program year. If finalized as proposed, for the FY 2023 program year, hospitals participating in the HAC Reduction Program will not be given a measure score, a Total HAC score, nor will hospitals receive a payment penalty. We are also providing estimated and newly established performance standards for the Hospital VBP Program. For the Hospital Readmissions Reduction Program, we are proposing to resume the use of the one affected measure under the proposed measure suppression policy for the FY 2024 applicable period following suppression of this measure for the FY 2023 applicable period, and incorporating measure updates to the six condition/procedure measures addressed by the Hospital Readmission Reduction Program to account for patient history of COVID–19.

Under various statutory authorities, we either discuss continued program implementation or propose to make changes to the Medicare IPPS, the LTCH PPS, other related payment methodologies and programs for FY 2023 and subsequent fiscal years, and other policies and provisions included in this rule. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).
- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of the BBRA (Pub. L. (Pub. L.) 106–113) and section 307(b)(1) of the BIPA (Pub. L. 106–554) (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of LTCHs described in section 1886(d)(1)(B)(iv) of the Act.
- Sections 1814(l), 1820, and 1834(g) of the Act, which specify that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.
- Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act.
- Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase that would otherwise apply to the standardized amount applicable to a subsection (d) hospital for discharges occurring in a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.
- Section 1866(k) of the Act, which provides for the establishment of a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-exempt cancer hospitals.''
- Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program, under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year.
- Section 1886(p) of the Act, which establishes a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.
- Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, which establishes the Hospital Readmissions Reduction Program. Under the program, payments for discharges from an applicable hospital as defined under section 1886(d) of the Act will be reduced to

account for certain excess readmissions. section 15002 of the 21st Century Cures Act directs the Secretary to compare hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries (dual-eligibles) in determining the extent of excess readmissions.

- Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share hospital (DSH) payments under section 1886(d)(5)(F) of the Act and for a new uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under section 1886(d)(5)(F) of the Act for DSH (''the empirically justified amount''), and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act; (2) 1 minus the percent change in the percent of individuals who are uninsured; and (3) a hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.
- Section 1886(m)(5) of the Act, which requires the Secretary to reduce by two percentage points the annual update to the standard Federal rate for discharges for a long-term care hospital (LTCH) during the rate year for LTCHs that do not submit data in the form, manner, and at a time, specified by the Secretary.
- Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67) and amended by section 51005(a) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS, with implementation beginning in FY 2016. Section 51005(b) of the Bipartisan Budget Act of 2018 amended section 1886(m)(6)(B) by adding new clause (iv), which specifies that the IPPS comparable amount defined in clause (ii)(I) shall be reduced by 4.6 percent for FYs 2018 through 2026.
- Section 1899B of the Act, as added by section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185), which provides for the establishment of standardized data reporting for certain post-acute care providers, including LTCHs.
- Section 1861(e) of the Act provides the specific statutory authority for the hospital CoPs; section 1820(e) of the Act provides similar authority for CAHs. The hospital provision at section 1861(e)(9) of the Act authorizes the Secretary to issue any regulations he or she deems necessary to protect the health and safety of patients receiving services in those facilities; the CAH provision at section 1820(e)(3) of the Act authorizes the Secretary to issue such other criteria as he or she may require.

2. Summary of the Major Provisions

The following is a summary of the major provisions in this proposed rule. In general, these major provisions are being proposed as part of the annual update to the payment policies and payment rates, consistent with the applicable statutory provisions. A general summary of the proposed changes in this proposed rule is presented in section I.D. of the preamble of this proposed rule.

a. Proposed MS–DRG Documentation and Coding Adjustment

Section 631 of the American Taxpayer Relief Act of 2012 (ATRA, Pub. L. 112–240) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment to the standardized amount of Medicare payments to acute care hospitals to account for changes in MS–DRG documentation and coding that do not reflect real changes in case-mix, totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. The FY 2014 through FY 2017 adjustments represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Pub. L. 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Pub. L. 110–90. Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.) Therefore, for FY 2023, we are proposing to make an adjustment of + 0.5 percent to the standardized amount.

b. Proposed Use of FY 2021 Data and Proposed Methodology Modifications for the FY 2023 IPPS and LTCH PPS Ratesetting

For the IPPS and LTCH PPS ratesetting, our longstanding goal is always to use the best available data overall. In section I.F. of the preamble of this proposed rule, we discuss our proposal to return to our historical practice of using the most recent data available for purposes of FY 2023 ratesetting, including the FY 2021 MedPAR claims and FY 2020 cost report data, with certain proposed modifications to our usual ratesetting methodologies to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries at IPPS hospitals and LTCHs as compared to FY 2021. As discussed in greater detail in section I.F of the preamble of this proposed rule, we believe that it is reasonable to assume that some Medicare beneficiaries will continue to be hospitalized with COVID–19 at IPPS hospitals and LTCHs in FY 2023. Given this expectation, we believe it is appropriate to use FY 2021 data, as the most recent available data during the period of the COVID–19 PHE, for purposes of the FY 2023 IPPS and LTCH PPS ratesetting. However, as also discussed in greater detail in section I.F. of the preamble of this proposed rule, we believe it is reasonable to assume based on the information available at this time that there will be fewer COVID–19 hospitalizations in FY 2023 than in FY 2021. Therefore, we are proposing to use the FY 2021 data for purposes of the FY 2023 IPPS and LTCH PPS ratesetting but with modifications to our usual ratesetting methodologies to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries at IPPS hospitals and LTCHs as compared to FY 2021. As discussed in section I.O. of Appendix A of this proposed rule, we are also requesting comments on, as an alternative to our proposed approach, the use of the FY 2021 data for purposes of FY 2023 ratesetting without the proposed modifications to our usual methodologies for the calculation of the FY 2023 MS–DRG and MS–LTC–DRG relative weights or the usual methodologies used to determine the FY 2023 outlier fixed-loss amount for IPPS cases and LTCH PPS standard Federal payment rate cases.

c. Proposed Continuation of the Low Wage Index Hospital Policy

To help mitigate wage index disparities between high wage and low

wage hospitals, in the FY 2020 IPPS/LTCH PPS rule (84 FR 42326 through 42332), we adopted a policy to increase the wage index values for certain hospitals with low wage index values (the low wage index hospital policy). This policy was adopted in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals. We also indicated our intention that this policy would be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. We are proposing for the low wage index hospital policy to continue for FY 2023, and are also proposing to apply this policy in a budget neutral manner by applying an adjustment to the standardized amounts.

d. Proposed Permanent Cap on Wage Index Decreases

Consistent with section 1886(d)(3)(E) of the Act, we adjust the IPPS standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level and update the wage index annually based on a survey of wages and wage-related costs of short-term, acute care hospitals. As described in section III.N. of the preamble of this proposed rule, we have further considered the comments we received during the FY 2022 rulemaking recommending a permanent 5 percent cap policy to prevent large year-to-year variations in wage index values as a means to reduce overall volatility for hospitals. Under the authority at sections 1886(d)(3)(E) and 1886(d)(5)(I)(i) of the Act, for FY 2023 and subsequent years, we are proposing to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, we are proposing that a hospital's wage index for FY 2023 would not be less than 95 percent of its final wage index for FY 2022, and that for subsequent years, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. We are also proposing to apply this proposed wage index cap policy in a budget neutral manner through a national adjustment to the standardized amount under our authority in sections 1886(d)(3)(E) and 1886(d)(5)(I)(i) of the Act.

e. Proposed DSH Payment Adjustment and Additional Payment for Uncompensated Care

Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, Medicare disproportionate share hospitals (DSHs) receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remaining amount, equal to 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, is paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH will receive an additional payment based on its share of the total amount of uncompensated care for all Medicare DSHs for a given time period.

In this proposed rule, we are proposing to update our estimates of the three factors used to determine uncompensated care payments for FY 2023. We are also proposing to continue to use uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA) in conjunction with more recently available data in the calculation of Factor 2. For FY 2023, we are proposing to use the two most recent years of audited data on uncompensated care costs from Worksheet S–10 of the FY 2018 cost reports and the FY 2019 cost reports to calculate Factor 3 in the uncompensated care payment methodology for all eligible hospitals. In addition, for FY 2024 and subsequent fiscal years, we are proposing to use a three-year average of the data on uncompensated care costs from Worksheet S–10 for the three most recent fiscal years for which audited data are available. Beginning in FY 2023, we are proposing to discontinue the use of low-income insured days as a proxy for uncompensated care to determine Factor 3 for Indian Health Service (IHS) and Tribal hospitals and hospitals located in Puerto Rico. In addition, we are proposing certain methodological changes for calculating Factor 3 for FY 2023 and subsequent fiscal years.

We recognize that our proposal to discontinue the use of the low-income insured days proxy to calculate uncompensated care payments for Indian Health Service (IHS) and Tribal hospitals and hospitals located in Puerto Rico could result in a significant financial disruption for these hospitals. Accordingly, we are proposing to use our exceptions and adjustments authority under section 1886(d)(5)(I) to establish a new supplemental payment for IHS and Tribal hospitals and hospitals located in Puerto Rico, beginning in FY 2023.

Additionally, we are proposing to revise our regulation governing the calculation of the Medicaid fraction of the DSH calculation. Under this proposal, we would revise our regulation to explicitly reflect our interpretation of the language ''regarded as'' ''eligible for medical assistance under a State plan approved under title XIX'' in section 1886(d)(5)(F)(vi) of the Act to mean patients who receive health insurance authorized by a section 1115 demonstration or patients who pay for all or substantially all of the cost of such health insurance with premium assistance authorized by a section 1115 demonstration, where state expenditures to provide the health insurance or premium assistance may be matched with funds from Title XIX. Moreover, of the groups we ''regard as'' Medicaid eligible, we propose to include in the Medicaid fraction only the days of those patients who obtain health insurance directly or with premium assistance that provides essential health benefits (EHB) as set forth in 42 CFR part 440, subpart C, for an Alternative Benefit Plan (ABP), and for patients obtaining premium assistance, only the days of those patients for which the premium assistance is equal to or greater than 90 percent of the cost of the health insurance, provided the patient is not also entitled to Medicare Part A.

f. Proposed Changes to GME Payments Based on *Milton S. Hershey Medical Center, et al.* v. *Becerra* Litigation

On May 17, 2021, the U.S. District Court for the District of Columbia ruled against CMS's method of calculating direct GME payments to teaching hospitals when those hospitals' weighted full-time equivalent (FTE) counts exceed their direct GME FTE cap. In *Milton S. Hershey Medical Center, et al.* v. *Becerra,* the court ordered CMS to recalculate reimbursement owed, holding that CMS's regulation impermissibly modified the statutory weighting factors. The plaintiffs in these consolidated cases alleged that as far back as 2005, the proportional reduction that CMS applied to the weighted FTE count when the weighted FTE count exceeded the FTE cap conflicted with the Medicare statute, and it was an arbitrary and capricious exercise of agency discretion under the Administrative Procedure Act. The court held that the

proportional reduction methodology impermissibly modified the weighting factors statutorily assigned to residents and fellows. The court granted the motion for summary judgment to plaintiffs' motions, denied defendant's, and remanded to the Agency so that it could recalculate plaintiffs' reimbursement payments consistent with the court's opinion.

After reviewing the statutory language regarding the direct GME FTE cap and the court's opinion, we have decided to propose a modified policy to be applied prospectively for all teaching hospitals, as well as retroactively to the providers and cost years in Hershey and certain other providers as described in greater detail in section V.F.2. of the preamble of this proposed rule. The proposed modified policy would address situations for applying the FTE cap when a hospital's weighted FTE count is greater than its FTE cap, but would not reduce the weighting factor of residents that are beyond their initial residency period to an amount less than 0.5. Specifically, effective for cost reporting periods beginning on or after October 1, 2022, we are proposing that the hospital's unweighted number of FTE residents exceeds the FTE cap, and the number of weighted FTE residents also exceeds that FTE cap, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the FTE cap. If the number of weighted FTE residents does not exceed that FTE cap, then the allowable weighted FTE count for direct GME payment is the actual weighted FTE count.

g. Reduction of Hospital Payments for Excess Readmissions

We are proposing to make changes to policies for the Hospital Readmissions Reduction Program, which was established under section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. For FY 2017 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG) surgery. In this FY 2023 IPPS/LTCH PPS proposed rule, we are discussing the following policies: (1) Proposal to resume use of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) for the FY 2024 program year; (2) modification of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) to exclude COVID–19 diagnosed patients from the measure denominator, beginning with the Hospital Specific Reports (HSRs) for the FY 2023 program year; and (3) modification of all six condition/procedure specific measures to include a covariate adjustment for patient history of COVID–19 within one year prior to the index admission beginning with the FY 2023 program year. We are also seeking comment on updating the to incorporate provider performance for socially at-risk populations.

h. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. In this proposed rule, we are proposing to: (1) Suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) and five Hospital Acquired Infection (HAI) measures, for the FY 2023 Program year; and (2) update the baseline periods for certain measures for the FY 2025 program year. We are also proposing to revise the scoring and payment methodology for the FY 2023 program year such that hospitals will not receive Total Performance Scores (TPSs). Instead, we are proposing to award each hospital a payment incentive multiplier that results in a value-based incentive payment that is equal to the amount withheld for the fiscal year (2 percent). We note that we are also announcing technical updates to the measures in the Clinical Outcomes Domain.

i. Hospital-Acquired Condition (HAC) Reduction Program

We are proposing changes to the HAC Reduction program, which was established under Section 1886(p) of the Act, to provide an incentive to hospitals to reduce the incidence of hospital-acquired conditions. We refer readers to the FY 2022 IPPS/LTCH PPS final rule for further details on our measure suppression policy (86 FR 45301 through 45304). In this FY 2023 IPPS/LTCH PPS proposed rule, we are proposing to: (1) Suppress the CMS PSI 90 measure and the five CDC NHSN HAI measures from the calculation of measure scores and the Total HAC Score, thereby not penalizing any hospital under the HAC Reduction Program FY 2023 program year; (2) publicly and confidentially report CDC NHSN HAI measure results but not calculate or report measure results for the CMS PSI 90 measure for the HAC Reduction Program FY 2023 program year; (3) suppress CY 2021 CDC NHSN HAI measures data from the FY 2024 HAC Reduction Program Year; (4) update the measure specification to the minimum volume threshold for the CMS PSI 90 measure beginning with the FY 2023 program year; (5) update the measure specifications to risk-adjust for COVID–19 diagnosis in the CMS PSI 90 measure beginning with the FY 2024 HAC Reduction Program Year; (6) request information from stakeholders on the potential adoption of two digital National Healthcare Safety Network (NHSN) measures: The NHSN Healthcare-associated *Clostridioides difficile* Infection Outcome measure and NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure; (7) request information on overarching principles for measuring healthcare quality disparities across CMS Quality Programs; (8) update the NHSN CDC HAI data submission requirements for newly opened hospitals beginning in the FY 2024 HAC Reduction Program Year; and (9) clarify the removal of the no mapped location policy beginning with the FY 2023 program year.

j. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, subsection (d) hospitals are required to report data on measures selected by the Secretary for a fiscal year in order to receive the full annual percentage increase.

In this FY 2023 IPPS/LTCH PPS proposed rule, we are proposing several changes to the Hospital IQR Program. We are proposing the adoption of 10 new measures: (1) Hospital Commitment to Health Equity beginning with the CY 2023 reporting period/FY 2025 payment determination; (2) Screening for Social Drivers of Health beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (3) Screen Positive Rate for Social Drivers of Health beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting

period/FY 2026 payment determination; (4) Cesarean Birth electronic clinical quality measure (eCQM) with inclusion in the measure set beginning with the CY 2023 reporting period/FY 2025 payment determination, and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (5) Severe Obstetric Complications eCQM with inclusion in the measure set beginning with the CY 2023 reporting period/FY 2025 payment determination, and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (6) Hospital-Harm—Opioid-Related Adverse Events eCQM (NQF #3501e) beginning with the CY 2024 reporting period/FY 2026 payment determination; (7) Global Malnutrition Composite Score eCQM (NQF #3592e) beginning with the CY 2024 reporting period/FY 2026 payment determination; (8) Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #3559) beginning with two voluntary periods, followed by mandatory reporting for the reporting period which runs from July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination; (9) Medicare Spending Per Beneficiary (MSPB) Hospital (NQF #2158) beginning with the FY 2024 payment determination; and (10) Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA/TKA (NQF #1550) beginning with the FY 2024 payment determination. We are proposing refinements to two current measures beginning with the FY 2024 payment determination: (1) Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA; and (2) Excess Days in Acute Care (EDAC) After Hospitalization for Acute Myocardial Infarction (AMI) (NQF #2881). We are also requesting comment on the potential future development and inclusion of two National Healthcare Safety Network (NHSN) measures: (1) Healthcare-Associated *Clostridioides difficile* Infection Outcome; and (2) Hospital-Onset Bacteremia & Fungemia Outcome.

We are proposing changes to current policies related to eCQMs and hybrid measures: (1) A proposal to modify the eCQM reporting and submission requirements to increase the number of eCQMs to be reported beginning with the CY 2024 reporting period/FY 2026 payment determination; (2) a proposal to remove the zero denominator declarations and case threshold exemption policies for hybrid measures beginning with the FY 2026 payment determination; (3) a proposal for the data submission and reporting requirements for patient-reported outcome-based performance measures (PRO–PMs) beginning with the FY 2026 payment determination; and (4) a proposal to modify the eCQM validation policy to increase the requirement from 75 percent to 100 percent of requested medical records, beginning with the FY 2025 payment determination.

With respect to public reporting, we are proposing to establish a hospital designation related to maternity care to be publicly-reported on a public-facing website beginning in Fall 2023, and are also seeking comments on other potential associated activities regarding this designation. Additionally, we are seeking comments on ongoing ways we can advance digital quality measurement and use of Fast Healthcare Interoperability Resources (FHIR).

k. PPS-Exempt Cancer Hospital Quality Reporting Program

Section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. There is no financial impact to PCH Medicare payment if a PCH does not participate.

In this FY 2023 IPPS/LTCH PPS proposed rule, we are proposing to adopt a patient safety exception into the measure removal policy. We are also proposing to begin public display of the 30-Day Unplanned Readmissions for Cancer Patients measure (NQF #3188) (PCH–36), the Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life measure (NQF #0210) (PCH–32), the Proportion of Patients Who Died from Cancer Not Admitted to Hospice measure (NQF #0215) (PCH–34), the Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life measure (NQF #0213) (PCH–33), and the Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days measure (NQF #0216) (PCH–35). In addition, along with the Hospital IQR and HAC Reduction Programs, we are requesting comment on the potential adoption of two digital National Healthcare Safety Network (NHSN) measures: The NHSN Healthcare-associated *Clostridioides difficile* Infection Outcome measure and NHSN Hospital-Onset Bacteremia and Fungemia Outcome measure.

l. Medicare Promoting Interoperability Program

For CY 2023, we are proposing several changes to the Medicare Promoting Interoperability Program. Specifically, we are proposing: (1) To require and modify the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program (PDMP) measure while maintaining the associated points at 10 points beginning with the EHR reporting period in CY 2023; (2) to expand the Query of PDMP measure to include Schedule II, III, and IV drugs beginning with the CY 2023 EHR reporting period; (3) to add a new Health Information Exchange (HIE) Objective option, the Enabling Exchange under the Trusted Exchange Framework and Common Agreement (TEFCA) measure (requiring a yes/no response), as an optional alternative to fulfill the objective, beginning with the CY 2023 EHR reporting period; (4) to modify the Public Health and Clinical Data Exchange Objective by adding an Antibiotic Use and Antibiotic Resistance (AUR) measure in addition to the current four required measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting beginning in the CY 2023 EHR reporting period; (5) to consolidate the current options from three to two levels of active engagement for the Public Health and Clinical Data Exchange Objective and to require the reporting of active engagement for the measures under the objective beginning with the CY 2023 EHR reporting period; (6) to modify the scoring methodology for the Medicare Promoting Interoperability Program beginning in CY 2023; (7) to institute public reporting of certain Medicare Promoting Interoperability Program data beginning with the CY 2023 EHR reporting period; (8) to remove regulation text for the objectives and measures in the Medicare Promoting Interoperability Program from paragraph (e) under 42 CFR 495.24 and add new paragraph (f) beginning in CY 2023; and (9) to adopt two new eCQMs in the Medicare Promoting Interoperability Program's eCQM measure set beginning with the CY 2023 reporting period, two new eCQMs in the Medicare Promoting Interoperability Program's eCQM measure set beginning with the CY 2024 reporting period, and modify the eCQM data reporting and submission requirements to increase the number of eCQMs required to be reported and the total number of eCQMs

to be reported beginning with the CY 2024 reporting period, which is in alignment with the eCQM updates proposed for the Hospital IQR Program.

m. Condition of Participation (CoP) Requirements for Hospitals and CAHs To Report Data Elements To Address Any Future Pandemics and Epidemics as Determined by the Secretary

In this proposed rule, we would revise the hospital and CAH infection prevention and control CoP requirements to continue COVID–19 reporting requirements commencing either upon the conclusion of the current COVID–19 PHE declaration or the effective date of this proposed rule, whichever is later, and lasting until April 30, 2024 (unless the Secretary determines an earlier end date). We also propose additional requirements to address future PHEs related to epidemics and pandemics. Specifically, when the Secretary has declared a PHE, we propose to require hospitals and CAHs to report specific data elements to the CDC's National Health Safety Network (NHSN), or other CDC-supported surveillance systems, as determined by the Secretary. The proposed requirements of this section would apply to local, state, and national PHEs as declared by the Secretary. Additionally, we are proposing that the hospital (or CAH) provide the information specified on a daily basis, unless the Secretary specifies a lesser frequency contingent upon the state of the PHE and ongoing risks.

n. Comment Solicitation on IPPS and Outpatient Prospective Payment System (OPPS) Payment Adjustments for Wholly Domestically Made National Institute for Occupational Safety and Health (NIOSH)-Approved Surgical N95 Respirators

As discussed in section X.C. of the preamble of this proposed rule, the Biden-Harris Administration has made it a priority to ensure America is prepared to continue to respond to COVID–19, and to combat future pandemics. A significant action to improve hospital preparedness and readiness for future threats might be to provide payment adjustments to hospitals to recognize the additional resource costs they incur to acquire NIOSH-approved surgical N95 respirators that are wholly domestically made. These surgical respirators, which faced severe shortage at the onset of the COVID–19 pandemic, are essential for the protection of beneficiaries and hospital personnel that interface with patients. The Department of Health and Human Services (HHS) recognizes that procurement of surgical N95 respirators that are wholly domestically made, while critical to pandemic preparedness and protecting health care workers and patients, can result in additional resource costs for hospitals.

We are interested in feedback and comments on the appropriateness of payment adjustments that would account for these additional resource costs. We believe such a payment adjustment could help achieve a strategic policy goal, namely, sustaining a level of supply resilience for surgical N95 respirators that is critical to protect the health and safety of personnel and patients in a public health emergency. We are considering such payment adjustments to apply to 2023 and potentially subsequent years. We realize there may be different ways a payment adjustment to recognize the additional resource costs hospitals incur when purchasing wholly domestically made NIOSH-approved surgical N95 respirators could be implemented and seek comment on two potential frameworks and alternative approaches.

3. Summary of Costs and Benefits

The following table provides a summary of the costs, savings, and benefits associated with the major provisions described in section I.A.3. of the preamble of this proposed rule.

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Provision Description	Description of Costs, Transfers, Savings, and Benefits
Proposed Adjustment for MS-DRG Documentation and Coding Changes	Section 414 of the MACRA replaced the single positive adjustment we intended to make in FY 2018 once the recoupment required by section 631 of the ATRA was complete with a 0.5 percentage point positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percentage point by section 15005 of the 21st Century Cures Act.) For FY 2023, we are proposing to make an adjustment of +0.5 percentage point to the standardized amount consistent with the MACRA.
Proposed Medicare DSH Payment Adjustment and Additional Payment for Uncompensated Care and Proposed Supplemental Payment	For FY 2023, we are proposing to update our estimates of the three factors used to determine uncompensated care payments. We are proposing to continue to use uninsured estimates produced by OACT as part of the development of the NHEA in conjunction with more recently available data in the calculation of Factor 2. For FY 2023, we are proposing to use the two most recent years of audited data on uncompensated care costs from Worksheet S–10 of the FY 2018 cost reports and the FY 2019 cost reports to calculate Factor 3 in the uncompensated care payment methodology for all eligible hospitals. In addition, for FY 2024 and subsequent fiscal years, we are proposing to use a three-year average of the data on uncompensated care costs from Worksheet S-10 for the three most recent fiscal years for which audited data are available. Beginning in FY 2023, we are proposing to discontinue the use of low-income insured days as a proxy for uncompensated care to determine Factor 3 for Indian Health Service (IHS) and Tribal hospitals and hospitals located in Puerto Rico. In addition, we are proposing certain methodological changes for calculating Factor 3 for FY 2023 and subsequent fiscal years. We project that the amount available to distribute as payments for uncompensated care for FY 2023 will decrease by approximately $654 million, as compared to our estimate of the uncompensated care payments that will be distributed in FY 2022. The uncompensated care payments have redistributive effects, based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are projected to be eligible to receive Medicare DSH payments, and the calculated payment amount is not directly tied to a hospital's number of discharges. Because we recognize that our proposal to discontinue the use of the low-income insured days proxy to calculate uncompensated care payments for Indian Health Service (IHS) and Tribal hospitals and hospitals located in Puerto Rico could result in a significant financial disruption for these hospitals, we are proposing to use our exceptions and adjustments authority under section 1886(d)(5)(I) of the Act to establish a new supplemental payment for IHS and Tribal hospitals and hospitals located in Puerto Rico, beginning in FY 2023. This proposal is not budget neutral and we estimate the impact of this proposed change for FY 2023 would increase Medicare spending by approximately $92 million. Additionally, we are proposing to revise our regulation governing the calculation of the Medicaid fraction of the DSH calculation. Under this proposal, we would revise our regulations to explicitly reflect our interpretation of the language "regarded as" "eligible for medical assistance under a State plan approved under title XIX" in section 1886(d)(5)(F)(vi) of the Act to mean patients who receive health insurance authorized by a section 1115 demonstration itself or patients who pay for all or substantially all of the cost of such health insurance with premium assistance authorized by a section 1115 demonstration, where state expenditures to provide the health insurance or premium assistance may be matched with funds from Title XIX. Moreover, of the groups we "regard" as Medicaid eligible, we propose to include in the Medicaid fraction only the days of those patients who obtain health insurance directly or with premium assistance that provides essential health benefits (EHB) as set forth in 42 CFR part 440, subpart C, for an Alternative Benefit Plan (ABP), and for patients obtaining

Provision Description	Description of Costs, Transfers, Savings, and Benefits
	premium assistance, only the days of those patients for which the premium assistance is equal to or greater than 90 percent of the cost of the health insurance, provided the patient is not also entitled to Medicare Part A. To the extent that this proposal has an impact on expenditures, that impact is not estimable because we do not have information on the number of section 1115 days by hospital which could be included in the Medicaid fraction absent the proposed revision to the regulation, which would be required to make an estimate.
Proposed Changes to GME Payments Based on *Milton S. Hershey Medical Center, et al. v. Becerra* Litigation	After reviewing the statutory language regarding the direct GME FTE cap and the court's opinion in *Milton S. Hershey Medical Center, et al. v. Becerra*, we are proposing a modified policy to be applied prospectively for all teaching hospitals, Specifically, effective for cost reporting periods beginning on or after October 1, 2022, we are proposing that the hospital's unweighted number of FTE residents exceeds the FTE cap, and the number of weighted FTE residents also exceeds that FTE cap, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the FTE cap. If the number of weighted FTE residents does not exceed that FTE cap, then the allowable weighted FTE count for direct GME payment is the actual weighted FTE count. We estimate the impact of this proposed change for FY 2023 to be approximately $170 million.
Update to the IPPS Payment Rates and Other Payment Policies	As discussed in Appendix A of this proposed rule, acute care hospitals are estimated to experience a decrease of approximately $ 0.3 billion in FY 2023, primarily driven by: (1) a combined $0.7 billion increase in FY 2023 operating payments, including uncompensated care payments and proposed supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and (2) a combined decrease of $ 1.1 billion resulting from estimated changes in new technology add-on payments, the proposed change to the GME weighting methodology, the expiration of the temporary changes to the low-volume hospital payment adjustment, and capital payments, as modeled for this proposed rule.
Update to the LTCH PPS Payment Rates and Other Payment Policies	As discussed in Appendix A of this proposed rule, based on the best available data for the 339 LTCHs in our database, we estimate that the proposed changes to the payment rates and factors that we present in the preamble of and Addendum to this proposed rule, which reflect the proposed update to the LTCH PPS standard Federal payment rate for FY 2023, would result in an estimated increase in payments in FY 2023 of approximately $25 million.
Proposed Changes to the Hospital Readmissions Reduction Program	For the FY 2021 program year and subsequent years, DRG reductions in payments are based on a hospital's risk-adjusted readmission rate during a multi -year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG) surgery. Overall, in this proposed rule, we estimate that 2,364 hospitals would have their base operating DRG payments reduced by their determined proxy FY 2023 hospital-specific readmission adjustment1. As a result, we estimate that the Hospital Readmissions Reduction Program would save approximately $400 million in FY 2023.
Value-Based Incentive Payments under the Hospital VBP Program	We estimate that there would be no net financial impact to the Hospital VBP Program for the FY 2023 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS-DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating MS-DRG payment amount reductions for the FY 2023 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2023 discharges is approximately $1.7 billion.
Proposed Changes to the HAC Reduction Program	For the FY 2023 program year, we are proposing to suppress all six measures in the HAC Reduction Program, only calculate measure results for the NHSN CDC HAI measures, and not calculate measure scores or Total HAC Scores for any hospital. Accordingly, for the FY 2023 HAC Reduction Program, no hospital would receive a payment reduction. As a result, for the FY 2023 program year, we anticipate reductions to the Medicare trust fund that is otherwise estimated at approximately $350 million.
Proposed Changes to the Hospital IQR Program	Across 3,150 IPPS hospitals, we estimate that our proposed changes for the Hospital IQR Program in this proposed rule would result in a total information collection burden increase of 746,300 hours associated with our proposed policies and updated burden estimates and a total cost increase of approximately $23,437,906 across a 4-year period from the CY 2023 reporting period/FY 2025 payment determination through the CY 2026 reporting period/FY 2028 payment determination.

Provision Description	Description of Costs, Transfers, Savings, and Benefits
Proposed Changes to the Medicare Promoting Interoperability Program	Across 4,500 eligible hospitals and CAHs, we estimate that our proposed changes for the Medicare Promoting Interoperability Program in this proposed rule would result in a total information collection burden increase of 5,513 hours associated with our proposed policies and updated burden estimates and a total cost increase of approximately $233,730 across a 2-year period from the CY 2023 EHR reporting period through the CY 2024 EHR reporting period.
Condition of Participation (CoP) Requirements for Hospitals and CAHs To Report Data Elements to Address Any Future Pandemics and Epidemics as Determined by the Secretary	As detailed in section XII.B.10. of the preamble of this proposed rule (Collection of Information requirements), we estimate that our proposed changes to the CoPs, which would require hospitals and CAHs to comply with these reporting provisions, would result in a lower bound estimated burden increase of 483,600 hours based on weekly reporting (52 weeks per year) and a upper bound estimated burden increase of 6,789,000 hours (365 days per year)based on daily reporting of the required information by approximately 6,200 hospitals and CAHs and at an average response time of 1.5 hours for weekly reporting and 3 hours for daily reporting, for a registered nurse with an average hourly salary of $79. This would result in an estimated total of $38,204,400 for weekly reporting (or approximately $6,162 per facility) and $536,331,000 for daily reporting (or approximately $86,505 per facility) annually for all hospitals and CAHs.

[1]For the purpose of modeling the estimated FY 2023 payment adjustment factors that account for the suppression of the pneumonia readmission measure for this proposed rule, we used the data from the FY 2022 Hospital Readmissions Reduction Program for the five non-suppressed measures (that is, AMI, HF, COPD, THA/TKA, and CABG).

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B. Background Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Act sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for a new additional Medicare payment beginning on October 1, 2013, that considers the amount of uncompensated care furnished by the hospital relative to all other qualifying hospitals.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. In general, to qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment. In addition, certain transformative new devices and certain antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway by demonstrating that, absent an add-on payment, they would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments and, as we are proposing beginning in FY 2023 for IHS and Tribal hospitals and hospitals located in Puerto Rico, the proposed new supplemental payment.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as an isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

Under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through FY 2022. For discharges occurring on or after October 1, 2007, but before October 1, 2022, an MDH receives the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. MDHs are a major source of care for Medicare beneficiaries in their areas. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area (or, as amended by the Bipartisan Budget Act of 2018, a hospital located in a State with no rural area that meets certain statutory criteria), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years). As section 50205 of the Bipartisan Budget Act extended the MDH program through FY 2022 only, for FY 2023, beginning on October 1, 2022, the MDH program will no longer be in effect absent a change in law. Because the MDH program is not authorized by statute beyond September 30, 2022, beginning October 1, 2022, all hospitals that previously qualified for MDH status under section 1886(d)(5)(G) of the Act will no longer have MDH status and will be paid based on the IPPS Federal rate.

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services in accordance with a prospective payment system established by the Secretary. The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Inpatient rehabilitation facility (IRF) hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care

institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for IRF hospitals and units, LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are included along with the IPPS annual update in this document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs continue to be paid solely under a reasonable cost-based system, subject to a rate-of-increase ceiling on inpatient operating costs. Similarly, extended neoplastic disease care hospitals are paid on a reasonable cost basis, subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). Section 1206(a) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, effective for LTCH's cost reporting periods beginning in FY 2016 cost reporting period, LTCHs are generally paid for discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS.

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v) of the Act and existing regulations under 42 CFR part 413.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413.

C. Summary of Provisions of Recent Legislation That Would Be Implemented in This Proposed Rule

1. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10)

Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA, Pub. L. 114–10) specifies a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. These adjustments follow the recoupment adjustment to the standardized amounts under section 1886(d) of the Act based upon the Secretary's estimates for discharges occurring from FYs 2014 through 2017 to fully offset $11 billion, in accordance with section 631 of the ATRA. The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.

D. Summary of the Provisions of This Proposed Rule

In this proposed rule, we set forth proposed payment and policy changes to the Medicare IPPS for FY 2023 operating costs and capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2023.

The following is a general summary of the changes that we are proposing to make in this proposed rule.

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of this proposed rule, we include the following:

- Proposed changes to MS–DRG classifications based on our yearly review for FY 2023.
- Proposed adjustment to the standardized amounts under section 1886(d) of the Act for FY 2023 in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA.
- Proposed recalibration of the MS–DRG relative weights, including a proposed 10 percent cap on decreases in an MS–DRG relative weight from one fiscal year to the next.
- A discussion of the proposed FY 2023 status of new technologies approved for add-on payments for FY 2022, a presentation of our evaluation and analysis of the FY 2023 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Pub. L. 108–173, obtained in a town hall meeting) for applications not submitted under an alternative pathway, and a discussion of the proposed status of FY 2023 new technology applicants under the alternative pathways for certain medical devices and certain antimicrobial products.
- A proposal to use National Drug Codes (NDCs) to identify cases involving use of therapeutic agents approved for new technology add-on payments.
- A proposal to publicly post online future applications for new technology add-on payments. Specifically, beginning with the FY 2024 application cycle, we are proposing to post online the completed application forms and certain related materials and updated application information submitted subsequent to the initial application submission for new technology add-on payments, with the exception of certain cost and volume information and certain additional materials (as discussed more fully in section II.F.9. of this proposed rule), no later than the issuance of the proposed rule.

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble of this proposed rule we are proposing to make revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include, but were not limited to, the following:

- The proposed FY 2023 wage index update using wage data from cost reporting periods beginning in FY 2019.
- Calculation, analysis, and implementation of the proposed occupational mix adjustment to the wage index for acute care hospitals for FY 2023 based on the 2019 Occupational Mix Survey.
- Proposed application of the rural, imputed and frontier State floors, and continuation of the low wage index hospital policy.
- Proposed revisions to the wage index for acute care hospitals, based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.
- Proposed adjustment to the wage index for acute care hospitals for FY 2023 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- Proposed permanent cap on annual wage index decreases.
- Proposed labor-related share for the proposed FY 2023 wage index.

3. Other Decisions and Proposed Changes to the IPPS for Operating Costs

In section V. of the preamble of this proposed rule, we discuss proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

- Proposed inpatient hospital update for FY 2023.
- Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- Proposed payment adjustment for low-volume hospitals for FY 2023 and subsequent years.
- The statutorily required IME adjustment factor for FY 2023.
- Proposed changes to the methodologies for determining Medicare DSH payments and the additional payments for uncompensated care.
- Proposed new supplemental payment for IHS/Tribal and Puerto Rico hospitals.
- Proposed revisions to the regulations regarding the counting of days associated with section 1115 demonstrations in the Medicaid fraction.
- Discussion of statutory expiration of the MDH program at the end of FY 2022.
- Proposed requirements for payment adjustments under the Hospital Readmissions Reduction Program for FY 2023.
- The provision of estimated and newly established performance standards for the calculation of value-based incentive payments, as well as a proposal to suppress multiple measures and provide net-neutral payment adjustments under the Hospital Value-Based Purchasing Program.
- Proposed requirements for payment adjustments to hospitals under the HAC Reduction Program for FY 2023.
- Discussion of and proposed changes relating to the implementation of the Rural Community Hospital Demonstration Program in FY 2023.
- Proposed GME payment change in response to *Milton S. Hershey Medical Center et al* v. *Becerra* litigation.
- Proposed nursing and allied health education program Medicare Advantage (MA) add-on rates and direct GME MA percent reductions for CYs 2020 and 2021.
- Proposal to allow Medicare GME affiliation agreements within certain rural track full-time equivalent limitations.
- Proposed payment adjustment for certain clinical trial and expanded access use immunotherapy cases.

4. Proposed FY 2023 Policy Governing the IPPS for Capital-Related Costs

In section VI. of the preamble to this proposed rule, we discuss the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2023.

5. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VII. of the preamble of this proposed rule, we discuss—

- Proposed changes to payments to certain excluded hospitals for FY 2023.
- Proposed continued implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

6. Proposed Changes to the LTCH PPS

In section VIII. of the preamble of this proposed rule, we set forth proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2023.

7. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section IX. of the preamble of this proposed rule, we address the following:

- Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program.
- Proposed changes to the requirements for the quality reporting program for PPS-exempt cancer hospitals (PCHQR Program).
- For the Long Term Care Hospital Quality Reporting Program (LTCH QRP), we are requesting information on CMS' overarching principles for measuring healthcare disparities across CMS Quality Programs, including the LTCH QRP. We are also requesting information on the potential adoption of one future National Healthcare Safety Network (NHSN) digital quality measure (dQM) for the LTCH QRP, as well as quality measure concepts under consideration for future years.
- Proposed changes to requirements pertaining to eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

8. Other Proposals and Comment Solicitations Included in This Proposed Rule

Section X. of the preamble to this proposed rule includes the following:

- Proposals to codify policies related to the costs incurred for qualified and non-qualified deferred compensation plans.
- Proposed changes pertaining to the CoPs at 42 CFR part 482 for hospitals, and at 42 CFR part 485, subpart F, for CAHs.
- Solicitation of comments on the appropriateness of payment adjustments that would account for the additional resource costs for hospitals for the procurement of wholly domestically made NIOSH-approved surgical N95 respirators.

9. Other Provisions of This Proposed Rule

Section XI. of the preamble to this proposed rule includes our discussion of the MedPAC Recommendations.

Section XII. of the preamble to this proposed rule includes the following:

- A descriptive listing of the public use files associated with the proposed rule.
- The collection of information requirements for entities based on our proposals.
- Information regarding our responses to public comments.

10. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In sections II. and III. of the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2023 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We proposed to establish the threshold amounts for outlier cases. In addition, in section IV. of the Addendum to this proposed rule, we address the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2023 for certain hospitals excluded from the IPPS.

11. Determining Prospective Payment Rates for LTCHs

In section V. of the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2023 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2023. We are proposing to establish the adjustments for the wage index, labor-related share, the cost-of-living adjustment, and high-cost outliers, including the applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates.

12. Impact Analysis

In Appendix A of the proposed rule, we set forth an analysis of the impact the proposed changes would have on affected acute care hospitals, CAHs, LTCHs and other entities.

13. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the appropriate percentage changes for FY 2023 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient services provided for LTCH PPS discharges.

14. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2022 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We address these recommendations in Appendix B of this proposed rule. For further information relating specifically to the MedPAC March 2022 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's website at *https://www.medpac.gov.*

E. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care and patient access to their digital health information.

To further interoperability in post-acute care settings, CMS and the Office of the National Coordinator for Health Information Technology (ONC) participate in the Post-Acute Care Interoperability Workgroup (PACIO) to facilitate collaboration with industry stakeholders to develop Health Level Seven International® (HL7) Fast Healthcare Interoperability Resources® (FHIR) standards. These standards could support the exchange and reuse of patient assessment data derived from the post-acute care (PAC) setting assessment tools, such as Minimum Data Set (MDS), Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI), Long Term Care Hospital (LTCH) Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS), Outcome and Assessment Information Set (OASIS), and other sources.[1] [2] The PACIO Project has focused on HL7 FHIR implementation guides for functional status, cognitive status and new use cases on advance directives, re-assessment timepoints, and Speech, Language, Swallowing Cognitive communications and Hearing (SPLASCH).[3] We encourage PAC provider and health internet technology (IT) vendor participation as the efforts advance. The CMS Data Element Library (DEL) continues to be updated and serves as a resource for PAC assessment data elements and their associated mappings to health IT standards, such as Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED).[4] The DEL furthers CMS' goal of data standardization and interoperability. Standards in the DEL can be referenced on the CMS website (*https://del.cms.gov/DELWeb/pubHome*) and in the ONC Interoperability Standards Advisory (ISA). The 2022 ISA is available at *https://www.healthit.gov/isa/sites/isa/files/inline-files/2022-ISA-Reference-Edition.pdf.*

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted December 13, 2016) required HHS and ONC to take steps further interoperability for providers in settings across the care continuum.[5] Specifically, section 4003(b) of the Cures Act required ONC to take steps to advance interoperability through the development of a trusted exchange framework and common agreement aimed at establishing a universal floor of interoperability across the country. On January 18, 2022, ONC announced a significant milestone by releasing the Trusted Exchange Framework [6] and Common Agreement Version 1.[7] The Trusted Exchange Frameworkis a set of non-binding principles for health information exchange, and the Common Agreement is a contract that advances those principles. The Common Agreement and the incorporated by reference Qualified Health Information Network Technical Framework Version 1 establish the technical infrastructure model and governing approach for different health information networks and their users to securely share clinical

[1] HL7 FHIR Release 4. Available at: *https://www.hl7.org/fhir/.*

[2] HL7 FHIR. PACIO Functional Status Implementation Guide. Available at: *https://paciowg.github.io/functional-status-ig/.*

[3] PACIO Project. Available at: *http://pacioproject.org/about/.*

[4] CMS Data Element Library Fact Sheet. Available at: *https://www.cms.gov/newsroom/fact-sheets/cms-data-element-library-fact-sheet.*

[5] Public Law 114–255, sections 4001 through 4008. Available at: *https://www.govinfo.gov/content/pkg/PLAW-114publ255/html/PLAW-114publ255.htm.*

[6] The Trusted Exchange Framework (TEF): Principles for Trusted Exchange (Jan. 2022). Available at: *https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf.*

[7] Common Agreement for Nationwide Health Information Interoperability Version 1 (Jan. 2022). Available at: *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

information with each other, all under commonly agreed to terms. The technical and policy architecture of how exchange occurs under the Trusted Exchange Framework and the Common Agreement follows a network-of-networks structure, which allows for connections at different levels and is inclusive of many different types of entities at those different levels, such as health information networks, healthcare practices, hospitals, public health agencies, and Individual Access Services (IAS) Providers.[8] For more information, we refer readers to *https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement.*

We invite providers to learn more about these important developments and how they are likely to affect hospitals.

F. Proposed Use of FY 2021 Data and Proposed Methodology Modifications for the FY 2023 IPPS and LTCH PPS Ratesetting

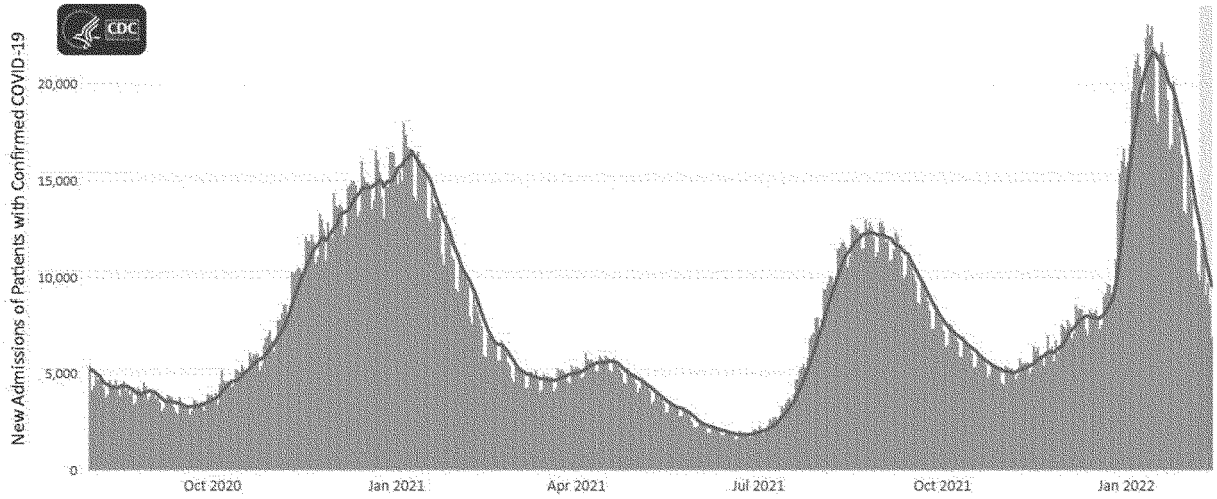
We primarily use two data sources in the IPPS and LTCH PPS ratesetting: Claims data and cost report data. The claims data source is the MedPAR file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital bills for discharges in a fiscal year. The cost report data source is the Medicare hospital cost report data files from the most recent quarterly Healthcare Cost Report Information System (HCRIS) release. Our goal is always to use the best available data overall for ratesetting. Ordinarily, the best available MedPAR data is the most recent MedPAR file that contains claims from discharges for the fiscal year that is 2 years prior to the fiscal year that is the subject of the rulemaking. Ordinarily, the best available cost report data is based on the cost reports beginning 3 fiscal years prior to the fiscal year that is the subject of the rulemaking. However, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44789 through 44793), we finalized our proposal to use FY 2019 data for the FY 2022 ratesetting for circumstances where the FY 2020 data (the most recently available data at the time of rulemaking) was significantly impacted by the COVID–19 PHE.

As we discussed in the FY 2022 IPPS/LTCH PPS final rule, the FY 2020 MedPAR claims file and the FY 2019 HCRIS dataset both contained data that was significantly impacted by the COVID–19 PHE, primarily in that the utilization of services at IPPS hospitals and LTCHs was generally markedly different for certain types of services in FY 2020 than would have been expected in the absence of the PHE. However, the most recent vaccination and hospitalization data from the CDC at the time of development of that rule supported our belief at the time that the risk of COVID–19 in FY 2022 would be significantly lower than the risk of COVID–19 in FY 2020 and there would be fewer COVID–19 hospitalizations for Medicare beneficiaries in FY 2022 than there were in FY 2020. Therefore, we finalized our proposal to use FY 2019 data for the FY 2022 ratesetting for circumstances where the FY 2020 data was significantly impacted by the COVID–19 PHE, based on the belief that FY 2019 data from before the COVID–19 PHE would be a better overall approximation of the FY 2022 inpatient experience at both IPPS hospitals and LTCHs. For example, we used the FY 2019 MedPAR claims data for purposes where we ordinarily would have used the FY 2020 MedPAR claims data. We also used cost report data from the FY 2018 HCRIS file for purposes where we ordinarily would have used the FY 2019 HCRIS file (since the FY 2019 cost report data from HCRIS contained many cost reports ending in FY 2020 based on each hospital's cost reporting period).

Similar to our analysis of the FY 2020 MedPAR claims file and the FY 2019 HCRIS dataset for the FY 2022 IPPS/LTCH PPS rulemaking, the FY 2021 MedPAR claims file and the FY 2020 HCRIS dataset also both contain data that was significantly impacted by the virus that causes COVID–19, primarily in that the utilization of services at IPPS hospitals and LTCHs was again generally markedly different for certain types of services in FY 2021 than would have been expected in the absence of the virus that causes COVID–19. Specifically, the share of admissions at IPPS hospitals and LTCHs for MS–DRGs and MS–LTC–DRGs associated with the treatment of COVID–19 continued to remain significantly higher than levels prior to the COVID–19 PHE. For example, in FY 2019, the share of IPPS cases and LTCH PPS standard Federal payment rate cases grouped to MS–DRG and MS–LTC–DRG 177 (Respiratory infections and inflammations with MCC) was approximately 1 percent and 2 percent, respectively. In comparison, in FY 2021, the share of IPPS cases and LTCH PPS standard Federal payment rate cases grouped to MS–DRG 177 was approximately 6 percent and 8 percent, respectively. However, as we discuss further in this section, in light of the expected continued impact on hospitalizations of the virus that causes COVID–19, we believe it is appropriate to use the FY 2021 data reflecting this impact for this FY 2023 IPPS/LTCH PPS rulemaking, with some proposed modifications to our usual ratesetting methodologies to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries at IPPS hospitals and LTCHs as compared to FY 2021.

The CDC graph below illustrates new inpatient hospital admissions of patients with confirmed COVID–19 from August 1, 2020 through February 15, 2022. (*https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/02182022/images/hospitalizations_02182022.jpg?_=35767,* accessed February 22, 2022)

[8] The Common Agreement defines Individual Access Services (IAS) as ''with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, to the extent consistent with Applicable Law, to an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.'' The Common Agreement defines ''IAS Provider'' as: ''Each QHIN, Participant, and Subparticipant that offers Individual Access Services.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*



The low point of the graph (late June 2021) approximately coincides with the time of the development of the FY 2022 IPPS/LTCH PPS final rule and generally supports, in conjunction with the other factors discussed in that rulemaking (including the most recent vaccination data from the CDC), our assumption in the final rule that the FY 2022 time period would be more similar to the time period prior to the PHE. However, as can be seen in the graph, the virus that causes COVID–19 has continued to significantly impact hospitalizations for the time period subsequent to the development of the FY 2022 IPPS/LTCH PPS final rule. As the CDC has noted, the most recent increase in hospitalizations has been primarily associated with the Omicron variant of the virus.[9] The CDC has stated that new variants will continue to emerge. Viruses constantly change through mutation and sometimes these mutations result in a new variant of the virus. The CDC and other public health organizations monitor all variants of the virus that causes COVID–19 in the United States and globally. Scientists monitor all variants but may classify certain ones as variants being monitored, variants of interest, variants of concern and variants of high consequence. Some variants spread more easily and quickly than other variants, which may lead to more cases of COVID–19. Even if a variant causes less severe disease in general, an increase in the overall number of cases could cause an increase in hospitalizations. (see *https://www.cdc.gov/coronavirus/2019-ncov/variants/about-variants.html,* accessed February 25, 2022)

[9] *https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html.*

Given the effects of the virus that causes COVID–19 in the Medicare FY 2020 data, the Medicare FY 2021 data, and the CDC hospitalization data, coupled with the expectation for future variants, we believe that it is reasonable to assume that some Medicare beneficiaries will continue to be hospitalized with COVID–19 at IPPS hospitals and LTCHs in FY 2023. Accordingly, we believe it is appropriate to use FY 2021 data, specifically the FY 2021 MedPAR claims file and the FY 2020 HCRIS dataset (which contains data from many cost reports ending in FY 2021 based on each hospital's cost reporting period) as the most recent available data during the period of the COVID–19 PHE, for purposes of the FY 2023 IPPS and LTCH PPS ratesetting. However, we also believe it is reasonable to assume based on the information available at this time that there will be fewer COVID–19 hospitalizations in FY 2023 than in FY 2021 given the more recent trends in the CDC hospitalization data since the Omicron variant peak in January, 2022. Accordingly, because we anticipate Medicare inpatient hospitalizations for COVID–19 will continue in FY 2023 but at a lower level, we are proposing to use FY 2021 data for purposes of the FY 2023 IPPS and LTCH PPS ratesetting but with modifications to our usual ratesetting methodologies to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries at IPPS hospitals and LTCHs as compared to FY 2021.

First, we are proposing to modify the calculation of the FY 2023 MS–DRG and MS–LTC–DRG relative weights. We observed that COVID–19 cases were impacting the relative weights as calculated using the FY 2021 MedPAR data for a few COVID–19-related MS–DRGs and MS–LTC–DRGs. As an example, for MS–DRG and MS–LTC–DRG 870 (Septicemia or Severe Sepsis with MV >96 hours), the MS–DRG and MS–LTC–DRG relative weights calculated using the FY 2021 MedPAR data are approximately 9 and 3 percent higher, respectively, compared to their relative weights if calculated excluding COVID–19 cases. Because this MS–DRG contains a mix of COVID–19 cases and non-COVID–19 cases with different average costs, the relative weight for this MS–DRG is dependent on that mix of cases. As noted previously, we believe it is reasonable to assume that there will be fewer COVID–19 hospitalizations among Medicare beneficiaries in FY 2023 than there were in FY 2021; however it is not possible to know precisely how COVID–19 hospitalizations in FY 2023 will compare to FY 2021. We believe that averaging the relative weights as calculated with and without the COVID–19 cases reflected in the FY 2021 MedPAR data would reflect a reasonable estimation of the case mix for FY 2023 based on the information available at this time, and more accurately estimate the relative resource use for the cases treated in FY 2023. Therefore, we are proposing to calculate the relative weights for FY 2023 by first calculating two sets of weights, one including and one excluding COVID–19 claims, and then averaging the two sets of relative weights to determine the proposed FY 2023 relative weight values. We believe this proposed modification to our relative weight setting methodology would appropriately reduce, but not remove entirely, the effect of COVID–19 cases on the relative weight calculations, consistent with our expectation that Medicare inpatient hospitalizations for COVID–19 will continue in FY 2023 at a lower level as compared to FY 2021,

and provide a more accurate estimate of relative resource use for FY 2023 than if we were to calculate the proposed relative weights using all applicable cases in the FY 2021 data. The proposal for modifying the methodology for determining the FY 2023 IPPS MS–DRG relative weights is discussed in greater detail in section II.E. of the preamble of this proposed rule. The proposal for modifying the methodology for determining the FY 2023 LTCH PPS MS–LTC–DRG relative weights is discussed in greater detail in section VIII.B. of the preamble of this proposed rule.

We also are proposing to modify our methodologies for determining the FY 2023 outlier fixed-loss amount for IPPS cases and LTCH PPS standard Federal payment rate cases. The methodologies for determining both of these outlier fixed-loss amounts include calculating and applying a charge inflation factor to increase charges from the claim year to the rulemaking year, as well as calculating and applying CCR adjustment factors to adjust CCRs used to make payments in the current year to the rulemaking year. The charge inflation factors calculated using the two most recently available years of MedPAR claims data (FY 2020 and FY 2021) that would ordinarily be used for this FY 2023 proposed rule to inflate the charges on the FY 2021 MedPAR claims were abnormally high as compared to recent historical levels prior to the PHE (for example, for the IPPS, approximately 10 percent based on the FY 2020 and FY 2021 MedPAR claims data as compared to approximately 6 percent based on the FY 2018 and FY 2019 MedPAR claims data). Furthermore, the IPPS operating and capital CCR adjustment factors calculated based on the percentage changes in the CCRs from the December 2020 update of the PSF to the December 2021 update of the PSF that would ordinarily be used for this FY 2023 proposed rule to adjust the CCRs from the December 2021 update of the PSF were also abnormally high as compared to recent historical levels prior to the PHE (for example, for the IPPS operating CCR adjustment factor, a factor of approximately 1.03 based on the December 2020 and December 2021 updates to the PSF as compared to a factor of approximately 0.97 based on the March 2019 and March 2020 updates to the PSF). We believe these abnormally high charge inflation and CCR adjustment factors as compared to historical levels were partially due to the high number of COVID–19 cases with higher charges that were treated in IPPS hospitals and LTCHs in FY 2021. As we previously stated, we believe there will be fewer COVID–19 cases in FY 2023 than in FY 2021. Therefore, we do not believe it is reasonable to assume charges and CCRs will continue to increase at these abnormally high rates. Consequently, when determining the FY 2023 outlier fixed-loss amounts for IPPS cases and LTCH PPS standard Federal payment rate cases, we are proposing to inflate the charges on the FY 2021 MedPAR claims using charge inflation factors computed by comparing the average covered charge per case in the March 2019 MedPAR file of FY 2018 to the average covered charge per case in the March 2020 MedPAR file of FY 2019, which is the last 1-year period prior to the COVID–19 PHE. We also are proposing to adjust the CCRs from the December 2021 update of the PSF by comparing the percentage change in the national average case-weighted CCR from the March 2019 update of the PSF to the national average case-weighted CCR from the March 2020 update of the PSF, which is the last 1-year period prior to the COVID–19 PHE. We believe using the charge inflation factors and CCR adjustment factors derived from data prior to the COVID–19 PHE would provide a more reasonable approximation of the increase in costs that will occur from FY 2021 to FY 2023 because we do not believe the charge inflation that has occurred during the PHE will continue as the number of higher cost COVID–19 cases declines. The proposal for modifying the methodology for determining the FY 2023 outlier fixed-loss amounts for IPPS cases is discussed in greater detail in section II.A.4. of the addendum to this proposed rule. The proposal for modifying the methodology for determining the FY 2023 outlier fixed-loss amounts for LTCH PPS standard Federal payment rate cases is discussed in greater detail in section V.D.3. of the addendum to this proposed rule.

As discussed in section I.O. of Appendix A of this proposed rule, we are also requesting comments on, as an alternative to our proposed approach, the use of the FY 2021 data for purposes of FY 2023 ratesetting without these proposed modifications to our usual methodologies for the calculation of the FY 2023 MS–DRG and MS–LTC–DRG relative weights or the usual methodologies used to determine the FY 2023 outlier fixed-loss amount for IPPS cases and LTCH PPS standard Federal payment rate cases. We note that the FY 2023 outlier fixed-loss amount would be significantly higher under this alternative approach. In order to illustrate the effect of our proposed modifications on the relative weights and fixed loss amount, we are making available supplemental information, including the relative weights and fixed loss amount calculated without the proposed modifications to our usual methodologies, as described in section I.O. of Appendix A of this proposed rule. We refer the reader to section I.O. of Appendix A of this proposed rule for a discussion of the files that we are making available with regard to our alternative approach.

II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually to account for changes in resource consumption. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. Adoption of the MS–DRGs and MS–DRG Reclassifications

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766) and the FYs 2011 through 2022 IPPS/LTCH PPS final rules (75 FR 50053 through 50055; 76

FR 51485 through 51487; 77 FR 53273; 78 FR 50512; 79 FR 49871; 80 FR 49342; 81 FR 56787 through 56872; 82 FR 38010 through 38085, 83 FR 41158 through 41258, 84 FR 42058 through 42165, 85 FR 58445 through 58596, 86 FR 44795 through 44961, respectively).

C. Proposed FY 2023 MS–DRG Documentation and Coding Adjustment

1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110–90 and the Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA)

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS–DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. By increasing the number of MS–DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS–DRGs encourage hospitals to improve their documentation and coding of patient diagnoses.

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we indicated that the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for additional documentation and coding. In that final rule with comment period, we exercised our authority under section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix. Our actuaries estimated that maintaining budget neutrality required an adjustment of –4.8 percentage points to the national standardized amount. We provided for phasing in this –4.8 percentage point adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of –1.2 percentage points for FY 2008, –1.8 percentage points for FY 2009, and –1.8 percentage points for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007 (Pub. L. 110–90). Section 7(a) of Public Law 110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to –0.6 percentage point for FY 2008 and –0.9 percentage point for FY 2009.

As discussed in prior year rulemakings, and most recently in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56780 through 56782), we implemented a series of adjustments required under sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90, based on a retrospective review of FY 2008 and FY 2009 claims data. We completed these adjustments in FY 2013 but indicated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53274 through 53275) that delaying full implementation of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 until FY 2013 resulted in payments in FY 2010 through FY 2012 being overstated, and that these overpayments could not be recovered under Public Law 110–90.

In addition, as discussed in prior rulemakings and most recently in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38008 through 38009), section 631 of the American Taxpayer Relief Act of 2012 (ATRA) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment or adjustments totaling $11 billion by FY 2017. This adjustment represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013.

2. Adjustments Made for FYs 2018, 2019, 2020, 2021, and 2022 as Required Under Section 414 of Public Law 114–10 (MACRA) and Section 15005 of Public Law 114–255

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percentage point positive adjustment for each of FYs 2018 through 2023. In the FY 2017 rulemaking, we indicated that we would address the adjustments for FY 2018 and later fiscal years in future rulemaking. Section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted on December 13, 2016, amended section 7(b)(1)(B) of the TMA, as amended by section 631 of the ATRA and section 414 of the MACRA, to reduce the adjustment for FY 2018 from a 0.5 percentage point positive adjustment to a 0.4588 percentage point positive adjustment. As we discussed in the FY 2018 rulemaking, we believe the directive under section 15005 of Public Law 114–255 is clear. Therefore, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38009) for FY 2018, we implemented the required +0.4588 percentage point adjustment to the standardized amount. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41157), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42057), FY 2021 IPPS/LTCH PPS final rule (85 FR 58444 and 58445), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 44794 and 44795), consistent with the requirements of section 414 of the MACRA, we implemented 0.5 percentage point positive adjustments to the standardized amount for FY 2019, FY 2020, FY 2021, and FY 2022, respectively. We indicated the FY 2018, FY 2019, FY 2020, FY 2021, and FY 2022 adjustments were permanent adjustments to payment rates. We also stated that we plan to propose a future adjustment required under section 414 of the MACRA for FY 2023 in future rulemaking.

3. Proposed Adjustment for FY 2023

Consistent with the requirements of section 414 of the MACRA, we are proposing to implement a 0.5 percentage point positive adjustment to the standardized amount for FY 2023. This would constitute a permanent adjustment to payment rates. This proposed 0.5 percentage point positive adjustment is the final adjustment prescribed by section 414 of the MACRA. Along with the 0.4588 percentage point positive adjustment for FY 2018, and the 0.5 percentage point positive adjustments for FY 2019, FY 2020, FY 2021, and FY 2022, this final proposed adjustment will result in combined positive adjustment of 2.9588 percentage points (or the sum of the adjustments for FYs 2018 through 2023) to the standardized amount.

D. Proposed Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for Proposed FY 2023 MS–DRG Updates

a. Conversion of MS–DRGs to the International Classification of Diseases, 10th Revision (ICD–10)

As of October 1, 2015, providers use the International Classification of Diseases, 10th Revision (ICD–10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system instead of the ICD–9–CM coding system, which was used through September 30, 2015. The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the ICD–10–CM and ICD–10–PCS Official Guidelines for Coding and Reporting. For a detailed discussion of the conversion of the MS–DRGs to ICD–10, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56789).

b. Basis for Proposed FY 2023 MS–DRG Updates

Given the need for more time to carefully evaluate requests and propose updates, as discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38010), we changed the deadline to request updates to the MS–DRGs to November 1 of each year, which provided an additional five weeks for the data analysis and review process. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32472), we stated that with the continued increase in the number and complexity of the requested changes to the MS–DRG classifications since the adoption of ICD–10 MS–DRGs, and to consider as many requests as possible, more time is needed to carefully evaluate the requested changes, analyze claims data, and consider any proposed updates. We further stated we were changing the deadline to request changes to the MS–DRGs to October 20 of each year to allow for additional time for the review and consideration of any proposed updates. However, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58445), due to the unique circumstances for the FY 2021 IPPS/LTCH PPS final rule for which we waived the delayed effective date, we maintained the deadline of November 1, 2020 for FY 2022 MS–DRG classification change requests. We also noted that we expected to reconsider a change in the deadline beginning with comments and suggestions submitted for FY 2023. In the FY 2022 IPPS/LTCH PPS proposed rule, we stated that while we continue to believe that a change in the deadline from November 1 to October 20 would provide hospitals sufficient time to assess potential impacts and inform future MS–DRG recommendations, we were maintaining the deadline of November 1 for FY 2023 MS–DRG classification change requests. As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44795), we received public comments expressing support for a future change to the deadline for requesting updates to the MS–DRG classifications from November 1 to October 20, and we noted in response that we may consider any changes to the deadline or frequency for submissions of requests for MS–DRG classification changes for future fiscal years. Beginning with FY 2024 MS–DRG classification change requests, we are changing the deadline to request changes to the MS–DRGs to October 20th of each year to allow for additional time for the review and consideration of any proposed updates. As previously discussed, we continue to believe such a change would allow hospitals sufficient time to assess potential impacts and inform future MS–DRG recommendations, while also providing CMS the additional time needed for evaluation of the requested changes, analysis of claims data, and consideration of any proposed updates.

We are also changing the process for submitting requested updates to the MS–DRG classifications, beginning with the FY 2024 MS–DRG classification change requests. CMS is in the process of implementing a new electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™), that will be available for users to begin gaining familiarity with a new approach and process to submit new technology add-on payment applications, requests for ICD–10–PCS procedure codes, and other requests. To simplify and streamline the process for submission of standardized applications and requests that inform payment policy under the IPPS, we will also be using this new system for submission of MS–DRG classification change requests. We believe that submission of MS–DRG reclassification requests through MEARIS™ will not only help CMS to track such requests, but it will also create efficiencies for requestors when compared to the previous submission process.

Accordingly, beginning with the FY 2024 MS–DRG classification change requests, CMS will only accept such requests submitted via MEARIS™, and will no longer consider any such requests that are sent via email. We anticipate that, beginning April 5, 2022, MEARIS™ will be available for users to begin gaining familiarity with this new approach for submitting MS–DRG classification change requests. MEARIS™, including the mechanism for submitting MS–DRG classification change requests, can be accessed at *https://mearis.cms.gov.* We encourage users to register and begin using this system to provide feedback on their experience with this initial version. We note that within MEARIS™, we have built in several resources to support users, including a ''Resources'' section (available at *https://mearis.cms.gov/public/resources*) and technical support available under ''Useful Links'' at the bottom of the MEARIS™ site. Questions regarding the MEARIS™ system can be submitted to CMS using the form available under ''Contact'' at *https://mearis.cms.gov/public/resources?app=msdrg.*

We also note that, as discussed in section II.D.17. of the preamble of this proposed rule, effective January 5, 2022, MEARIS™ was made available for users to begin gaining familiarity with a new approach and process to submit ICD–10–PCS procedure code requests.

As noted previously, interested parties had to submit MS–DRG classification change requests for FY 2023 by November 1, 2021. As we have discussed in prior rulemaking, we may not be able to fully consider all of the requests that we receive for the upcoming fiscal year. We have found that, with the implementation of ICD–10, some types of requested changes to the MS–DRG classifications require more extensive research to identify and analyze all of the data that are relevant to evaluating the potential change. We note in the discussion that follows those topics for which further research and analysis are required, and which we will continue to consider in connection with future rulemaking. Interested parties should submit any comments and suggestions for FY 2024 by October 20, 2022 via the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™) at *https://mearis.cms.gov/public/home.*

As we did for the FY 2022 IPPS/LTCH PPS proposed rule, for this FY 2023 IPPS/LTCH PPS proposed rule we are providing a test version of the ICD–10

MS–DRG GROUPER Software, Version 40, so that the public can better analyze and understand the impact of the proposals included in this proposed rule. We note that this test software reflects the proposed GROUPER logic for FY 2023. Therefore, it includes the new diagnosis and procedure codes that are effective for FY 2023 as reflected in Table 6A.—New Diagnosis Codes—FY 2023 and Table 6B.—New Procedure Codes—FY 2023 associated with this proposed rule and does not include the diagnosis codes that are invalid beginning in FY 2023 as reflected in Table 6C.—Invalid Diagnosis Codes—FY 2023 associated with this proposed rule. We note that at the time of the development of this proposed rule there were no procedure codes designated as invalid for FY 2023, and therefore, there is no Table 6D—Invalid Procedure Codes—FY 2023 associated with this proposed rule. These tables are not published in the Addendum to this proposed rule, but are available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to this proposed rule. Because the diagnosis codes no longer valid for FY 2023 are not reflected in the test software, we are making available a supplemental file in Table 6P.1a that includes the mapped Version 40 FY 2023 ICD–10–CM codes and the deleted Version 39.1 FY 2022 ICD–10–CM codes that should be used for testing purposes with users' available claims data. Therefore, users will have access to the test software allowing them to build case examples that reflect the proposals included in this proposed rule. In addition, users will be able to view the draft version of the ICD–10 MS–DRG Definitions Manual, Version 40.

The test version of the ICD–10 MS–DRG GROUPER Software, Version 40, the draft version of the ICD–10 MS–DRG Definitions Manual, Version 40, and the supplemental mapping files in Table 6P.1a of the FY 2022 and FY 2023 ICD–10–CM diagnosis codes are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

Following are the changes that we are proposing to the MS–DRGs for FY 2023. We are inviting public comments on each of the MS–DRG classification proposed changes, as well as our proposals to maintain certain existing MS–DRG classifications discussed in this proposed rule. In some cases, we are proposing changes to the MS–DRG classifications based on our analysis of claims data and consultation with our clinical advisors. In other cases, we are proposing to maintain the existing MS–DRG classifications based on our analysis of claims data and consultation with our clinical advisors. As discussed in section I.F. of the preamble of this proposed rule, we are proposing to use the FY 2021 MedPAR data for purposes of this FY 2023 IPPS rulemaking, with certain proposed modifications to the relative weight and outlier methodologies. For this FY 2023 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2021 update of the FY 2021 MedPAR file, which contains hospital bills received from October 1, 2020 through September 30, 2021, for discharges occurring through September 30, 2021. In our discussion of the proposed MS–DRG reclassification changes, we refer to these claims data as the ''September 2021 update of the FY 2021 MedPAR file.''

As explained in previous rulemaking (76 FR 51487), in deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on the judgment of our clinical advisors to determine whether patients are clinically distinct or similar to other patients represented in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58448), we finalized our proposal to expand our existing criteria to create a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG. Specifically, we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. We stated our belief that applying these criteria to the NonCC subgroup would better reflect resource stratification as well as promote stability in the relative weights by avoiding low volume counts for the NonCC level MS–DRGs. We noted that in our analysis of MS–DRG classification requests for FY 2021 that were received by November 1, 2019, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups. We also noted that the application of the NonCC subgroup criteria going forward may result in modifications to certain MS–DRGs that are currently split into three severity levels and result in MS–DRGs that are split into two severity levels. We stated that any proposed modifications to the MS–DRGs would be addressed in future rulemaking consistent with our annual process and reflected in Table 5—Proposed List of Medicare Severity Diagnosis Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay for the applicable fiscal year.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44798), we finalized a delay in applying this technical criterion to existing MS–DRGs until FY 2023 or future rulemaking, in light of the PHE. Commenters recommended that a complete analysis of the MS–DRG changes to be proposed for future rulemaking in connection with the expanded three-way severity split criteria be conducted and made available to enable the public an opportunity to review and consider the redistribution of cases, the impact to the relative weights, payment rates, and hospital case mix to allow meaningful comment prior to implementation.

In our analysis of the MS–DRG classification requests for FY 2023 that we received by November 1, 2021, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups, as described in the following table.

Criteria Number	Three-Way Split 123 (MCC vs CC vs NonCC)	Two-Way Split 1_23 MCC vs (CC+NonCC)	Two-Way Split 12_3 (MCC+CC) vs NonCC
1. At least 500 cases in the MCC/CC/NonCC group	500+ cases for MCC group; and 500+ cases for CC group; and 500+ cases for NonCC group	500+ cases for MCC group; and 500+ cases for (CC+NonCC) group	500+ cases for (MCC+CC) group; and 500+ cases for NonCC group
2. At least 5% of the patients are in the MCC/CC/NonCC group	5%+ cases for MCC group; and 5%+ cases for CC group; and 5%+ cases for NonCC group	5%+ cases for MCC group; and 5%+ cases for (CC+NonCC) group	5%+ cases for (MCC+CC) group; and 5%+ cases for NonCC group
3. There is at least a 20% difference in average cost between subgroups	20%+ difference in average cost between MCC group and CC group; and 20%+ difference in average cost between CC group and NonCC group	20%+ difference in average cost between MCC group and (CC+NonCC) group	20%+ difference in average cost between (MCC+ CC) group and NonCC group
4. There is at least a $2,000 difference in average cost between subgroups	$2,000+ difference in average cost between MCC group and CC group; and $2,000+ difference in average cost between CC group and NonCC group	$2,000+ difference in average cost between MCC group and (CC+ NonCC) group	$2,000+ difference in average cost between (MCC+ CC) group and NonCC group
5. The R2 of the split groups is greater than or equal to 3	R2 > 3.0 for the three way split within the base MS-DRG	R2 > 3.0 for the two way 1_23 split within the base MS-DRG	R2 > 3.0 for the two way 12_3 split within the base MS-DRG

In general, once the decision has been made to propose to make further modifications to the MS–DRGs as described previously, such as creating a new base MS–DRG, or in our evaluation of a specific MS–DRG classification request to split (or subdivide) an existing base MS–DRG into severity levels, all five criteria must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. We note that in our analysis of requests to create a new MS–DRG, we typically evaluate the most recent year of MedPAR claims data available. For example, we stated earlier that for this FY 2023 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2021 update of the FY 2021 MedPAR file. However, in our evaluation of requests to split an existing base MS–DRG into severity levels, as noted in prior rulemaking (80 FR 49368), we typically analyze the most recent 2 years of data. This analysis includes 2 years of MedPAR claims data to compare the data results from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. The first step in our process of evaluating if the creation of a new CC subgroup within a base MS–DRG is warranted is to determine if all the criteria are satisfied for a three-way split. If the criteria fail, the next step is to determine if the criteria are satisfied for a two-way split. If the criteria for both of the two-way splits fail, then a split (or CC subgroup) would generally not be warranted for that base MS–DRG. If the three-way split fails on any one of the five criteria and all five criteria for both two-way splits (1_23 and 12_3) are met, we would apply the two-way split with the highest R2 value. We note that if the request to split (or subdivide) an existing base MS–DRG into severity levels specifies the request is for either one of the two-way splits (1_23 or 12_3), in response to the specific request, we will evaluate the criteria for both of the two-way splits, however we do not also evaluate the criteria for a three-way split.

For this FY 2023 IPPS/LTCH PPS proposed rule, using the September 2021 update of the FY 2021 MedPAR file, we also analyzed how applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would affect the MS–DRG structure beginning in FY 2023. Findings from our analysis indicated that approximately 41 MS–DRGs would be subject to change based on the three-way severity level split criterion finalized in FY 2021. Specifically, we found that applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would result in the deletion of 123 MS–DRGs (41 MS–DRGs × 3 severity levels = 123) and the creation of 75 new MS–DRGs. These updates would also involve a redistribution of cases, which would impact the relative weights, and, thus, the payment rates proposed for particular types of cases. We refer the reader to Table 6P.1b for the list of the 123 MS–DRGs that would be subject to deletion and the list of the 75 new MS–DRGs that would be proposed for creation for FY 2023 under this policy if the NonCC subgroup criteria were applied.

In light of the ongoing public health emergency (PHE), we continue to have concerns about the impact of implementing this volume of MS–DRG changes at this time, and believe it may be appropriate to continue to delay application of the NonCC subgroup criteria to existing MS–DRGs to maintain more stability in the current MS–DRG structure and until such time additional analyses can be performed to assess impacts, as discussed in response to comments in the FY 2022 IPPS/LTCH PPS final rule. Therefore, we are proposing not to apply the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split for FY 2023, and to instead maintain the current structure of the 41 MS–DRGs that currently have a three-way severity level split (total of 123 MS–DRGs) that would otherwise be subject to these criteria. We intend to address the application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split in future rulemaking.

2. Pre-MDC: MS–DRG 018 Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44798 through 44806), we finalized our proposal to assign procedure codes describing CAR T-cell, non-CAR T-cell, and other immunotherapies to Pre-MDC MS–DRG

018 and to revise the title for Pre-MDC MS–DRG 018 to ''Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies'' to reflect this assignment. In that discussion, we noted that a few commenters recommended we continue to work with stakeholders on ways to improve the predictability and stability of hospital payments for these complex, novel cell therapies and that we should continue to monitor and assess the appropriateness of therapies assigned to MS–DRG 018, if they continue to be aligned on resource use, and whether additional refinements or MS–DRGs may be warranted in the future.

We also noted that the process of code creation and proposed assignment to the most appropriate MS–DRG exists independently, regardless of whether there is an associated application for a new technology add-on payment for a product or technology submitted for consideration in a given fiscal year. Specifically, requests for a new code(s) or updates to existing codes are addressed through the ICD–10 Coordination and Maintenance Committee meetings, held annually in the spring and fall, where code proposals are presented and the public is provided the opportunity to comment. All codes finalized from the fall meeting are subsequently proposed for assignment under the ICD–10 MS–DRGs through rulemaking. We refer the reader to section II.D.17 of the preamble of this proposed rule for additional information regarding the ICD–10 Coordination and Maintenance Committee meeting process.

There were no requests or proposals for new procedure codes to describe the administration of a CAR T-cell or another type of gene or cellular therapy discussed at the September 14–15, 2021 ICD–10 Coordination and Maintenance Committee meeting. For the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting, there were topics included on the agenda and in the related meeting materials that included proposals for new procedure codes to describe the administration of a CAR T-cell or another type of gene or cellular therapy product. The agenda and related meeting materials for these specific topics are available via the internet on the CMS website at *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.*

As stated in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44805) and noted previously, the process of code creation and proposed assignment to the most appropriate MS–DRG exists independently, regardless of whether there is an associated application for a new technology add-on payment for a product or technology submitted for consideration in a given fiscal year. We also clarified that the assignment of a procedure code to a MS–DRG is not dependent upon a product's Food and Drug Administration (FDA) approval. Similarly, the creation of a code to describe a technology that is utilized in the performance of a procedure or service does not require FDA approval of the technology.

Because the diagnosis and procedure code proposals that are presented at the March meeting for an October 1 implementation (upcoming FY) are not finalized in time to include in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes in association with the proposed rule, as noted in prior rulemaking, we use our established process to examine the MS–DRG assignment for the predecessor codes to determine the most appropriate MS–DRG assignment. Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis or treatment of the condition. We have noted in prior rulemaking that this process does not automatically result in the new procedure code being assigned to the same MS–DRG or to have the same designation (O.R. versus Non-O.R.) as the predecessor code.

In response to commenters' recommendation that we continue to assess the appropriateness of the therapies assigned to Pre-MDC MS–DRG 018, we are providing the results of our data analysis using the September 2021 update of the FY 2021 MedPAR file for cases reporting the administration of a CAR T-cell or other immunotherapy in Pre-MDC MS–DRG 018 and the number of cases reporting a secondary diagnosis of Z00.6 (Encounter for examination for normal comparison and control in clinical research program). We note that if a procedure code that is assigned to the logic for Pre-MDC MS–DRG 018 is not listed it is because there were no cases found. We also note there were no cases reporting diagnosis code Z00.6 as a principal diagnosis. Our findings are shown in the following table.

MS-DRG	ICD-10-PCS Code	Number of Cases	Average Length of Stay	Average Costs	Secondary Diagnosis Z00.6
018	All cases	558	16.5	$194,717	185
	XW033C7 - Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7	50	13.2	$212,265	16
	XW033M7 - Introduction of brexucabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	11	14.1	$157,950	4
	XW033N7 - Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	4	11.3	$310,561	1
	XW043C7 - Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7	435	16.7	$186,038	152
	XW043M7 - Introduction of brexucabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 7	43	20.3	$264,932	7
	XW043N7 -Introduction of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7	15	14.2	$182,700	5

The data show that there is a wide range in the volume of cases (4 cases versus 435 cases), average length of stay (11.3 days versus 20.3 days), and average costs ($157,950 versus $310,561) reporting the administration of CAR T-cell therapies in MS–DRG 018. This is to be expected since these therapies continue to evolve and the ICD–10–PCS coding to identify and describe these therapies also continues to be refined through the ICD–10 Coordination and Maintenance Committee meeting process. As additional claims data becomes available for these therapies, we will continue to evaluate to determine if further modifications to Pre-MDC MS–DRG 018 are warranted.

In response to our statement in the FY 2022 IPPS/LTCH PPS final rule that we plan to continue engaging with stakeholders on additional options for consideration in this field of cellular and gene therapies, we received additional feedback and suggestions, including recommendations for Town Hall meetings/listening sessions to discuss the interconnectedness of these issues; exploration of what was described as a different set and kind of MS–DRGs that would reward providers for controlling patient care costs, without consideration of product costs outside of their control; and evaluation of the creation and assignment of multiple MS–DRGs for cell and gene therapy cases: One to cover patient care costs, the other to cover product costs across therapeutic product categories.

We appreciate this additional feedback and will continue to consider these issues and suggestions in connection with future rulemaking. We also intend to continue engaging with stakeholders by sharing updates from our analysis of claims data as we examine and explore potential refinements for these therapies under the IPPS.

a. Laser Interstitial Thermal Therapy (LITT)

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44812 through 44814), we finalized the reassignment of 31 ICD–10–PCS procedure codes describing laser interstitial thermal therapy (LITT) of various body parts to more clinically appropriate MS–DRGs, as shown in Table 6P.2b associated with the FY 2022 IPPS/LTCH PPS final rule and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS,* including the reassignment of procedure codes D0Y0KZZ (Laser interstitial thermal therapy of brain) and D0Y1KZZ (Laser interstitial thermal therapy of brain stem), which were reassigned from MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator), MS–DRG 024 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC), and MS–DRGs 025, 026, and 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 040, 041, and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC and without CC/MCC, respectively).

We also finalized the redesignation of these two LITT procedures (codes D0Y0KZZ and D0Y1KZZ) and the reassignment from extensive O.R. procedures in MS–DRGs 981, 982 and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to non-extensive O.R procedures in MS–DRGs 987, 989, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) (86 FR 44889).

For FY 2023, we received two requests from the manufacturers of the LITT technology (Medtronic and Monteris® Medical) to reverse the MS–DRG reassignment for the ICD–10 procedure codes that identify LITT of the brain and brain stem (codes D0Y0KZZ and D0Y1KZZ) from the MS–DRGs for peripheral, cranial nerve and other nervous system procedures (MS–DRGs 040, 041, and 042) back to the MS–DRGs for craniotomy and endovascular procedures (MS–DRGs 023, 024, 025, 026, and 027). The first

requestor acknowledged that the technique utilized in the performance of LITT procedures for the brain and brain stem are minimally invasive and do not involve a craniotomy however, the requestor also stated the procedures assigned to MS–DRGs 025, 026, and 027 are not exclusive to craniotomies. The requestor further stated that these LITT procedures involve a twist drill or burr hole and are similar to other non-craniotomy procedures in MS–DRGs 025, 026, and 027 including radioactive elements and neurostimulator leads that involve inserting these devices into the brain.

In its review of the other procedures assigned to MS–DRGs 040, 041, and 042, the requestor stated that there are distinct clinical differences between the invasiveness of LITT that involves instrumentation being placed deeply within the brain tissue and the non-invasiveness of stereotactic radiosurgery that does not involve entering the brain with instrumentation. The requestor also indicated LITT utilizes a different modality via direct thermal ablation compared to stereotactic radiosurgery that utilizes externally-generated ionizing radiation.

The requestor performed its own data analysis for LITT procedures of the brain and brain stem using MedPAR data from FY 2019 through FY 2022 impact files. According to the requestor, its findings demonstrate that the costs of the cases reporting LITT of the brain or brain stem are better aligned with MS–DRGs 025, 026, and 027 compared to MS–DRGs 040, 041, and 042.

The second requestor similarly discussed the steps and resources involved in the performance of LITT procedures for the brain and brain stem, provided its detailed analysis on the indications for LITT (brain tumors and epileptic foci), compared LITT to other procedures in MS–DRGs 025, 026, and 027 and stated that the majority of the procedures currently assigned to MS–DRGs 040, 041, 042 are not performed for the treatment of brain cancer or epilepsy. The requestor stated that the LITT procedure is on the inpatient only list and is only performed on Medicare beneficiaries in the inpatient hospital setting. The requestor provided the top 10 principal diagnoses associated with LITT of brain cases it found based on its analysis, and identified the diagnoses for which there were less than 10 cases with an asterisk, as reflected in the following table.

ICD-10-CM Code	Description	Cases
C79.31	Secondary malignant neoplasm of brain	39
G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus	17
C71.9	Malignant neoplasm of brain, unspecified	13
C71.1	Malignant neoplasm of frontal lobe	*
C71.2	Malignant neoplasm of temporal lobe	*
G40.419	Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus	*
I67.89	Other cerebrovascular disease	*
G40.919	Epilepsy, unspecified, intractable, without status epilepticus	*
G40.804	Other epilepsy, intractable, without status epilepticus	*
C71.3	Malignant neoplasm of parietal lobe	*

The requestor asserted that the statement in the FY 2022 IPPS/LTCH PPS final rule that the technique to perform the LITT procedure on brain and brain stem structures is considered minimally invasive and does not involve a craniotomy, and that therefore, continued assignment to the craniotomy MS–DRGs is not clinically appropriate, mischaracterizes both the LITT procedures and universe of services assigned to MS–DRGs 023 through 027. The requestor acknowledged that the craniotomy procedures listed in the logic for MS–DRGs 023 through 027 include open procedures but stated the logic also lists less invasive procedures including percutaneous and percutaneous endoscopic procedures. The requestor asserted that open procedures are a minority of the ICD–10–PCS codes assigned to these MS–DRGs.

In addition, the requestor stated that LITT and craniotomy are in fact very clinically similar; in that both procedures are intended to remove and destroy the targeted tumor and lesion with a different surgical tool used (scalpel versus heated ablation probe). According to the requestor, brain LITT procedures involve insertion of laser probes into the brain which requires opening both the skull and dura, similar to a craniotomy. The requestor also stated that craniotomy and LITT share several procedural characteristics and provided the following list.

- Require an operating room;
- Performed under general anesthesia;
- Require creation of burr holes and invasive skull fixation;
- Require a sterile field, incision, opening of the skull and dura;
- Cause tissue to be immediately destroyed or excised;
- Carry a risk of immediate intracranial bleeding;
- Require closure of the scalp wound;
- Risk intracranial infection; and
- Require a hospital stay of one or more nights.

In contrast, the requestor stated that procedures assigned to MS–DRGs 040, 041, and 042 are primarily nerve procedures or excision or detachment procedures performed on parts of the body other than the head, including the upper and lower extremities. According to the requestor, none of the procedures in MS–DRGs 040, 041, and 042 require drilling into the patient's skull, a step which is integral to LITT. The requestor provided the following top 10 principal

diagnoses associated with cases it found in MS–DRGs 040, 041, and 042 during its analysis and stated that most of the procedures assigned to MS–DRGs 040, 041, and 042 are not typically performed in the treatment of brain cancer or epilepsy.

ICD-10-CM Code	Description	Cases
I63.9	Cerebral infarction, unspecified	1,928
I63.40	Cerebral infarction due to embolism of unspecified cerebral artery	610
I63.89	Other cerebral infarction	489
G45.9	Transient cerebral ischemic attack, unspecified	456
I63.412	Cerebral infarction due to embolism of left middle cerebral artery	378
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy	371
I63.411	Cerebral infarction due to embolism of right middle cerebral artery	341
I63.512	Cerebral infarction due to unspecified occlusion or stenosis of left middle cerebral artery	335
C79.31	Secondary malignant neoplasm of brain	326
I63.81	Other cerebral infarction due to occlusion or stenosis of small artery	271

However, the requestor stated an exception is stereotactic radiosurgery (SRS) procedures performed on the brain and brain stem that are assigned to MS–DRGs 040, 041, and 042 and are used to treat brain cancer. According to the requestor, craniotomy, LITT and SRS are all image-guided procedures used to treat a variety of brain disorders including tumors and epilepsy, although it stated that is where any similarity between LITT and SRS ends and where the procedural similarities between craniotomy and LITT begin.

The requestor stated SRS is a non-invasive procedure that gradually destroys or inactivates tissues in or around the brain and is typically performed on an outpatient basis while inpatient SRS treatment is rare. According to the requestor, SRS does not require an operating room, is rarely done under general anesthesia (children and highly claustrophobic individuals being an exception), and does not require (but can use) rigid skull fixation. In addition, the requestor stated that because it is non-invasive, there is no need for a sterile field, incision, opening/closing of the skull, opening/closing of the dura, suturing/stapling the wound, and produces essentially no risk of immediate intracranial bleeding or delayed infection. According to the requestor, LITT is much more invasive than SRS using a head frame and involves and requires the same surgical skill and hospital resources as craniotomies.

Following the submission of the two FY 2023 MS–DRG classification change requests for LITT, these same two requestors (the manufacturers of the LITT technology) submitted a joint code proposal requesting an overall change to how LITT is classified within the ICD–10–PCS classification and for consideration as an agenda topic to be discussed at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting. The proposal was presented and discussed at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting. We refer the reader to the CMS website at *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials* for additional detailed information regarding the request, including a recording of the discussion and the related meeting materials. Public comments in response to the code proposal were due by April 8, 2022.

Because the diagnosis and procedure code proposals that are presented at the March ICD–10–CM Coordination and Maintenance Committee meeting for an October 1 implementation (upcoming FY) are not finalized in time to include in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes in association with the proposed rule, as we have noted in prior rulemaking and discuss further in this section, we use our established process to examine the MS–DRG assignment for the predecessor codes to determine the most appropriate MS–DRG assignment. Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We have noted in prior rulemaking that this process does not automatically result in the new procedure code being assigned to the same MS–DRG or to have the same designation (O.R. versus Non-O.R.) as the predecessor code. Under this established process, the MS–DRG assignment for the upcoming fiscal year for any new diagnosis or procedure codes finalized after the March meeting would be reflected in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes associated with the final rule for that fiscal year. However, in light of the unique circumstances relating to these procedures, for which there is a pending proposal to reclassify LITT within ICD–10–PCS and for new procedure codes discussed at the March meeting, as well as an MS–DRG reclassification request to reassign the existing codes describing these procedures, we address in this section first, the code proposal discussed at the March meeting and the possible MS–DRG assignments for any new codes that may be approved, and then secondly, the requested reassignment of the existing codes, in the event the new codes are not approved.

To summarize, as discussed at the March meeting, the code proposal is to reclassify LITT procedures from the Radiation Therapy section of ICD–10–PCS (Section D) to the Medical and Surgical section of ICD–10–PCS. Specifically, the proposal is to reclassify LITT procedures to the root operation Destruction. In ICD–10–PCS, the root operation Destruction is defined as physical eradication of all or a portion

of a body part by the direct use of energy, force, or a destructive agent. According to the requestors, LITT is misclassified to section D—Radiation Therapy in ICD–10–PCS possibly because of terminology that was used for predicate devices, whose indications included the phrase ''interstitial irradiation or thermal therapy'' in describing LITT's method of action. The requestors stated LITT is thermal therapy, destroying soft tissue using heat generated by a laser probe at the target site and that the LITT procedure does not use ionizing radiation, which is what the term ''radiation'' commonly refers to in the general medical sense. The requestors also stated that by itself, radiation is a broad term and provided an example that the spectrum of electromagnetic radiation technically encompasses low energy non-ionizing radio waves, microwaves, and infrared to high energy ionizing X-rays and gamma rays while ionizing radiation creates ions in the cells it passes through by removing electrons, a process which kills or alters the cells over time.

The requestors further stated that only certain medical uses of radiation are classified to section D—Radiation Therapy. For instance, section D—Radiation Therapy categorizes treatments using ionizing radiation, including beam radiation, brachytherapy, and stereotactic radiosurgery. All of these deliver concentrated ionizing radiation to eradicate abnormal cells, most commonly neoplasms. Other treatments classified to section D—Radiation Therapy, such as hyperthermia, are used as adjuncts to ionizing radiation. The requestors asserted that while LITT eradicates abnormal cells, it does so with heat, not ionizing radiation and rather than a radiation therapy procedure, LITT is a surgical procedure. According to the requestors, LITT would be more appropriately classified as an ablation procedure with the root operation Destruction.

The original request for a new code(s) to describe the LITT technology was initially discussed at the September 24–25, 2008 ICD–9–CM Coordination and Maintenance Committee meeting. At that time, the requestor sought an April 1, 2009 implementation date. Public comments opposed an April 1, 2009 implementation date, therefore, effective October 1, 2009 (FY 2010), ICD–9–CM procedure codes were created to identify procedures performed utilizing the LITT technology. The following table lists the ICD–9–CM procedure codes describing LITT and their respective MDC and MS–DRG assignments under the ICD–9 based MS–DRGs. We refer the reader to the ICD–9 and ICD–10 MS–DRG Definitions Manual Files V33 (available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download-Items/FY2016-Final-Rule-Correction-Notice-Files* (in the Downloads section) for complete documentation of the GROUPER logic for ICD–9.

ICD-9-CM Procedure Code	Description	MDC	MS-DRG
17.61	Laser interstitial thermal therapy [LITT] of lesion or tissue of brain under guidance	MDC 01	023-027
17.62	Laser interstitial thermal therapy [LITT] of lesion or tissue of head or neck under guidance	MDC 10	625-627
		MDC 17	820-822
		MDC 17	826-828
17.63	Laser interstitial thermal therapy [LITT] of lesion or tissue of liver under guidance	MDC 06	356-358
		MDC 07	405-407
17.69	Laser interstitial thermal therapy [LITT] of lesion or tissue of other and unspecified site under guidance	MDC 04	163-165
		MDC 09	584-585
		MDC 12	715-718
		MDC 17	820-822
		MDC 17	826-828

The requestors maintain that although LITT was used to treat a variety of anatomic sites when it was first introduced, its current primary use is intracranial, specifically to treat brain tumors and epileptic foci. However, the requestors stated it is also used to treat radiation necrosis, an inflammatory response from prior treatment with ionizing radiation.

Currently, in the U.S. there are only two LITT systems in use, Visualase™ MRI-Guided Laser Ablation (Medtronic) and the Neuroblate® System (Monteris® Medical). The requestors also stated that over the last six years, the Indications for Use (IFU) for one of the two U.S. approved LITT technologies (Neuroblate®) has been updated to reflect the system's current use in the brain and to align with the intended neurosurgical patient population. The requestor indicated applications in the spine are also anticipated in the future within the central nervous system.

As previously noted, the deadline for receipt of public comments for the proposed reclassification of LITT procedures that was presented at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting along with the corresponding proposal for new procedure codes was April 8, 2022, and the final code decisions on these proposals are not yet available for inclusion in Table 6B.—New Procedure Codes associated with this FY 2023 IPPS/LTCH PPS proposed rule. However, as discussed in prior rulemaking (86 FR 44805), codes that are finalized after the March meeting are reviewed and subject to our established process of initially reviewing the predecessor codes MS–DRG assignment and designation, while considering

other relevant factors (for example, severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition) as previously described. The codes that are finalized after the March meeting are specifically identified with a footnote in Tables 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes that are made publicly available in association with the final rule via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.* The public may provide feedback on these finalized assignments, which is then taken into consideration for the following fiscal year.

Accordingly, as previously discussed, the MS–DRG assignment for any new procedure codes describing LITT, if finalized following the March meeting, would be reflected in Table 6B.—New Procedure Codes associated with the final rule for FY 2023. However, in light of the unique circumstances with respect to these procedures, for which there is both a proposal for reclassifying LITT from the Radiation Therapy section of the procedure code classification to the Medical/Surgical section with new ICD–10–PCS procedure code(s) and a separate MS–DRG reclassification request on the existing procedure codes, we are providing the opportunity for public comment on possible MS–DRG assignments for the requested new procedure codes describing LITT that may apply based on the application of our established process and analysis, in the event the new codes are finalized for FY 2023. We note that while we discuss the potential MS–DRG assignments for new procedure codes describing LITT, stakeholders may use current coding information to consider the potential MS–DRG assignments for any other procedure codes that may be finalized after the March meeting and submit public comments for consideration. Specifically, in the ICD–10 Coordination and Maintenance Committee meeting materials (available via the internet on the CMS website at *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials*), for each procedure code proposal we provide the current coding that is applicable within the classification and that should be reported in the absence of a more unique code, or until such time a new code is created and becomes effective. The procedure code(s) listed in current coding are generally, but not always, the same code(s) that are considered as the predecessor code(s) for purposes of MS–DRG assignment. As previously noted, our process for determining the MS–DRG assignment for a new procedure code does not automatically result in the new procedure code being assigned to the same MS–DRG or having the same designation (O.R. versus Non-O.R.) as the predecessor code. However, this current coding information can be used in conjunction with the GROUPER logic, as set forth in the ICD–10 MS–DRG Definitions Manual and publicly available via the internet on our CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* to review the MS–DRG assignment of the current code(s) and examine the potential MS–DRG assignment of the proposed code(s), to assist in formulating any public comments for submission to CMS for consideration.

We note that, unlike the typical code request for a new or revised procedure code that involves a new technology or a new approach to performing an existing procedure, the circumstances for this particular request are distinct in that the code request would reclassify LITT within the ICD–10–PCS classification from section D—Radiation Therapy to the root operation Destruction in the Medical and Surgical section of ICD–10–PCS. Therefore, in light of the unique considerations with respect to the requested reclassification of the LITT procedures in connection with the pending code proposal, we believe it is appropriate to utilize the assignments and designations of the procedure codes describing Destruction of the respective anatomic body site as predecessor codes rather than the current codes describing LITT from the Radiation Therapy section of ICD–10–PCS in considering potential MS–DRG assignment for the requested new LITT procedure codes.

As previously discussed, under our established process for determining the MS–DRG assignment for newly approved procedure codes, we examine the MS–DRG assignment for the predecessor codes to determine the most appropriate MS–DRG assignment for the new codes. Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. As we have noted in prior rulemaking, this process does not automatically result in the new procedure code being assigned to the same MS–DRG or to have the same designation (O.R. versus Non-O.R.) as the predecessor code.

Applying this established review process to the proposed codes for the LITT procedures, we believe that, based on the predecessor codes, and as previously noted, the potential assignments and designations would align with the assignments and designations of the procedure codes describing Destruction of the respective anatomic body site. For example, as discussed earlier in this section of this proposed rule, the code request involved reclassifying LITT procedures from section D—Radiation Therapy to the root operation Destruction in the Medical and Surgical section of ICD–10–PCS. The root operation Destruction is appropriate to identify and report procedures, such as ablation, that are performed on various body parts. The code request also involved creating what is referred to as a qualifier value, to uniquely describe LITT as the modality. The qualifier value is the seventh character or digit, in a valid ICD–10–PCS procedure code.

The following ICD–10–PCS table illustrates an example of the proposed procedure codes for LITT of the brain and brain stem, and cervical, thoracic, and lumbar spinal cord body parts, including the qualifier value that was presented and discussed at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting.

Section	**0** Medical and Surgical
Body System	**0** Central Nervous System and Cranial Nerves
Operation	**5** Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent

Body Part	Approach	Device	Qualifier
0 Brain **W** Cervical Spinal Cord **X** Thoracic Spinal Cord **Y** Lumbar Spinal Cord	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**ADD 3** Laser Interstitial Thermal Therapy **Z** No Qualifier

We note that the code proposal presented only provided the body part value 0 Brain, for reporting any LITT procedures performed on the brain, as well as, the brain stem, consistent with the current available body part option in Table 005, Destruction of Central Nervous System and Cranial Nerves, where the predecessor code is located. The predecessor code(s) and associated MS–DRG assignments for the proposed new procedure code(s) describing LITT of the brain and spinal cord under MDC 01 are identified as follows.

ICD-10-PCS Code	Description	MS-DRG
00500ZZ	Destruction of brain, open approach	023-027
00503ZZ	Destruction of brain, percutaneous approach	
00504ZZ	Destruction of brain, percutaneous endoscopic approach	
005W0ZZ	Destruction of cervical spinal cord, open approach	028-030
005W3ZZ	Destruction of cervical spinal cord, percutaneous approach	
005W4ZZ	Destruction of cervical spinal cord, percutaneous endoscopic approach	
005X0ZZ	Destruction of thoracic spinal cord, open approach	
005X3ZZ	Destruction of thoracic spinal cord, percutaneous approach	
005X4ZZ	Destruction of thoracic spinal cord, percutaneous endoscopic approach	
005Y0ZZ	Destruction of lumbar spinal cord, open approach	
005Y3ZZ	Destruction of lumbar spinal cord, percutaneous approach	
005Y4ZZ	Destruction of lumbar spinal cord, percutaneous endoscopic approach	

As shown in the table, the procedure codes describing destruction of brain with an open, percutaneous or percutaneous endoscopic approach are assigned to MS–DRGs 023 through 027 (craniotomy and endovascular procedures) and the procedure codes describing destruction of cervical, thoracic or lumbar spinal cord with an open, percutaneous or percutaneous endoscopic approach are assigned to MS–DRG 028 (Spinal Procedures with MCC), MS–DRG 029 (Spinal Procedures with CC or Spinal Neurostimulators), and MS–DRG 030 (Spinal Procedures without CC/MCC).

We refer the reader to Table 6P.2a associated with this proposed rule (and available via the internet at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*) to review the potential MDCs, MS–DRGs, and O.R. versus Non-O.R. designations identified based on this analysis of the proposed new procedure codes describing LITT as presented and discussed at the meeting. We note that Table 6P.2a also includes the predecessor codes that we utilized to inform this analysis. If finalized, the new procedure codes would be included in the FY 2023 code update files that are made available in late May/early June via the internet on the CMS website at *https://www.cms.gov/medicare/coding/icd10.* Additionally, if finalized, the new procedure codes describing LITT would be displayed in Table 6B.—New Procedure Codes, and the existing codes describing LITT would be deleted and reflected in Table 6D.—Invalid Procedure Codes, in association with the FY 2023 IPPS/LTCH PPS final rule. We refer the reader to section II.D.14. for further information regarding the files.

As previously discussed, we also received requests to reassign the existing ICD–10 procedure codes that identify LITT of the brain and brain stem (codes D0Y0KZZ and D0Y1KZZ). In the event there is not support for the proposed reclassification of LITT procedures and the corresponding new procedure codes as presented at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting, we are also providing the results of our analysis of these existing codes and our proposed MS–DRG assignments for FY 2023, if those existing codes are retained.

We examined claims data from the September 2021 update of the FY 2021 MedPAR file for MS–DRGs 023, 024, 025, 026, and 027, in addition to MS–DRGs 040, 041, and 042 for cases reporting LITT of the brain (code D0Y0KZZ) or brain stem (code D0Y1KZZ). We note that if a procedure code is not listed it is because there were no cases found reporting that procedure code. Our findings are shown in the following tables.

MS-DRG	ICD-10-PCS Code	Number of Cases	Average Length of Stay	Average Costs
23	All Cases	11,599	10.1	$45,134
	D0Y0KZZ	1	15	$60,994
	All other cases	11,598	10.1	$45,133
24	All Cases	4,391	5.2	$31,759
25	All Cases	19,586	9	$35,956
	D0Y0KZZ	77	5.6	$27,148
	All other cases	19,509	9	$35,991
26	All Cases	6,956	5.1	$24,566
	D0Y0KZZ	25	2.6	$24,741
	All other cases	6,931	5.1	$24,565
27	All Cases	7,323	2.4	$20,498
	D0Y0KZZ	20	2.1	$34,874
	All other cases	7,303	2.4	$20,459

MS-DRG	ICD-10-PCS Code	Number of Cases	Average Length of Stay	Average Costs
40	All Cases	3,547	9.9	$30,212
	D0Y0KZZ	14	8.1	$40,458
	All other cases	3,533	9.9	$30,171
41	All Cases	4,958	5	$19,090
	D0Y0KZZ	16	3.4	$23,278
	D0Y1KZZ	1	1	$10,222
	All other cases	4,942	5	$19,076
42	All Cases	1,667	2.9	$15,451
	D0Y0KZZ	24	1.7	$22,426
	D0Y1KZZ	1	2	$32,668
	All other cases	1,642	2.9	$15,325

As shown, we found a total of 123 cases reporting LITT of the brain across MS–DRGs 023, 025, 026, and 027. There were no cases found in MS–DRG 024. The cases reporting LITT of the brain grouped to these MS–DRGs because another O.R. procedure that is assigned to the respective MS–DRG was also reported. We refer the reader to Table 6P.2b for the list of the other O.R. procedures we identified that were also reported with LITT of the brain.

For MS–DRGs 040, 041, and 042, we found a total of 54 cases reporting LITT of the brain and 2 cases reporting LITT of the brain stem. While the average costs of the cases reporting LITT of the brain were higher compared to all the cases in their respective MS–DRGs, the average length of stay was shorter. For example, the data demonstrates a shorter average length of stay (8.1 days versus 9.9 days) and higher average costs ($40,458 versus $30,212) for the 14 cases reporting LITT of brain in MS–DRG 040 compared to all the cases in MS–DRG 040. There were no cases found to report LITT of brain stem in MS–DRG 040. For MS–DRG 041, we found 16 cases reporting LITT of brain with an average length of stay of 3.4 days and average costs of $23,278 and 1 case reporting LITT of brain stem with an average length of stay of 1 day and average costs of $10,222. The average length of stay for all the cases in MS–DRG 041 is 5 days with average costs of $19,090. The data demonstrates a shorter average length of stay (3.4 days and 1 day, respectively, versus 5 days) for the 16 cases reporting LITT of brain and the 1 case reporting LITT of brain stem. The data also demonstrates higher average costs ($23,278 versus $19,090) for the 16 cases reporting LITT of brain, and lower average costs for the 1 case reporting LITT of brain stem ($10,222 versus $19,090), as compared to the average costs of all cases in MS–DRG 041. For MS–DRG 042, we found 24 cases reporting LITT of brain with an average length of stay of 1.7 days and average costs of $22,426 and 1 case reporting LITT of brain stem with an average length of stay of 2 days and average costs of $32,668. The average length of stay for all the cases in MS–DRG 042 is 2.9 days with average costs of $15,451. The data demonstrates a shorter average length of stay (1.7 days

and 2 days, respectively, versus 2.9 days) for the 24 cases reporting LITT of brain and the 1 case reporting LITT of brain stem. The data also demonstrate higher average costs ($22,426 and $32,668, respectively versus $15,451) for the 24 cases reporting LITT of brain and the 1 case reporting LITT of brain stem, compared to all the cases in MS–DRG 042.

Based on the findings from our analysis, we considered whether other factors, such as the reporting of secondary MCC and CC diagnoses, may have contributed to the higher average costs for these cases. Specifically, we conducted additional analyses of the claims data from the September 2021 update of the FY 2021 MedPAR file to determine what secondary MCC diagnoses were also reported for the 14 cases reporting LITT of brain in MS–DRG 040 and what secondary CC diagnoses were reported for the 17 cases (16 for LITT of brain and 1 for LITT of brain stem) in MS–DRG 041. Our findings are shown in the following tables.

Secondary MCC Diagnoses Reported with LITT of Brain in MS-DRG 040				
ICD-10-CM Code as Secondary Diagnosis	**Description**	**Frequency of Diagnosis**	**Average Length of Stay**	**Average Costs**
D61.810	Antineoplastic chemotherapy induced pancytopenia	1	9	$59,102
G93.5	Compression of brain	6	12.2	$56,313
G93.6	Cerebral edema	11	9.3	$43,788
I61.1	Nontraumatic intracerebral hemorrhage in hemisphere, cortical	1	48	$80,745
J69.0	Pneumonitis due to inhalation of food and vomit	2	28	$60,889
J96.01	Acute respiratory failure with hypoxia	3	17	$41,486

Secondary CC Diagnoses Reported with LITT of Brain and Brain Stem in MS-DRG 041				
ICD-10-CM Code as Secondary Diagnosis	**Description**	**Frequency of Diagnosis**	**Average Length of Stay**	**Average Costs**
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung	1	1	$9,755
C79.51	Secondary malignant neoplasm of bone	1	29	$22,347
D61.818	Other pancytopenia	1	1	$29,883
D62	Acute posthemorrhagic anemia	1	2	$9,101
E22.2	Syndrome of inappropriate secretion of antidiuretic hormone	1	2	$17,940
E44.0	Moderate protein-calorie malnutrition	1	1	$29,883
F33.0	Major depressive disorder, recurrent, mild	1	8	$57,999
F33.1	Major depressive disorder, recurrent, moderate	1	1	$20,461
F84.0	Autistic disorder	1	1	$12,450
G40.89	Other seizures	1	1	$12,109
G40.919	Epilepsy, unspecified, intractable, without status epilepticus	1	1	$34,287
G81.91	Hemiplegia, unspecified affecting right dominant side	1	2	$17,940
G81.94	Hemiplegia, unspecified affecting left nondominant side	1	8	$57,999
G96.01	Cranial cerebrospinal fluid leak, spontaneous	1	1	$25,514
H47.10	Unspecified papilledema	1	29	$22,347
I16.1	Hypertensive emergency	1	1	$30,372
I42.8	Other cardiomyopathies	1	1	$55,389
I48.21	Permanent atrial fibrillation	1	1	$29,883
I50.22	Chronic systolic (congestive) heart failure	1	1	$55,389
I50.32	Chronic diastolic (congestive) heart failure	1	1	$29,883
I69.354	Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side	1	1	$12,109
N39.0	Urinary tract infection, site not specified	2	15.5	$16,866
Q01.9	Encephalocele, unspecified	1	2	$9,101
Q04.8	Other specified congenital malformations of brain	2	1	$13,925
R47.01	Aphasia	3	3.3	$28,841
Z68.42	Body mass index [BMI] 45.0-49.9, adult	1	1	$10,222
Z94.0	Kidney transplant status	1	1	$25,514

We note that we did not find any other O.R. procedures reported on the claims in addition to the procedures for LITT of brain or brain stem for MS–DRGs 040, 041 and 042.

The data shows that at least one of the listed secondary MCC diagnoses was reported with each claim for LITT of brain identified in MS–DRG 040 and the average length of stay for these cases ranged from 9 days to 48 days and the average costs of these cases ranged from $41,486 to $80,745. We note that this data reflects the frequency with which each of the listed diagnoses was reported on a claim with LITT of brain. Therefore, multiple MCCs from this list of diagnoses may have been reported on a single claim. In addition, while the logic for case assignment to MS–DRG 040 requires at least one secondary MCC diagnosis, we conducted additional detailed analyses for MS–DRG 040, as shown in Table 6P.2f, to determine whether there were also secondary CC diagnoses reported in conjunction with one or more of the listed MCC diagnoses that may be contributing to the higher average costs for cases reporting LITT of brain in MS–DRG 040 in comparison to all the cases in MS–DRG 040. We found that 6 of the 14 cases reporting at least one or more secondary MCC diagnosis also reported one or more secondary CC diagnosis, which would appear to support that the severity of illness for these patients, as identified by the secondary MCC and CC diagnoses, may be more directly related to the higher average costs for these patients than the LITT procedure itself.

Similarly, the data for MS–DRG 041 show the frequency with which each of the listed secondary CC diagnoses was reported with LITT of brain or brain stem. Results from the analysis for the 17 cases (16 for LITT of brain and 1 for LITT of brain stem) show the average length of stay for these cases ranged from 1 day to 29 days and the average costs ranged from $9,101 to $57,999. These data analysis findings for MS–DRG 041 also appear to support our belief that the severity of illness for these patients, as identified by the listed secondary CC diagnoses, may be more directly related to the higher average costs for these patients than the LITT procedure itself.

As stated previously, we did not find any other O.R. procedures reported on the claims in addition to the procedures for LITT of brain or brain stem for MS–DRGs 040, 041 and 042. Since the logic for case assignment to MS–DRG 042 is not based on the reporting requirement of any CC or MCC diagnoses, we conducted a detailed analysis of the claims data to determine what other factors may be contributing to the higher average costs and shorter average length of stay for these cases in comparison to all the cases in MS–DRG 042. We refer the reader to Table 6P.2g associated with this proposed rule for the findings from our analysis. As shown in the data, the majority of the cases (15 of 25) had a principal diagnosis of epilepsy, 8 cases had a principal diagnosis related to malignant neoplasm of the brain or brain structures, 1 case had a principal diagnosis of hemangioma of intracranial structures and 1 case had a principal diagnosis of unspecified convulsions. The data also demonstrate that 16 of the 25 cases reported in MS–DRG 042 include patients who were under the age of 65, with ages ranging from 32 years old to 64 years old. We note that patients diagnosed with epilepsy are eligible for coverage since it is a condition that qualifies under certain criteria. It is not entirely clear if the age of these patients had any impact on the average length of stay since the average length of stay of the 24 cases reporting LITT of brain was 1.7 days and the 1 case reporting LITT of brain stem was 2 days.

As stated previously, the logic for case assignment to MS–DRG 042 is not dependent on the reporting of any CC or MCC diagnoses, however, based on the diagnoses reflected in the claims data for MS–DRG 042, it is possible that conditions such as obesity and chronic conditions requiring the long-term use of certain therapeutic agents may be contributing factors to the consumption of resources, separately from the LITT procedure. We found 17 of the 25 cases reporting LITT of brain or brain stem to also report one or both of these conditions.

We also reviewed the number of cases of LITT of the brain or brain stem procedures reported in the data since the transition to ICD–10. Specifically, we examined the claims data for cases reporting LITT of brain or brain stem as a standalone procedure or with another procedure in the FY 2016 through FY 2021 MedPAR data files across all MS–DRGs. The findings from our analysis are shown in table 6P.2e associated with this proposed rule.

The data demonstrates that since the implementation of ICD–10, a shift in the reporting of LITT of brain and brain stem procedures has occurred. For example, the FY 2016, FY 2017 and FY 2018 MedPAR data reflect that the number of cases for which LITT of brain or brain stem procedures were reported as a standalone procedure is higher in comparison to the number of cases reported with another procedure. Conversely, the FY 2019, FY 2020, and FY 2021 MedPAR data reflect that the number of cases for which LITT of brain or brain stem procedures were reported as a standalone procedure is lower in comparison to the number of cases reported with another procedure. The data also reflect that the average length of stay is shorter and the average costs are lower for cases reporting LITT of brain or brain stem as a standalone procedure in comparison to the average length of stay and average costs for cases reported with another procedure across the FY 2016 through FY 2021 MedPAR data files. Lastly, the data demonstrate that overall, the number of cases for which LITT of brain or brain stem procedures was performed had remained fairly stable at over 100 cases with increases in the FY 2017, FY 2020 and FY 2021 MedPAR data files of 156, 154 and 185 cases, respectively.

We also analyzed claims data from the September 2021 update of the FY 2021 MedPAR file for cases reporting LITT of other anatomic sites across all MS–DRGs. Although the requestors indicated that LITT is primarily performed on intracranial lesions, as shown in Table 6P.2c associated with this proposed rule, we identified a small number of cases reporting LITT of the lung, rectum, liver, breast, and prostate, for a total of 29 cases where LITT was performed on other body parts/anatomic sites.

For example, we found a total of 5 cases reporting LITT of lung across 5 different MS–DRGs. Of these 5 cases, 2 cases had a longer average length of stay and higher average costs in comparison to all the cases in their respective MS–DRG. Specifically, for MS–DRG 163 (Major Chest Procedures with MCC), we found 1 case reporting LITT of lung with an average length of stay of 17 days and average costs of $41,467. The average length of stay for all cases in MS–DRG 163 is 10.7 days with average costs of $38,367. The data demonstrates a difference of 6.3 days (17 − 10.7=6.3) for the average length of stay and a difference of $3,100 in average costs ($41,467 − $38,367=$3,100) for the 1 case reporting LITT of lung in MS–DRG 163 compared to all the cases in MS–DRG 163. For MS–DRG 167 (Other Respiratory System O.R. Procedures with CC), we found 1 case reporting LITT of lung with an average length of stay of 7 days and average costs of $22,975. The average length of stay for all cases in MS–DRG 167 is 4.6 days with average costs of $15,397. The data demonstrates a difference of 2.4 days (7 − 4.6=2.4) for the average length of stay and a difference of $7,578 in average costs ($22,975 − $15,397=$7,578) for the 1

case reporting LITT of lung in MS–DRG 167 compared to all the cases in MS–DRG 167. The data for the remaining 3 cases reporting LITT of lung demonstrated a shorter average length of stay and lower average costs in comparison to all the cases in their respective MS–DRGs.

We found 1 case reporting LITT of rectum in MS–DRG 357 (Other Digestive System O.R. Procedures with CC) with a shorter average length of stay (4 days versus 5.6 days) and lower average costs ($3,069 versus $18,065) as compared to all the cases in MS–DRG 357. We also found 1 case reporting LITT of liver in MS–DRG 405 (Pancreas Liver and Shunt Procedures with MCC) with a longer average length of stay (20 days versus 12.3 days) and higher average costs ($49,0695 versus $43,771) as compared to all the cases in MS–DRG 405.We also found 1 case reporting LITT of right breast in MS–DRG 580 (Other Skin Subcutaneous Tissue and Breast Procedures with CC) with a longer average length of stay (19 days versus 5.4 days) and higher average costs ($32,064 versus $13,767) as compared to all the cases in MS–DRG 580.

Lastly, we found 21 cases reporting LITT of prostate across 14 MS–DRGs. Of those 21 cases, 6 cases had a longer average length of stay or higher average costs, or both, in comparison to the average length of stay and average costs of all the cases in their respective MS–DRG. For example, in MS–DRG 650 (Kidney Transplant with Hemodialysis with MCC) we found 1 case reporting LITT of prostate with an average length of stay of 36 days and average costs of $67,238. The average length of stay for all cases in MS–DRG 650 is 8.1 days with average costs of $38,139. The data demonstrates a difference of 27.9 days (36 − 8.1=27.9) for the average length of stay and a difference of $29,099 in average costs ($67,238 − $38,139= $29,099) for the 1 case reporting LITT of prostate in MS–DRG 650 compared to all the cases in MS–DRG 650. We also found 1 case reporting LITT of prostate in MS–DRG 659 (Kidney and Ureter Procedures for Non-Neoplasm with MCC) with an average length of stay of 26 days. The average length of stay for all cases in MS–DRG 659 is 7.8 days, demonstrating a difference of 18.2 days (26 − 7.8=18.2). We found 1 case reporting LITT of prostate in MS–DRG 712 (Testes Procedures without CC/MCC) with average costs of $15,669. The average costs for all cases in MS–DRG 712 is $10,482, demonstrating a difference of $5,187 ($15,669 − $10,482=$5,187). We found 1 case reporting LITT of prostate in MS–DRG 987 with an average length of stay of 23 days and average costs of $35,465. The average length of stay for all cases in MS–DRG 987 is 10.9 days with average costs of $26,657. The data demonstrates a difference of 12.1 days (23 − 10.9=12.1) for the average length of stay and a difference of $8,808 in average costs ($35,465 − $26,657= $8,808) for the 1 case reporting LITT of prostate in MS–DRG 987 compared to all the cases in MS–DRG 987. Lastly, we found 2 cases reporting LITT of prostate in MS–DRG 988 (Non-Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC) with average costs of $17,126. The average costs for all cases in MS–DRG 988 is $13,670, demonstrating a difference of $3,456 ($17,126 − $13,670= $3,456) for the 2 cases reporting LITT of prostate in MS–DRG 988.

We refer the reader to Table 6P.2c for the detailed findings from our analysis. We note that if the procedure code describing LITT of a specific anatomic site is not listed it is because there were no cases found.

We note that for the 10 cases previously described, for which LITT of a different anatomic site from the brain or brain stem was reported and had a longer average length of stay or higher average costs, or both, in comparison to the average length of stay and average costs of all the cases in their respective MS–DRG, that with the exception of MS–DRG 712, all the other MS–DRGs include a ''with MCC'' or ''with CC'' designation, or were reported in a surgical MS–DRG. We believe that these other factors may have contributed to the longer average length of stay and higher average costs for these cases, therefore we conducted additional analyses of the claims data to determine what diagnoses or procedures were also reported. We refer the reader to Table 6P.2d associated with this proposed rule for the findings from our detailed analysis of these 10 cases.

As shown in Table 6P.2d, the data demonstrate that a number of MCC and/or CC secondary diagnoses were reported for each of the 10 cases and that the surgical procedures that were reported in addition to the LITT procedure seem to have contributed to the longer average length of stay and higher average costs for those cases when compared to the average length of stay and average costs for all the cases in their respective MS–DRG. For example, in case number 1 there are 2 diagnoses that are designated as MCC conditions and 5 diagnoses that that are designated as CC conditions with procedure codes describing a kidney transplant, hemodialysis, and insertion of a ureteral stent that were reported along with LITT of prostate. For case number 3 there are 4 diagnoses that are designated as MCC conditions and 6 diagnoses that are designated as CC conditions with procedure codes describing bronchoscopic treatment of a bronchial tumor with and without stents, as well as the use of mechanical ventilation. Overall, the data appear to indicate that the performance of the LITT procedure was not the underlying reason for, or main driver of, the increase in resource utilization for those cases.

As noted, the requestors indicated that LITT is primarily being performed on intracranial lesions. However, as summarized, we identified a limited number of cases reporting LITT procedures for other anatomic sites. We are interested in comments regarding the use of and experience with LITT for these other anatomic sites.

Based on our analysis of the FY 2021 MedPAR claims data for cases reporting LITT of brain or brain stem (codes D0Y0KZZ and D0Y1KZZ) in MS–DRGs 040, 041, and 042, we agree with the requestors that the average costs of these cases are higher as compared to the average costs of all cases assigned to MS–DRGs 040, 041, and 042. For the reasons summarized, we also believe that other factors, including the reporting of secondary MCC and CC diagnoses, may be contributing to the higher average costs for these cases. As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44813), we examined procedure codes D0Y0KZZ and D0Y1KZZ describing LITT of brain and brain stem, respectively, and stated that the technique to perform the LITT procedure on these structures is considered minimally invasive and does not involve a craniotomy, therefore, continued assignment to the craniotomy MS–DRGs is not clinically appropriate. Our clinical advisors continue to maintain that LITT is a minimally invasive procedure, requiring only a tiny incision for purposes of a burr hole and that patients are often only kept overnight (as reflected in the detailed claims data). However, we also recognize that craniotomy and LITT share common procedural characteristics including use of an operating room, carry risk of immediate intracranial bleeding or infection, and cause tissue to be immediately destroyed or excised. While the data do not demonstrate that the LITT procedure is the underlying reason for the higher average costs and consumption of resources for the small number of cases reporting LITT of brain (54 cases) or brain stem (2 cases) that we found in MS–DRGs 040, 041, and 042,

the data do demonstrate that the patients receiving this treatment therapy have brain tumors or epilepsy combined with multiple comorbidities or chronic conditions necessitating long-term use of medications, or both, and we note the indications for LITT (brain tumors and epileptic foci) are better aligned with MS–DRGs 025, 026, and 027 as compared to MS–DRGs 040, 041, and 042.

As we discuss further in this section, we intend to more fully evaluate the logic for the procedures specifically involving a craniotomy, as well as the overall structure of MS–DRGs 023 through 027, and we believe that reassignment of cases reporting LITT of brain or brain stem to MS–DRGs 025, 026, and 027 would be an appropriate first step in connection with these efforts. For example, while we recognize the distinctions between open craniotomy procedures and minimally invasive percutaneous intracranial procedures, we also recognize that the current logic for MS–DRGs 025 through 027 also includes other endovascular intracranial procedures performed using percutaneous or percutaneous endoscopic approaches, and we believe that further review of the clinical coherence of the procedures assigned to these MS–DRGs may be warranted. Our clinical advisors note that while the typical patient treated with LITT usually has a single small scalp incision through which a hole approximately the diameter of a straw is drilled, with no extensive surgical exposure, that LITT can still be employed for another subset of more complex patients, including patients with primary brain malignancies and those with larger metastatic lesions or multiple lesions. For this subset of more complex patients, a longer post-operative stay with direct medical supervision may be necessary. As such, we believe reassigning these procedures to MS–DRGs 025 through 027 for FY 2023 would be appropriate as we consider restructuring MS–DRGs 023 through 027, including how to better align the clinical indications with the performance of specific intracranial procedures. Accordingly, for these reasons, in the event there is not support for the proposed reclassification of LITT procedures and the corresponding new procedure codes as presented at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting, we are proposing to reassign the existing procedure codes describing LITT of the brain or brain stem from MS–DRGs 040, 041, and 042 to MS–DRGs 025, 026, and 027 for FY 2023. We are also proposing to maintain the MS–DRG assignments for the existing procedure codes describing LITT of other anatomic sites as finalized and displayed in Table 6P.2b in association with the FY 2022 IPPS/LTCH PPS final rule, for FY 2023. We note that we did not receive any comments or requests to reconsider those finalized MS–DRG assignments for FY 2023.

As noted, in connection with our analysis of cases reporting LITT procedures performed on the brain or brain stem in MDC 01, we have started to examine the logic for case assignment to MS–DRGs 023 through 027 to determine where further refinements could potentially be made to better account for differences in the technical complexity and resource utilization among the procedures that are currently assigned to those MS–DRGs. Specifically, we are in the process of evaluating procedures that are performed using an open craniotomy (where it is necessary to surgically remove a portion of the skull) versus a percutaneous burr hole (where a hole approximately the size of a pencil is drilled) to obtain access to the brain in the performance of a procedure. We are also reviewing the indications for these procedures, for example, malignant neoplasms versus epilepsy to consider if there may be merit in considering restructuring the current MS–DRGs to better recognize the clinical distinctions of these patient populations in the MS–DRGs. We believe it is worthwhile to also compare the claims data for epilepsy patients who are treated with a neurostimulator implant versus a LITT procedure, as well as the claims data for patients with a diagnosis of epilepsy or malignant neoplasms who undergo a LITT procedure. Our analysis also includes reviewing the claims data with regard to the cases that reflect a procedure that is generally performed with another O.R. procedure versus a standalone procedure.

As we continue this analysis of the claims data with respect to MS–DRGs 023 through 027, we are also seeking public comments and feedback on other factors that should be considered in the potential restructuring of these MS–DRGs. As previously described, we are examining procedures by their approach (open versus percutaneous), clinical indications, and procedures that involve the insertion or implantation of a device. We recognize the logic for MS–DRGs 023 through 027 has grown more complex over the years and believe there is opportunity for further refinement. We refer the reader to the ICD–10 MS–DRG Definitions Manual, version 39.1, which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 023 through 027. Feedback and other suggestions may be submitted by October 20, 2022 and directed to the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™), discussed in section II.D.1.b of the preamble of this proposed rule at *https://mearis.cms.gov/public/home.*

b. Vagus Nerve Stimulation

We received a request to review the MS–DRG assignment for cases that identify patients who receive an implantable vagus nerve stimulation system for heart failure. The vagus nerve, also called the X cranial nerve or the 10th cranial nerve, is the longest and most complex of the cranial nerves. There is one vagus nerve on each side of the body that runs from the brain through the face and thorax to the abdomen. According to the requestor, cranial nerve stimulation (CNS), which includes vagus nerve stimulation, is a well-established therapy for various indications including epilepsy, treatment resistant depression (TRD) and obstructive sleep apnea (OSA), and is now being investigated and studied for use in patients with heart failure.

According to the requestor, heart failure, or the heart's inability to pump an adequate supply of blood and oxygen to support the other organs of the body, is an autonomic nervous system dysfunction. The brain controls the function of the heart through the sympathetic branch and the parasympathetic branches of the autonomic nervous system. In heart failure, there is an imbalance in the autonomic nervous system. The vagus nerve stimulation system for heart failure is comprised of an implantable pulse generator, an electrical lead, and a programming computer system. The pulse generator, which is usually implanted just under the skin of the pectoral region, sends the energy to the vagus nerve through the lead. The lead is a flexible insulated wire that is guided under the skin from the chest up to the neck and is implanted onto the vagus nerve and transmits tiny electrical impulses from the generator to the nerve. These electrical impulses to the vagus nerve are intended to activate the parasympathetic branch of the autonomic nervous system to restore balance.

The requestor stated that cases reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a principal diagnosis code describing epilepsy, TRD or OSA are assigned to surgical MS–DRGs 040, 041 and 042 (Peripheral Cranial Nerve and Other Nervous System Procedures with MCC, with CC or Peripheral Neurostimulator, and without CC/MCC, respectively) in MDC 01 (Diseases and Disorders of the Nervous System). However, when the same codes describing the insertion of a neurostimulator lead onto the vagus nerve and the insertion of a stimulator generator are reported with a principal diagnosis of heart failure, the cases instead are assigned to surgical MS–DRGs 252, 253 and 254 (Other Vascular Procedures with MCC, with CC, without MCC respectively) in MDC 05 (Diseases and Disorders of the Circulatory System).

The requestor stated that the treatment of autonomic nervous system dysfunction is the underlying therapeutic objective of cranial nerve stimulation for heart failure, and therefore the diagnosis of heart failure is more clinically coherent with other diagnoses in MDC 01. As a result, the requestor, who is developing the VITARIA® System, an active implantable neuromodulation system that uses vagus nerve stimulation to deliver autonomic regulation therapy (ART) for an indicated use that includes patients who have moderate to severe heart failure, submitted a request to reassign cases reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a principal diagnosis code describing heart failure, from MS–DRGs 252, 253 and 254 in MDC 05 to MS–DRGs 040, 041 and 042 in MDC 01. This requestor also submitted an application for new technology add-on payment for FY 2023. We refer readers to section II.F.6. of the preamble of this proposed rule for a discussion regarding the application for new technology add-on payments for the VITARIA® System for FY 2023.

According to the requestor, the following ICD–10–PCS procedure code pair identifies the insertion of a vagus nerve stimulation system for heart failure:

ICD-10-PCS Code	Description
00HE0MZ with 0JH60BZ	Insertion of neurostimulator lead into cranial nerve, open approach
	Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, open approach

The requestor performed its own analysis of Medicare claims from 2020 and stated that it found that patients enrolled in their pivotal clinical trials had an average length of stay of 6.38 days. According to the requestor this finding indicates a resource coherence more similar to cases assigned to MS–DRGs 040, 041 and 042, whose average lengths of stay ranges from 2 to 8 days, when compared to the average lengths of stay of 1 to 3 days for cases assigned to MS–DRGs 252 and 253. The requestor stated their own analysis of 2019 and 2020 Medicare claims data also showed that fewer than 11 cases with procedure codes describing the implantation of a vagus nerve stimulation system map to MS–DRGs 252, 253 and 254 annually but it is expected that Medicare patients will receive vagus nerve stimulation system for heart failure on an inpatient basis. Because of the shared clinical and resource similarity of the procedure to implant the VITARIA® system to other CNS procedures, regardless of indication, the requestor stated that CNS procedures for the treatment of heart failure should also be assigned to MS–DRGs 040, 041 and 042. The requestor also noted that the title of MS–DRGs 252, 253 and 254 is ''Other Vascular Procedures with MCC, with CC, without MCC respectively''. Since no vascular access is involved in the procedure to implant vagus nerve stimulation systems, the requestor stated MS–DRGs 252, 253 and 254 are not appropriate mappings for these procedures.

The ICD–10–CM diagnosis codes that describe heart failure are found in the following table. These diagnosis codes are all currently assigned to MDC 05.

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ICD-10-CM Code	Description
I09.81	Rheumatic heart failure
I11.0	Hypertensive heart disease with heart failure
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I50.1	Left ventricular failure, unspecified
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.810	Right heart failure, unspecified
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure
I50.9	Heart failure, unspecified
I97.130	Postprocedural heart failure following cardiac surgery
I97.131	Postprocedural heart failure following other surgery

The ICD–10–PCS codes that identify the insertion of a neurostimulator lead onto the vagus nerve are listed in the following table.

ICD-10-PCS Code	Description
00HE0MZ	Insertion of neurostimulator lead into cranial nerve, open approach
00HE3MZ	Insertion of neurostimulator lead into cranial nerve, percutaneous approach
00HE4MZ	Insertion of neurostimulator lead into cranial nerve, percutaneous endoscopic approach

ICD-10-PCS Code	Description
0JH60BZ	Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60CZ	Insertion of single array rechargeable stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60DZ	Insertion of multiple array stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60EZ	Insertion of multiple array rechargeable stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60MZ	Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH63BZ	Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63CZ	Insertion of single array rechargeable stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63DZ	Insertion of multiple array stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63EZ	Insertion of multiple array rechargeable stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63MZ	Insertion of stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH70BZ	Insertion of single array stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70CZ	Insertion of single array rechargeable stimulator generator into back subcutaneous tissue and fascia, open approach

The ICD–10–PCS codes that identify the insertion of a stimulator generator are listed in the following table.

ICD-10-PCS Code	Description
0JH70DZ	Insertion of multiple array stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70EZ	Insertion of multiple array rechargeable stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70MZ	Insertion of stimulator generator into back subcutaneous tissue and fascia, open approach
0JH73BZ	Insertion of single array stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73CZ	Insertion of single array rechargeable stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73DZ	Insertion of multiple array stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73EZ	Insertion of multiple array rechargeable stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73MZ	Insertion of stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH80BZ	Insertion of single array stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80CZ	Insertion of single array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80DZ	Insertion of multiple array stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80EZ	Insertion of multiple array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80MZ	Insertion of stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH83BZ	Insertion of single array stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83CZ	Insertion of single array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83DZ	Insertion of multiple array stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83EZ	Insertion of multiple array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83MZ	Insertion of stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH60BZ	Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60CZ	Insertion of single array rechargeable stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60DZ	Insertion of multiple array stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60EZ	Insertion of multiple array rechargeable stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60MZ	Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH63BZ	Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach

ICD-10-PCS Code	Description
0JH63CZ	Insertion of single array rechargeable stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63DZ	Insertion of multiple array stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63EZ	Insertion of multiple array rechargeable stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63MZ	Insertion of stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH70BZ	Insertion of single array stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70CZ	Insertion of single array rechargeable stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70DZ	Insertion of multiple array stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70EZ	Insertion of multiple array rechargeable stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70MZ	Insertion of stimulator generator into back subcutaneous tissue and fascia, open approach
0JH73BZ	Insertion of single array stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73CZ	Insertion of single array rechargeable stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73DZ	Insertion of multiple array stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73EZ	Insertion of multiple array rechargeable stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73MZ	Insertion of stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH80BZ	Insertion of single array stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80CZ	Insertion of single array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80DZ	Insertion of multiple array stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80EZ	Insertion of multiple array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80MZ	Insertion of stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH83BZ	Insertion of single array stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83CZ	Insertion of single array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83DZ	Insertion of multiple array stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83EZ	Insertion of multiple array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83MZ	Insertion of stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach

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Our analysis of this grouping issue confirmed that, when a procedure code describing the insertion of a neurostimulator lead onto the vagus

nerve and a procedure code describing the insertion of a stimulator generator are reported with a principal diagnosis code describing heart failure, these cases group to surgical MS–DRGs 252, 253 and 254 (Other Vascular Procedures with MCC, with CC, without MCC respectively).

We note that cases involving the use of a peripheral neurostimulator and a diagnosis from MDC 01 are assigned to MS–DRG 041 only. The GROUPER logic for MS–DRGs 040, 041, and 042 is reflected in the logic table:

MCC	CC	Peripheral Neurostimulator Combinations	MS-DRG
Yes	n/a	n/a	040 (Peripheral Cranial Nerve and Other Nervous System Procedures with MCC)
No	Yes	n/a	041 (Peripheral Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator)
No	No	Yes	041 (Peripheral Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator)
No	No	No	042 (Peripheral Cranial Nerve and Other Nervous System Procedures without CC/MCC)

We refer the reader to the ICD–10 MS–DRG Version 39.1 Definitions Manual (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*) for complete documentation of the GROUPER logic for the listed MS–DRGs.

We examined claims data from the September 2021 update of the FY 2021 MedPAR file for MS–DRGs 252, 253 and 254 to identify the subset of cases within MS–DRGs 252, 253 and 254 reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a principal diagnosis of heart failure. We found zero cases in MS–DRGs 252, 253 and 254 reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a principal diagnosis of heart failure. In an attempt to further examine this issue, we then examined claims data from the September 2021 update of the FY 2021 MedPAR file for MS–DRGs 252, 253 and 254 to identify the subset of cases within MS–DRGs 252, 253 and 254 reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a secondary diagnosis of heart failure and similarly found zero cases.

The results of the claims analysis demonstrate that there is not sufficient claims data in the MedPAR file on which to assess the resource use of cases reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a principal or secondary diagnosis of heart failure as compared to other cases assigned to MS–DRGs 252, 253, and 254.

In reviewing the requestor's concerns regarding clinical coherence, our clinical advisors acknowledge that heart failure is a complex syndrome involving autonomic nervous system dysfunction, however our clinical advisors disagree with assigning the diagnosis codes describing heart failure to MDC 01 (Diseases and Disorders of the Nervous System). Our clinical advisors note the concept of clinical coherence requires that the patient characteristics included in the definition of each MS–DRG relate to a common organ system or etiology. As the listed diagnosis codes describe heart failure, these diagnosis codes are appropriately assigned to MDC 05 (Diseases and Disorders of the Circulatory System). Our clinical advisors also state it would not be appropriate to move these diagnoses into MDC 01 because it could inadvertently cause cases reporting these same MDC 05 diagnoses with a circulatory system procedure to be assigned to an unrelated MS–DRG because whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in a MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

To further examine the impact of moving the diagnoses describing heart failure into MDC 01, we analyzed claims data for cases reporting a circulatory system O.R. procedure and a principal diagnosis of heart failure. Our findings are reflected in the following table.

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Cases Reporting Circulatory System O.R. Procedures with a Principal Diagnosis of Heart Failure				
MS-DRG	**Description**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
215	Other Heart Assist System Implant	375	12.9	$89,802
216	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC	554	17.7	$90,282
217	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC	9	9.2	$59,655
218	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC	2	6	$36,309
219	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC	147	16.8	$85,238
220	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC	7	8.4	$62,843
222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI HF or Shock with MCC	923	11.6	$61,254
223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI HF or Shock without MCC	80	6.3	$40,806
224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI HF or Shock with MCC	1	6	$41,102
226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC	1,602	8.1	$51,116
227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC	219	3.5	$40,176
228	Other Cardiothoracic Procedures with MCC	345	11.4	$43,864
229	Other Cardiothoracic Procedures without MCC	9	5.6	$28,662
231	Coronary Bypass with PTCA with MCC	13	17.2	$91,948
233	Coronary Bypass with Cardiac Catheterization or Open Ablation with MCC	482	17.3	$75,283
234	Coronary Bypass with Cardiac Catheterization or Open Ablation without MCC	4	19.8	$77,000
235	Coronary Bypass without Cardiac Catheterization with MCC	70	15	$61,655
236	Coronary Bypass without Cardiac Catheterization without MCC	6	5	$41,809
239	Amputation for Circulatory System Disorders Except Upper Limb and Toe with MCC	196	17.6	$43,110
240	Amputation for Circulatory System Disorders Except Upper Limb and Toe with CC	2	5	$10,803
242	Permanent Cardiac Pacemaker Implant with MCC	1,993	8.7	$33,121
243	Permanent Cardiac Pacemaker Implant with CC	105	5.2	$23,927
244	Permanent Cardiac Pacemaker Implant without CC/MCC	5	3.4	$21,763
245	AICD Generator Procedures	196	7.6	$42,062
246	Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries or Stents	4,529	7.4	$27,962
247	Percutaneous Cardiovascular Procedures with Drug-Eluting Stent without MCC	174	4.7	$19,268
248	Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Arteries or Stents	92	7.3	$26,922
249	Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent without MCC	7	5.1	$19,763
250	Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC	288	7	$25,284
251	Percutaneous Cardiovascular Procedures without Coronary Artery Stent without MCC	8	3.4	$14,789
252	Other Vascular Procedures with MCC	1,603	10.4	$32,014
253	Other Vascular Procedures with CC	29	4.6	$21,692
254	Other Vascular Procedures without CC/MCC	2	1	$10,169

Cases Reporting Circulatory System O.R. Procedures with a Principal Diagnosis of Heart Failure				
MS-DRG	Description	Number of Cases	Average Length of Stay	Average Costs
255	Upper Limb and Toe Amputation for Circulatory System Disorders with MCC	105	10.7	$24,075
256	Upper Limb and Toe Amputation for Circulatory System Disorders with CC	2	8	$14,155
258	Cardiac Pacemaker Device Replacement with MCC	267	6.8	$22,749
259	Cardiac Pacemaker Device Replacement without MCC	28	4.3	$21,145
260	Cardiac Pacemaker Revision Except Device Replacement with MCC	279	8.4	$28,176
261	Cardiac Pacemaker Revision Except Device Replacement with CC	20	4.3	$17,726
262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC	3	2.7	$18,186
263	Vein Ligation and Stripping	9	35.7	$50,529
264	Other Circulatory System O.R. Procedures	2,422	10.7	$28,866
265	AICD Lead Procedures	83	10	$38,286
266	Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC	666	13.9	$76,663
267	Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC	36	3.8	$44,643
268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC	46	16.7	$62,285
269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC	1	1	$14,357
270	Other Major Cardiovascular Procedures with MCC	1,026	13.8	$48,958
271	Other Major Cardiovascular Procedures with CC	22	8.7	$26,730
272	Other Major Cardiovascular Procedures without CC/MCC	2	1.5	$8,289
273	Percutaneous and Other Intracardiac Procedures with MCC	1,064	8.8	$33,132
274	Percutaneous and Other Intracardiac Procedures without MCC	41	6.2	$26,180
	Total Cases	**20,199**	**9.9**	**$40,428**

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As shown in the table, if we were to move diagnosis codes describing heart failure to MDC 01, 20,199 cases would be assigned to the surgical class referred to as ''unrelated operating room procedures'' as an unintended consequence because the surgical procedure reported on the claim would be considered unrelated to the MDC to which the case was assigned based on the principal diagnosis.

In response to the requestor's concerns regarding the title of MS–DRGs 252, 253 and 254, we note that, as stated in the ICD–10 MS–DRG Definitions Manual, ''In each MDC there is usually a medical and a surgical class referred to as ''other medical diseases'' and ''other surgical procedures,'' respectively. The ''other'' medical and surgical classes are not as precisely defined from a clinical perspective. The other classes would include diagnoses or procedures which were infrequently encountered or not well defined clinically. For example, the ''other'' medical class for the Respiratory System MDC would contain the diagnoses ''other somatoform disorders'' and ''congenital malformation of the respiratory system,'' while the ''other'' surgical class for the female reproductive MDC would contain the surgical procedures ''excision of liver'' (liver biopsy in ICD–9–CM) and ''inspection of peritoneal cavity'' (exploratory laparotomy in ICD–9–CM). The ''other'' surgical category contains surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in the particular MDC. There are, however, also patients who receive surgical procedures which are completely unrelated to the MDC to which the patient was assigned. An example of such a patient would be a patient with a principal diagnosis of pneumonia whose only surgical procedure is a destruction of prostate (transurethral prostatectomy in ICD–9–CM). Such patients are assigned to a surgical class referred to as ''unrelated operating room procedures.'' '' We further note that MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) are examples of the ''other'' surgical class, therefore it is expected that there will be procedures not as precisely clinically aligned within the definition (logic) of these MS–DRGs.

Considering that there is no data in the FY 2021 MedPAR file to support a reassignment of these cases based on resource consumption, the analysis of clinical coherence as discussed previously, and the impact that moving the diagnoses describing heart failure into MDC 01 from MDC 05 would have on heart failure cases, we do not believe a reassignment of these cases is appropriate at this time. We can

continue to evaluate the clinical coherence and resource consumption costs that impact this subset of cases and their current MS–DRG assignment as data become available for future rulemaking.

In summary for the reasons stated previously, we are not proposing to reassign cases reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a principal diagnosis of heart failure from MS–DRG 252, 253 and 254 to MS–DRGs 040, 041 and 042.

As we examined the GROUPER logic that would determine an assignment of a case to MS–DRGs 252, 253 and 254, we noted the logic for MS–DRGs 252, 253 and 254 includes ICD–10–PCS procedure codes that describe the insertion of the stimulator generator. We refer the reader to the ICD–10 MS–DRG Version 39.1 Definitions Manual (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*) for complete documentation of the GROUPER logic for the listed MS–DRGs. During our review of the stimulator generator insertion procedures assigned to these MS–DRGs, we identified the following 24 procedure codes that describe the insertion of a stimulator generator, differentiated by device type (for example single array or multiple array), that do not exist in the logic for MS–DRGs 252, 253 and 254.

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ICD-10-PCS Code	Description
0JH60BZ	Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60CZ	Insertion of single array rechargeable stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60DZ	Insertion of multiple array stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60EZ	Insertion of multiple array rechargeable stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH63BZ	Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63CZ	Insertion of single array rechargeable stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63DZ	Insertion of multiple array stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63EZ	Insertion of multiple array rechargeable stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH70BZ	Insertion of single array stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70CZ	Insertion of single array rechargeable stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70DZ	Insertion of multiple array stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70EZ	Insertion of multiple array rechargeable stimulator generator into back subcutaneous tissue and fascia, open approach
0JH73BZ	Insertion of single array stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73CZ	Insertion of single array rechargeable stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73DZ	Insertion of multiple array stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73EZ	Insertion of multiple array rechargeable stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH80BZ	Insertion of single array stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80CZ	Insertion of single array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, open approach

ICD-10-PCS Code	Description
0JH80DZ	Insertion of multiple array stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80EZ	Insertion of multiple array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH83BZ	Insertion of single array stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83CZ	Insertion of single array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83DZ	Insertion of multiple array stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83EZ	Insertion of multiple array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach

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For clinical consistency with the other procedure codes describing the insertion of the stimulator generator currently assigned to these MS–DRGs, we are proposing to add the 24 ICD–10–PCS codes listed previously to MS–DRGs 252, 253 and 254, (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 05 (Diseases and Disorders of the Circulatory System) effective October 1, 2022 for FY 2023.

Also, as we examined the GROUPER logic that would determine an assignment of a case to MS–DRG 041, we note the logic for case assignment to MS–DRG 041 as displayed in the ICD–10 MS–DRG Version 39.1 Definitions Manual, available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* contains code combinations or ''clusters'' representing the insertion of a neurostimulator lead and the insertion of a stimulator generator that are captured under a list referred to as ''Peripheral Neurostimulators.'' During our review of the procedure code clusters in this list, we noted that ICD–10–PCS procedure code clusters describing the insertion of a neurostimulator lead and the insertion of the stimulator generator differentiated by device type (for example single array or multiple array), approach and anatomical site placement are captured. However, procedure code clusters describing the insertion of stimulator generator, that is not differentiated by device type, and a neurostimulator lead were inadvertently excluded. We refer the reader to Table 6P.3a (which is available via the internet on the CMS website at *https://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) for the list of the 108 ICD–10–PCS code clusters that were inadvertently excluded and do not exist in the logic for MS–DRG 041.

For clinical consistency, our clinical advisors supported the addition of the 108 procedure code clusters to the GROUPER logic list referred to as ''Peripheral Neurostimulators'' for MS–DRG 041 that describe the insertion of stimulator generator, not differentiated by device type, and a neurostimulator lead. Therefore, we are proposing to add the 108 ICD–10–PCS code clusters listed in Table 6P.3a that describe the insertion of a stimulator generator, that is not differentiated by device type, and a neurostimulator lead to MS–DRG 041, effective October 1, 2022 for FY 2023.

4. MDC 02 (Diseases and Disorders of the Eye): Retinal Artery Occlusion

We received a request to reassign cases reporting diagnosis codes describing central retinal artery occlusion, and the closely allied condition branch retinal artery occlusion, from MS–DRG 123 (Neurological Eye Disorders) in MDC 02 (Diseases and Disorders of the Eye) to MS–DRGs 061, 062, and 063 (Ischemic Stroke Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with MCC, with CC, and without CC/MCC, respectively) in MDC 01 (Diseases and Disorders of the Nervous System).

Retinal artery occlusion refers to blockage of the retinal artery that carries oxygen to the nerve cells in the retina at the back of the eye, often by an embolus or thrombus. A blockage in the main artery in the retina is called central retinal artery occlusion (CRAO). A blockage in a smaller artery is called branch retinal artery occlusion (BRAO). According to the requestor, in the current mapping to MS–DRG 123, diagnoses of CRAO and BRAO are being captured inappropriately as eye disorders in MDC 02. Instead, the requestor stated that CRAO and BRAO are forms of acute ischemic stroke which occur when a vessel supplying blood to the brain is obstructed.

The requestor stated the retina is a core component of the central nervous system and there is growing recognition that damage to it is a vascular neurological problem and not an ophthalmological one. Patients with CRAO or BRAO are typically very sick, have an underlying condition, and are at imminent risk for further events including heart attack or brain stroke. A diagnosis of CRAO or BRAO requires an urgent, structured and multidisciplinary team-based examination to evaluate and treat other diagnoses that may be present such as high blood pressure, dyslipidemia, diabetes mellitus, obesity, obstructive sleep apnea and smoking to ameliorate the risks of a subsequent, potentially lethal, cardiovascular event.

The requestor further stated new evidence outlines treatment of patients with CRAO with acute stroke protocols, specifically with intravenous thrombolysis (IV tPA) or hyperbaric oxygen therapy (HBOT), to improve outcomes. According to the requestor, BRAO is less commonly treated with IV tPA than CRAO but also requires an urgent and thorough diagnostic workup as with any other form of stroke. The requestor stated the current assignment of these conditions to MS–DRG 123 does not properly recognize disease complexity and allocation of resources for care for these cases. The requestor stated that patients with CRAO or BRAO more closely resemble patients currently mapped to MS–DRGs 061, 062, and 063 in terms of in resource intensity and criticality and that in instances where HBOT is the chosen treatment modality, any revised MS–DRG mapping should include the ICD–10–PCS codes for HBOT.

The ICD–10–CM codes that describe CRAO and BRAO are found in the following table.

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ICD-10-CM Code	Description
H34.10	Central retinal artery occlusion, unspecified eye
H34.11	Central retinal artery occlusion, right eye
H34.12	Central retinal artery occlusion, left eye
H34.13	Central retinal artery occlusion, bilateral
H34.231	Retinal artery branch occlusion, right eye
H34.232	Retinal artery branch occlusion, left eye
H34.233	Retinal artery branch occlusion, bilateral
H34.239	Retinal artery branch occlusion, unspecified eye

Thrombolytic therapy is identified with the following ICD–10–PCS procedure codes.

ICD-10-PCS Code	Description
3E03017	Introduction of other thrombolytic into peripheral vein, open approach
3E03317	Introduction of other thrombolytic into peripheral vein, percutaneous approach
3E04017	Introduction of other thrombolytic into central vein, open approach
3E04317	Introduction of other thrombolytic into central vein, percutaneous approach
3E05017	Introduction of other thrombolytic into peripheral artery, open approach
3E05317	Introduction of other thrombolytic into peripheral artery, percutaneous approach
3E06017	Introduction of other thrombolytic into central artery, open approach
3E06317	Introduction of other thrombolytic into central artery, percutaneous approach

The requestor identified three ICD–10–PCS codes that they stated describe HBOT.

ICD-10-PCS Code	Description
5A05121	Extracorporeal hyperbaric oxygenation, intermittent
6A150ZZ	Decompression, circulatory, single
6A151ZZ	Decompression, circulatory, multiple

During our review of this issue, we included the three procedure codes as identified by the requestor as describing HBOT, as well as the similar procedure code 5A05221 (Extracorporeal hyperbaric oxygenation, continuous) that also describes HBOT, differing only in duration.

Our analysis of this grouping issue confirmed that, when a procedure code describing the administration of a thrombolytic agent or a procedure code describing HBOT is reported with principal diagnosis code describing CRAO or BRAO, these cases group to medical MS–DRG 123. To begin our analysis, we examined claims data from the September 2021 update of the FY 2021 MedPAR file for MS–DRG 123 to (1) identify cases reporting a principal diagnosis code describing CRAO or BRAO without a procedure code describing the administration of a thrombolytic agent or a procedure code describing HBOT; (2) identify cases reporting diagnosis codes describing CRAO or BRAO with a procedure code describing HBOT; and (3) identify cases reporting diagnosis codes describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent. Our findings are shown in the following table:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
123	All cases	2,642	2.5	$6,457
	Cases reporting a principal diagnosis of CRAO or BRAO without a procedure code describing the administration of a thrombolytic agent or a procedure code describing HBOT	774	2.2	$5,482
	Cases reporting a procedure code describing HBOT with a principal diagnosis of CRAO or BRAO	9	2	$6,491
	Cases reporting a procedure code describing the administration of a thrombolytic agent with a principal diagnosis of CRAO or BRAO	47	2.3	$14,335
	All other cases	1,812	2.6	$6,669

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As shown in the table, we identified a total of 2,642 cases within MS–DRG 123 with an average length of stay of 2.5 days and average costs of $6,457. Of these 2,642 cases, there are 774 cases that reported a principal diagnosis code describing CRAO or BRAO without a procedure code describing the administration of a thrombolytic agent or a procedure code describing HBOT with an average length of stay of 2.2 days and average costs of $5,482. There are nine cases that reported a principal diagnosis code describing CRAO or BRAO with a procedure code describing HBOT with an average length of stay of 2 days and average costs of $6,491. There are 47 cases that reported a principal diagnosis code describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent with an average length of stay of 2.3 days and average costs of $14,335.

The data analysis shows that the 774 cases in MS–DRG 123 reporting a principal diagnosis code describing CRAO or BRAO without a procedure code describing the administration of a thrombolytic agent or a procedure code describing HBOT have average costs lower than the average costs in the FY 2021 MedPAR file for MS–DRG 123 ($5,482 compared to $6,457), and the average length of stay is shorter (2.2 days compared to 2.5 days). For the nine cases in MS–DRG 123 reporting a principal diagnosis code describing CRAO or BRAO with a procedure code describing HBOT, the average length of stay is shorter (2 days compared to 2.5 days) and the average costs ($6,491 compared to $6,457) are slightly higher than the average length of stay and average costs compared to all cases in that MS–DRG. For the 47 cases in MS–DRG 123 reporting a principal diagnosis code describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent, the average length of stay is slightly shorter (2.3 days compared to 2.5 days) and the average costs are higher ($14,335 compared to $6,457) than the average length of stay and average costs compared to all cases in that MS–DRG.

We also examined claims data from the September 2021 update of the FY 2021 MedPAR file for MS–DRGs 061, 062, and 063. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
061	4,531	6.6	$23,720
062	7,955	3.7	$15,733
063	1,548	2.5	$13,023

Because MS–DRG 123 is a base DRG and there is a three-way split within MS–DRGs 061, 062, and 063, we also analyzed the 47 cases reporting a principal diagnosis code describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent and the nine cases reporting a principal diagnosis code describing CRAO or BRAO with a procedure code describing HBOT for the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC).

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
123	Cases reporting procedures describing the administration of a thrombolytic agent with a principal diagnosis of CRAO or BRAO with MCC	9	3.2	$20,220
	Cases reporting a procedure code describing HBOT with a principal diagnosis of CRAO or BRAO with MCC	1	3	$10,768
	Cases reporting procedures describing the administration of a thrombolytic agent with a principal diagnosis of CRAO or BRAO with CC	19	2.3	$13,145
	Cases reporting a procedure code describing HBOT with a principal diagnosis of CRAO or BRAO with CC	3	2	$6,107
	Cases reporting procedures describing the administration of a thrombolytic agent with a principal diagnosis of CRAO or BRAO without CC/MCC	19	1.8	$12,737
	Cases reporting a procedure code describing HBOT with a principal diagnosis of CRAO or BRAO without CC/MCC	5	1.8	$5,867

This data analysis shows the cases in MS–DRG 123 reporting a principal diagnosis code describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent or with a procedure code describing HBOT when distributed based on the presence or absence of a secondary diagnosis designated as a CC or an MCC have average costs lower than the average costs in the FY 2021 MedPAR file for MS–DRGs 061, 062, and 063 respectively, and the average lengths of stay are shorter. Accordingly, we do not believe the data adequately support a potential reassignment of these cases to MS–DRGs 061, 062, and 063 respectively.

Our clinical advisors reviewed this issue and the related data analysis and do not believe that the small subset of patients with a diagnosis of CRAO or BRAO receiving a thrombolytic agent or hyperbaric oxygen therapy warrant a separate MS–DRG or reassignment at this time. Our clinical advisors noted the average costs for cases of patients with a diagnosis of CRAO or BRAO receiving HBOT are only slightly higher than the average costs for all cases in MS–DRG 123 ($6,491 compared to $6,457). The average costs for cases of patients with a diagnosis of CRAO or BRAO receiving a thrombolytic agent are higher than the average costs for all cases in MS–DRG 123 however when distributed based on the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC) it is unclear to what degree the higher average costs for these cases are attributable to the severity of illness of the patient and other circumstances of the admission as opposed to the administration of a thrombolytic agent, as the claims data reflects a wide variance with regard to average costs for these cases.

Our clinical advisors further note that ischemia is defined as a condition in which the blood vessels become blocked, and blood flow is stopped or reduced. The condition has many potential causes, including a blockage caused by a blood clot, or due to buildup of deposits, such as cholesterol. Ischemia can occur anywhere in the body, and the different names for the condition depend on the organ or body part affected such as the brain (cerebral ischemia), heart (ischemic heart disease, myocardial ischemia, or cardiac ischemia), and intestines (mesenteric ischemia or bowel ischemia), legs (critical limb ischemia—a form of peripheral artery disease), and skin (cutaneous ischemia), while they are similar in that they all involve a blocked blood vessel.

In ICD–10 the body or organ system is the axis of the classification and diagnosis codes describing ischemia affecting other body parts are classified by the body or organ system affected. For example, codes describing myocardial ischemia are assigned to MDC 05 (Diseases and Disorders of the Circulatory System) and codes describing mesenteric ischemia are assigned to MDC 06 (Diseases and Disorders of the Digestive System). Our clinical advisors disagree with assigning the diagnosis codes describing CRAO and BRAO to MDC 01. Our clinical advisors note the concept of clinical coherence generally requires that the patient characteristics included in the definition of each MS–DRG relate to a common organ system or etiology and that a specific medical specialty should typically provide care to the patients in the DRG. While closely related, the eyes and the brain are different organs. Our clinical advisors state that because the diagnosis codes used to report CRAO and BRAO describe ischemia affecting the retina, these diagnosis codes are appropriately assigned to MDC 02 (Diseases and Disorders of the Eye). The retina is a collection of cells at the back of the eye where the processing of visual information begins. Due to the retina's vital role in vision, damage to it can cause permanent blindness. The presence of CRAO or BRAO requires input from an ophthalmologist and treatment for these diagnoses would be expected to utilize different resources than a diagnosis of cerebral ischemia which may or may not involve visual impairment. Other possible interventions for CRAO or BRAO included attempting to lower the intraocular pressure with medication or by using a small-gauge needle to remove fluid to try to dislodge the embolus or ocular massage to dislodge the clot, which are not interventions generally performed for a diagnosis of acute ischemic stroke.

To explore other mechanisms to address this request, we also reviewed claims data to consider the option of adding another severity level to the current structure of MS–DRG 123 (Neurological Eye Disorders) and assigning the cases with a principal diagnosis of CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent to the highest level. This option would involve modifying the current base MS–DRG to a two-way severity level split or to a three-way severity level split of ''with MCC or thrombolytic agent, with CC, and without CC/MCC.'' Therefore, it would include proposing new MS–DRGs if the data and our clinical advisors supported creation of new MS–DRGs. However, as displayed in the data findings in the table that follows, the data did not support this option. We applied the five criteria as described in section II.D.1.b. of the preamble of this

proposed rule to determine if it would be appropriate to subdivide cases currently assigned to MS–DRG 123 into severity levels. This analysis generally includes two years of MedPAR claims data to compare the data results from one year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. However, as discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25092), our MS–DRG analysis last year was based on ICD–10 claims data from the March 2020 update of the FY 2019 MedPAR file, which contains hospital claims received from October 1, 2018 through March 31, 2020, for discharges occurring through September 30, 2019 and the ICD–10 claims data from the September 2020 update of the FY 2020 MedPAR file, which contains hospital claims received from October 1, 2019 through September 30, 2020, for discharges occurring through September 30, 2020 given the potential impact of the PHE for COVID–19. Therefore, for this FY 2023 IPPS/LTCH PPS proposed rule, we reviewed the claims data for base MS–DRG 123 using the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, which were used in our analysis of claims data for MS–DRG reclassification requests for FY 2022. We also reviewed the claims data for base MS–DRG 123 using the September 2021 update of the FY 2021 MedPAR file, which were used in our analysis of claims data for MS–DRG reclassification requests for FY 2023. Our findings are shown in the table:

FY Data	Number of Cases	Number of Cases MCC	Number of Cases CC	Number of Cases NonCC	Average Costs No Split	Average Costs MCC	Average Costs CC	Average Costs NonCC	Average Costs MCC/CC Combo	Average Costs CC/NonCC Combo
2021	2,642	374	1,220	1,048	$6,457	$8,605	$6,738	$5,364	$7,176	$6,103
2020	2,664	345	1,163	1,156	$5,943	$7,710	$6,235	$5,122	$6,573	$5,681
2019	3,100	376	1,393	1,331	$5,659	$8,276	$5,743	$4,832	$6,282	$5,298

We applied the criteria to create subgroups for the three-way severity level split. We refer the reader to section II.D.1.b. of the preamble of this FY 2023 IPPS/LTCH PPS proposed rule, for related discussion regarding our finalization of the expansion of the criteria to include the NonCC subgroup and our proposal to continue to delay application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split to maintain more stability in the current MS–DRG structure. We found that the criterion that there be at least 500 cases for each subgroup was not met, as shown in the table based on the data in the FY 2019, FY 2020, and FY 2021 MedPAR files. Specifically, for the ''with MCC'', ''with CC'', and ''without CC/MCC'' split, there were only 376 cases in the ''with MCC'' subgroup based on the data in the FY 2019 MedPAR file, only 345 cases in the ''with MCC'' subgroup based on the data in the FY 2020 MedPAR file and only 374 cases in the ''with MCC'' subgroup based on the data in the FY 2021 MedPAR file.

We then applied the criteria to create subgroups for the two-way severity level splits. For the ''with MCC'' and ''without MCC'' (CC + NonCC) split, the criterion that there be at least 500 cases for each subgroup failed due to low volume each year, specifically, for the ''with MCC'' subgroup as previously described. For the ''with CC/MCC'' and ''without CC/MCC'' (NonCC) split, we found that the criterion that there be at least a $2,000 difference in average costs between the ''with CC/MCC'' and ''without CC/MCC'' subgroups also failed. In the FY 2019 MedPAR file, our data analysis shows average costs in the hypothetical ''with CC/MCC'' subgroup of $6,282 and average costs in the hypothetical ''without CC/MCC'' subgroup of $4,832, for a difference of only $1,450 ($6,282 minus $4,832 = $1,450). In the FY 2020 MedPAR file, our data analysis shows average costs in the hypothetical ''with CC/MCC'' subgroup of $6,573 and average costs in the hypothetical ''without CC/MCC'' subgroup of $5,122, for a difference of only $1,451 ($6,573 minus $5,122 = $1,451). In the FY 2021 MedPAR file, our data analysis shows average costs in the hypothetical ''with CC/MCC'' subgroup of $7,176 and average costs in the hypothetical ''without CC/MCC'' subgroup of $5,364, for a difference of only $1,812 ($7,176 minus $5,364 = $1,812). Our data analysis indicates that the current base MS–DRG 123 maintains the overall accuracy of the IPPS, and that the claims data do not support a three-way or a two-way severity level split for MS–DRG 123.

Lastly, we explored reassigning cases with a principal diagnosis of CRAO or BRAO that receive the administration of a thrombolytic agent to other MS–DRGs within MDC 02. However, our review did not support reassignment of these cases to any other medical MS–DRGs as these cases would not be clinically coherent with the cases assigned to those other MS–DRGs.

Therefore, based on the various data analyses we performed to explore the possible reassignment of cases with a principal diagnosis of CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent or a procedure code describing hyperbaric oxygen therapy, and the clinical analysis as previously discussed, for FY 2023 we are not proposing any MS–DRG changes for cases with a principal diagnosis of CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent or a procedure code describing hyperbaric oxygen therapy.

5. MDC 04 (Diseases and Disorders of the Respiratory System): Acute Respiratory Distress Syndrome (ARDS)

We received a request to reassign cases reporting diagnosis code J80 (Acute respiratory distress syndrome) as the principal diagnosis from MS–DRG 204 (Respiratory Signs and Symptoms) to MS–DRG 189 (Pulmonary Edema and Respiratory Failure).

According to the requestor, when a patient presents with the condition of acute respiratory failure that progresses to acute respiratory distress syndrome (ARDS) during the hospital stay, official coding guidance instructs to only report the diagnosis code for ARDS (code J80). The requestor stated that in the American Hospital Association's (AHA) *Coding Clinic for ICD–10–CM and ICD–10–PCS,* Fourth Quarter 2020 publication, for a patient who is admitted in acute hypoxic respiratory failure that progresses to ARDS, the advice is to assign code J80, Acute respiratory distress syndrome. Additionally, in the ICD–10–CM Tabular List of Diseases, per the Excludes 1 note under category J96 (Respiratory failure, not elsewhere

classified) only code J80 should be assigned when respiratory failure and ARDS are both documented. The same publication also maintained that ARDS is a life-threatening form of respiratory failure and is not an unrelated condition. Therefore, when acute respiratory failure is documented along with ARDS, only one code is reported to capture the highest level of severity.

The requestor also conveyed the Fourth Quarter 2020 publication's reference to previously published advice from the Fourth Quarter 2017 publication that stated, ''Acute respiratory distress syndrome (ARDS) is a life-threatening condition. ARDS is a rapidly progressive disorder that has symptoms of dyspnea, tachypnea, and hypoxemia. Fluid builds up in the alveoli and lowers the amount of oxygen that is circulated through the bloodstream. Low levels of oxygen in the blood threatens organ function. ARDS is often associated with sepsis, pneumonia, trauma and aspiration. The majority of people who develop ARDS are already in the hospital in critical condition from some other health complication. The focus of treatment is getting oxygen to the organs.''

We examined claims data from the September 2021 update of the FY 2021 MedPAR file for all cases in MS–DRG 204 and the cases reporting ARDS (code J80) as a principal diagnosis. Our findings are shown in the following table.

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
204	All Cases	5,241	2.8	$6,780
	Cases with principal diagnosis code J80 (Acute respiratory distress syndrome)	96	7.6	$15,077
	All other cases	5,145	2.7	$6,625

As shown in the table, the data demonstrate a longer average length of stay (7.6 days versus 2.8 days) and higher average costs ($15,077 versus $6,780) for the 96 cases reporting ARDS (code J80) as a principal diagnosis when compared to all 5,241 cases in MS–DRG 204.

We also examined claims data from the September 2021 update of the FY 2021 MedPAR file for all cases in MS–DRG 189. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
189	77,626	4.6	$9,780

The data analysis supports that cases reporting ARDS (code J80) are more appropriately aligned with the average length of stay and average costs of the cases in MS–DRG 189 in comparison to MS–DRG 204 when ARDS is reported as a principal diagnosis. We also agree that, consistent with the coding clinic advice, ARDS is a life-threatening form of respiratory failure and the conventions of the ICD–10–CM classification as displayed in the Tabular List of Diseases Excludes note, support the concept that cases reporting ARDS as a principal diagnosis are more clinically coherent with the other conditions currently assigned to MS–DRG 189.

For these reasons, we are proposing to reassign cases reporting ARDS (code J80) as a principal diagnosis from MS–DRG 204 to MS–DRG 189 effective FY 2023.

6. MDC 05 (Diseases and Disorders of the Circulatory System)

a. Percutaneous Transluminal Coronary Angioplasty (PTCA) Logic

We identified a replication issue from the ICD–9 based MS–DRGs to the ICD–10 based MS–DRGs for procedure code 02UG3JE (Supplement mitral valve created from left atrioventricular valve with synthetic substitute, percutaneous approach) that was created effective October 1, 2016 (FY 2017), to identify and describe further interventions that may occur for a patient who had previously undergone cardiac valve surgery to correct a congenital anomaly, such as repair of a complete common atrioventricular canal defect.

We used our established process in the assignment of new procedure code 02UG3JE to the most appropriate MS–DRG(s) for FY 2017. Procedure code 02UG3JE was proposed for assignment to the same MS–DRGs as its predecessor code. The predecessor code for procedure code 02UG3JE as shown in the 2017 ICD–10–PCS conversion table (available via the internet on the CMS web page at *https://www.cms.gov/Medicare/Coding/ICD10/2017-ICD-10-PCS-and-GEMs*) is 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach). The ICD–9–CM comparable translation for this code (02UG3JZ) is procedure code 35.97 (Percutaneous mitral valve repair with implant), which identifies the use of the MitraClip® technology that has been discussed extensively in prior rulemaking.

In the FY 2017 rulemaking, using our established process, new procedure code 02UG3JE was proposed and finalized for assignment to the following MS–DRGs for FY 2017, as also shown in Table 6B.—New Procedure Codes in association with the FY 2017 IPPS/LTCH PPS proposed and final rules (available via the internet on the CMS web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download*). We note that the listed MS–DRGs also reflect the MS–DRGs that the predecessor code (02UG3JZ) was assigned to at the time of the proposed rule.

MS-DRG	Description
231	Coronary Bypass with PTCA with MCC
232	Coronary Bypass with PTCA without MCC
233	Coronary Bypass with Cardiac Catheterization with MCC
234	Coronary Bypass with Cardiac Catheterization without MCC
235	Coronary Bypass without Cardiac Catheterization with MCC
236	Coronary Bypass without Cardiac Catheterization without MCC
273	Percutaneous Intracardiac Procedures with MCC
274	Percutaneous Intracardiac Procedures without MCC
981	Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC
982	Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC
983	Extensive O.R. Procedures Unrelated to Principal Diagnosis without CC/MCC

However, as also discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56809 through 56813), in connection with replication efforts between the ICD–9 and ICD–10 based MS–DRGs and the surgical hierarchy, the predecessor procedure code (02UG3JZ) was reassigned from MS–DRGs 273 and 274 to MS–DRG 228 (Other Cardiothoracic Procedures with MCC) and revised MS–DRG 229 (Other Cardiothoracic Procedures without MCC), and was removed from the PTCA logic for MS–DRGs 231 and 232. However, these proposed and finalized MS–DRG changes for procedure code 02UG3JZ were not considered for purposes of the MS–DRG assignments for new procedure code 02UG3JE, which were instead finalized as proposed based on the existing MS–DRG assignments for the predecessor code, and code 02UG3JE continued to remain on the PTCA list in the GROUPER logic for MS–DRGs 231 and 232.

Our clinical advisors stated that procedure code 02UG3JE does not describe a PTCA procedure. We analyzed claims data from the September 2021 update of the FY 2021 MedPAR file for cases in MS–DRGs 231 and 232 to determine if there were any cases reported with procedure code 02UG3JE, and there were no such cases found.

Accordingly, because the procedure described by procedure code 02UG3JE is not clinically consistent with a PTCA procedure and it was initially assigned to the list for PTCA procedures in the GROUPER logic as a result of replication in the transition from ICD–9 to ICD–10 based MS–DRGs, we are proposing to remove procedure code 02UG3JE from the list for PTCA procedures in the GROUPER logic for MS–DRGs 231 and 232 effective FY 2023. We are also proposing to maintain the MS–DRG assignment for procedure code 02UG3JE in MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures with and without MCC, respectively) for FY 2023.

b. Neuromodulation Device Implant for Heart Failure (Barostim™ Baroreflex Activation Therapy)

The BAROSTIM NEO™ System is the first neuromodulation device system designed to trigger the body's main cardiovascular reflex to target symptoms of heart failure. The system consists of an implantable pulse generator (IPG) that is implanted subcutaneously in the upper chest below the clavicle, a stimulation lead that is sutured to either the right or left carotid sinus to activate the baroreceptors in the wall of the carotid artery and a wireless programmer system that is used to non-invasively program and adjust BAROSTIM NEO™ therapy via telemetry. The BAROSTIM NEO™ System is indicated for the improvement of symptoms of heart failure in a subset of patients with symptomatic New York Heart Association (NYHA) class II and III heart failure with low cardiac ejection fractions who do not benefit from guideline directed pharmacologic therapy or qualify for Cardiac Resynchronization Therapy (CRT).

The BAROSTIM NEO™ System was approved for new technology add-on payments for FY 2021 (85 FR 58716 through 58717) and FY 2022 (86 FR 44974). We refer readers to section II.F.4.a. of the preamble of this proposed rule for a discussion regarding the proposed FY 2023 status of technologies approved for FY 2022 new technology add-on payments, including the BAROSTIM NEO™ System.

For this FY 2023 IPPS/LTCH PPS proposed rule, we received a request to (1) reassign the ICD–10–PCS procedure codes that describe the implantation of the BAROSTIM NEO™ System from MS–DRGs 252, 253 and 254 (Other Vascular Procedures with MCC, with CC, without MCC respectively) to MS–DRGs 222, 223, 224, 225, 226, and 227 (Cardiac Defibrillator Implant with and without Cardiac Catheterization with and without AMI/HF/Shock with and without MCC, respectively) and (2) reassign the procedure code that describes the placement of a BAROSTIM NEO™ IPG alone from MS–DRGs 252, 253 and 254 to MS–DRG 245 (AICD Generator Procedures).

The following ICD–10–PCS procedure codes uniquely identify the implantation of the BAROSTIM NEO™ System: 0JH60MZ (Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach) in combination with 03HK3MZ (Insertion of stimulator lead into right internal carotid artery, percutaneous approach) or 03HL3MZ (Insertion of stimulator lead into left internal carotid artery, percutaneous approach). The requestor noted that ICD–10–PCS codes 0JH60MZ, 03HK3MZ and 03HL3MZ are individually assigned to MDC 05 in MS–DRGs 252, 253, and 254 but not mapped to the logic of these MS–DRGs in a code combination or code cluster. According to the requestor this means that cases with a principal diagnosis from MDC 05 with procedure codes describing the implantation of a BAROSTIM NEO™ system (0JH60MZ with 03HL3MZ or 03HK3MZ); with procedure codes describing placement of the stimulator generator alone (0JH60MZ); or with procedure codes describing the placement of a carotid sinus lead only (03HL3MZ or 03HK3MZ) are all assigned to MS–DRGs 252, 253, and 254, despite the significant differences in the clinical coherence and resources required to perform these distinct procedures.

The requestor stated that cases reporting procedure codes describing the implantation of a BAROSTIM NEO™ system are more clinically similar to, and have costs that are more closely aligned to, cases within MS–DRGs 222, 223, 224, 225, 226, and 227. The requestor stated that according to its own analysis, the population of Medicare patients surgically treated with procedures assigned to MS–DRGs 222, 223, 224, 225, 226, and 227 is essentially identical to the population treated with the BAROSTIM NEO™ System. According to the requestor, this congruent patient population accounts for essentially all cases assigned to MS–DRGs 222, 223, 224, 225, 226, and 227. The requestor stated their analysis demonstrated that over 80% of the cases in MS–DRGs 222, 223, 224, 225, 226, and 227 had a diagnosis of heart failure, compared to only 30% of cases with a diagnosis of heart failure assigned to MS–DRGs 252, 253, and 254. The requestor stated that the subset of patients that have an indication for the implantation of a BAROSTIM NEO™ system also have indications for the implantation of Implantable Cardioverter Defibrillators (ICD), Cardiac Resynchronization Therapy Defibrillators (CRT–D) and/or Cardiac Contractility Modulation (CCM) devices, all of which also require the permanent implantation of a programmable, electrical pulse generator and at least one electrical lead. The requestor specifically highlighted that the procedure code combinations describing the implantation of a cardiac contractility modulation (CCM) device system, which consists of a programmable implantable pulse generator (IPG) and three leads, one of which is implanted into the right atrium and the other two leads which are inserted into the right ventricle is assigned to MS–DRGs 222, 223, 224, 225, 226, and 227, and the codes describing the insertion of contractility modulation device generator alone are assigned to MS–DRG 245. The requestor stated that the average resource utilization required to implant the BAROSTIM NEO™ System demonstrates a significant disparity compared to all procedures within MS–DRGs 252, 253, and 254 and noted that the cost of the BAROSTIM NEO™ implantable device is $35,000, which is in range with the cost of the other cardiac implantable devices (for example ICD, CRT–D, and CCM) assigned to MS–DRGs 222, 223, 224, 225, 226, and 227.

The requestor stated that the majority of the procedures assigned to MS–DRGs 252, 253, and 254 are primarily designed to identify, diagnose, clear and restructure veins and arteries, excluding those that require implantable devices. Furthermore, the requestor stated the surgical procedures within MS–DRGs 252, 253, and 254 are not intended to treat or improve the function of the heart, nor treat the symptoms of heart failure.

The requestor acknowledged that there are very few cases within the publicly available Medicare inpatient claims data that potentially includes procedure codes describing the implantation of a BAROSTIM NEO™ system. The requestors' own analysis revealed fewer than 11 cases with procedure codes describing the implantation of a BAROSTIM NEO™ system in the combined FY 2019 and FY 2020 MedPAR data and noted that during much of this time period, the BAROSTIM NEO™ System was only implanted as part of a controlled clinical trial. The requestor stated that this incomplete data should not be used to determine initial MS–DRG assignments, especially for new FDA designated 'breakthrough' medical technologies like the BAROSTIM NEO™ system. Rather, the requestor stated that CMS should use available information and expert knowledge to make initial MS–DRG assignments, while waiting for a substantial number of Medicare covered, post-approved claims from a disperse set of hospitals to reconsider MS–DRG assignments as necessary. The requestor cautioned that upon new technology add-on payments expiration, and if the inadequate MS–DRG assignment for these procedures continues, inpatient admissions to implant the BAROSTIM NEO™ system will be paid less than outpatient admissions to perform the same procedures.

The ICD–10–CM diagnosis codes that describe heart failure are found in the following table. These diagnosis codes are all currently assigned to MDC 05.

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ICD-10-CM Code	Description
I09.81	Rheumatic heart failure
I11.0	Hypertensive heart disease with heart failure
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I50.1	Left ventricular failure, unspecified
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.810	Right heart failure, unspecified
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure
I50.9	Heart failure, unspecified
I97.130	Postprocedural heart failure following cardiac surgery
I97.131	Postprocedural heart failure following other surgery

First, we examined claims data from the September 2021 update of the FY 2021 MedPAR file for MS–DRGs 252, 253 and 254 to identify cases reporting a diagnosis of heart failure and procedure codes describing the implantation of the BAROSTIM NEO™ system with or without a procedure code describing the performance of a cardiac catheterization as MS–DRGs 222, 223, 224, 225, 226, and 227 are defined by the performance of cardiac catheterization. Our findings are shown in the following table.

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
252	All cases	24,839	7.6	$27,488
	Cases with diagnosis of heart failure with 0JH60MZ and 03HL3MZ or 03HK3MZ with cardiac catheterization	0		
	Cases with diagnosis of heart failure with 0JH60MZ and 03HL3MZ or 03HK3MZ without cardiac catheterization	2	4.5	$67,588
253	All cases	18,373	5.2	$21,978
	Cases with diagnosis of heart failure with 0JH60MZ and 03HL3MZ or 03HK3MZ with cardiac catheterization	0		
	Cases with diagnosis of heart failure with 0JH60MZ and 03HL3MZ or 03HK3MZ without cardiac catheterization	1	1	$19,237

As shown in the table, the data analysis performed indicates that the two cases in MS–DRG 252 reporting procedure codes describing the implantation of a BAROSTIM NEO™ system have an average length of stay that is shorter than the average length of stay for all the cases in MS–DRG 252 (4.5 days versus 7.6 days) and higher average costs when compared to all the cases in MS–DRG 252 ($67,588 versus $27,488). These two cases did not also report a procedure code describing the performance of a cardiac catherization. The one case in MS–DRG 253 reporting procedure codes describing the implantation of a BAROSTIM NEO™ system had a length of stay that is shorter than the average length of stay for all the cases in MS–DRG 253 (1 day versus 5.2 days) and lower costs when compared to all the cases in MS–DRG 253 ($19,237 versus $21,978). This case did not also report a procedure code describing the performance of a cardiac catherization. We found zero cases in MS–DRG 254 reporting procedure codes describing the implantation of a BAROSTIM NEO™ system.

Our clinical advisors reviewed this data and note that is it difficult to detect patterns of complexity and resource intensity based on the three cases that reported procedure codes describing the implantation of a BAROSTIM NEO™ system. The claims data also reflect a wide variance with regard to the length of stay and average costs for the three cases that did report the implantation of a BAROSTIM NEO™ system. The results of the claims analysis demonstrate we do not have sufficient claims data on which to base and evaluate any proposed changes to the current MS–DRG assignment. Our clinical advisors also expressed concern in equating the implantation of a BAROSTIM NEO™ system to the placement of ICD, CRT–D, and CCM devices as these devices all differ in terms of technical complexity and anatomical placement of the electrical lead(s). Our clinical advisors note there is no intravascular component or vascular puncture involved when implanting a BAROSTIM NEO™ system. Our clinical advisors also note the placement of ICD, CRT–D, and CCM devices generally involve a lead being affixed to the myocardium, being threaded through the coronary sinus or crossing a heart valve and are procedures that involve a greater level of complexity than affixing the stimulator lead to either the right or left carotid sinus when implanting a BAROSTIM NEO™ system.

Next, to evaluate the request to reassign the procedure code that describes the placement of a BAROSTIM NEO™ IPG alone from MS–DRGs 252, 253 and 254 to MS–DRG 245 (AICD Generator Procedures), we examined claims data from the September 2021 update of the FY 2021 MedPAR file for all cases in MS–DRGs 252, 253 and 254 and compared the results to cases with a procedure code describing placement of the stimulator generator alone. Our findings are shown in the following table.

MS-DRGs 252-254: Cases Reporting Procedures Describing Placement of a BAROSTIM NEO™ Stimulator Generator

MS-DRG	ICD-10-PCS codes	Number of Cases	Average Length of Stay	Average Costs
252	All cases	24,839	7.6	$27,488
	Cases with procedure code 0JH60MZ alone	12	8.8	$56,622
253	All Cases	18,373	5.2	$21,978
	Cases with procedure code0JH60MZ alone	4	2.5	$30,451

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As shown in the table, the data analysis performed indicates that the 12 cases in MS–DRG 252 reporting a procedure code describing placement of the stimulator generator alone have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 252 (8.8 days versus 7.6 days) and higher average costs when compared to all the cases in MS–DRG 252 ($56,622 versus $27,488). The four cases in MS–DRG 253 reporting a procedure code describing placement of the stimulator generator alone have an average length of stay that is shorter than the average length of stay for all the cases in MS–DRG 253 (2.5 days versus 5.2 days) and higher average costs when compared to all the cases in MS–DRG 253 ($30,451 versus $21,978). We found zero cases in MS–DRG 254 reporting a procedure code describing placement of the stimulator generator alone.

Our clinical advisors reviewed this data, and found, similar to the analysis of the data from the three cases that reported procedure codes describing the implantation of a BAROSTIM NEO™ system, that it is difficult to detect patterns of complexity and resource intensity based on the few cases that reported procedure codes describing placement of the stimulator generator alone. The claims data similarly reflects a wide variance with regard to the length of stay and average costs for these cases that did report the placement of the stimulator generator alone, indicating there may have been other factors contributing to the higher costs. When reviewing the consumption of hospital resources for this small subset of cases, the claims data also suggest that the increased costs may be attributable to the severity of illness of the patient and other circumstances of the admission as the patients tended to have a major complication or co-morbid (MCC) condition reported based on the MS–DRG assigned.

We recognize the average costs of the small numbers of cases reporting a procedure code describing placement of the stimulator generator alone are greater when compared to the average costs of all cases in their respective MS–DRG. The MS–DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. We further note that section 1886(d)(5)(A) of the Act provides for Medicare payments to Medicare-participating hospitals in addition to the basic prospective payments for cases incurring extraordinarily high costs.

In response to the requestor's concerns regarding procedures currently assigned to MS–DRGs 252, 253 and 254, as discussed in section II.D.3.b. of the preamble of this proposed rule, we note that MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) are examples of the ''other'' surgical class, and therefore it is expected that there will be procedures not as precisely clinically aligned within the definition (logic) of these MS–DRGs. In regard to the concern about the implications for reimbursement when these procedures are performed in the outpatient setting as opposed to the inpatient setting, we note that the goals of reviewing the MS–DRG assignments of particular procedures are to better clinically represent the resources involved in caring for these patients and to enhance the overall accuracy of the system.

In response to the requestor's statement that CMS should use available information and expert knowledge to make initial MS–DRG assignments, while waiting for a substantial number of Medicare covered, post-approved claims from a disperse set of hospitals to reconsider MS–DRG assignments as necessary, we note that we use our established process for GROUPER assignments for new diagnosis and procedure codes. Specifically, consistent with our established process for assigning new diagnosis and procedure codes, we review the predecessor code and MS–DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis or treatment of the condition. We note that this process will not automatically result in the new diagnosis or procedure code being assigned to the same MS–DRG or having the same designation as the predecessor code. Members of the public have the opportunity to provide feedback on the assignment and designation of the codes if they disagree. We refer the reader to section II.D.17 of this proposed rule for a more detailed discussion of this process. We note that when BAROSTIM NEO™ applied for new technology add-on payment, it was noted that the technology could be uniquely identified using a combination of existing ICD–10–PCS codes that were already assigned to MS–DRGs, and this circumstance generally would not provide a basis for MS–DRG reassignment.

Lastly, our clinical advisors expressed concern regarding making proposed MS–DRG changes based on a specific, single technology (BAROSTIM NEO™ system), identified by only one unique procedure code combination versus considering proposed changes based on a group of related procedure codes that can be reported to describe that same type or class of technology, which is more consistent with the intent of the MS–DRGs.

We believe that as the number of cases reporting procedure codes describing the implantation of neuromodulation devices for heart failure increases, a better view of the associated costs and lengths of stay on average will be reflected in the data for purposes of assessing any reassignment of these cases. Our clinical advisors stated that it would not be appropriate to reassign cases for patients from MS–DRGs 252, 253 and 254 to MS–DRGs 222, 223, 224, 225, 226, and 227 in the absence of additional data to better determine the resource utilization for this subset of patients to help inform whether a reassignment would be clinically warranted. Therefore, for the reasons stated previously, we are proposing to maintain the assignment of cases reporting procedure codes that describe the implantation of a neuromodulation device in MS–DRGs 252, 253 and 254 for FY 2023. We are also proposing to maintain the assignment of cases reporting a procedure code describing placement of a stimulator generator alone in MS–DRGs 252, 253 and 254 for FY 2023.

During our review of this issue, as we examined the GROUPER logic that would determine an assignment of a case to MS–DRGs 222, 223, 224, 225, 226, and 227, we found two diagnosis codes describing heart failure that are not currently in the listed principal diagnoses in the GROUPER logic for MS–DRGs 222 and 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI, HF or Shock with and without MCC, respectively). These diagnosis codes are listed in the following table.

ICD-10-CM Code	Description
I97.130	Postprocedural heart failure following cardiac surgery
I97.131	Postprocedural heart failure following other surgery

As a result, when either of these codes are coded as a principal diagnosis, MS–DRGs 224 and 225 (Cardiac Defibrillator Implant with Cardiac Catheterization without AMI, HF, or Shock with and without MCC, respectively) are instead assigned when reported with a procedure code combination describing the implantation of a cardiac defibrillator and a procedure describing the performance of a cardiac catherization procedure. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 39.1, which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 222, 223, 224, and 225.

Our clinical advisors reviewed this issue and believe that cases reporting diagnosis code I97.130 or I97.131 as a principal diagnosis are associated with a severity of illness on par with cases reporting a principal diagnosis of a type of heart failure. To code postprocedural heart failure in ICD–10–CM, instructional notes at category I50 direct to ''code first heart failure following surgery'' (that is, I97.130 and I97.131) with a second code from subcategory of I50 listed after the postprocedural heart failure code to specify the type of heart failure. Our clinical advisors recommend adding diagnosis codes I97.130 and I97.131 to the logic list of principal diagnoses that describe heart failure for clinical consistency, recognizing that coding guidelines instruct to code I97.130 and I97.131 before the codes from subcategory of I50 that specify the type of heart failure, as the codes from subcategory of I50 are currently in the listed principal diagnoses in the GROUPER logic for MS–DRGs 222 and 223. Therefore, we are proposing to modify the GROUPER logic to allow cases reporting diagnosis code I97.130 or I97.131 as a principal diagnosis to group to MS–DRGs 222 and 223 when reported with qualifying procedures.

c. Cardiac Mapping

We identified a replication issue from the ICD–9 based MS–DRGs to the ICD–10 based MS–DRGs for procedure code 02K80ZZ (Map conduction mechanism, open approach). Cardiac mapping describes the creation of detailed maps to detect how the electrical signals that control the timing of the heart rhythm move between each heartbeat to identify the location of rhythm disorders. Cardiac mapping is generally performed during open-heart surgery or performed via cardiac catherization.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49363 through 49369), we discussed a request to remove the cardiac ablation and other specified cardiovascular procedures from the following MS–DRGs, and to create new MS–DRGs to classify these procedures:

- MS–DRG 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents);
- MS–DRG 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC);
- MS–DRG 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents);
- MS–DRG 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC);
- MS–DRG 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent with MCC); and
- MS–DRG 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent without MCC).

The requestor recommended that CMS assign the following ICD–9–CM procedure codes that identify and describe cardiac ablation procedures and the other percutaneous intracardiac procedures to the newly created MS–DRGs:

- 35.52 (Repair of atrial septal defect with prosthesis, closed technique);
- 35.96 (Percutaneous balloon valvuloplasty);
- 35.97 (Percutaneous mitral valve repair with implant);
- 37.26 (Catheter based invasive electrophysiologic testing);
- 37.27 (Cardiac mapping);
- 37.34 (Excision or destruction of other lesion or tissue of heart, endovascular approach);
- 37.36 (Excision, destruction, or exclusion of left atrial appendage (LAA)); and
- 37.90 (Insertion of left atrial appendage device).

We stated we agreed that creating these new MS–DRGs would better reflect utilization of resources and clinical cohesiveness for intracardiac procedures in comparison to intracoronary procedures. Therefore, after consideration of the public comments we received, we finalized our proposal to create MS–DRGs 273 (Percutaneous Intracardiac Procedures with MCC) and MS–DRG 274 (Percutaneous Intracardiac Procedures without MCC) for the FY 2016 ICD–10 MS–DRGs Version 33 and finalized the assignment of the procedures performed within the heart chambers using intracardiac techniques to the two new MS–DRGs.

In the FY 2016 rulemaking, we stated that the comparable ICD–10–PCS code translations for ICD–9–CM procedure code 37.27 (Cardiac mapping) were ICD–10–PCS codes 02K83ZZ (Map conduction mechanism, percutaneous approach) and 02K84ZZ (Map conduction mechanism, percutaneous endoscopic approach). However, code 02K80ZZ (Map Conduction Mechanism, Open Approach), which is also a comparable ICD–10–PCS code translation for ICD–9–CM procedure code 37.27, was inadvertently excluded. Consequently, procedure code 02K80ZZ continued to remain in the GROUPER logic for MS–DRGs 246, 247, 248, 249, 250 and 251.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58477), we finalized a revision to the titles for MS–DRGs 273 and 274 to ''Percutaneous and Other Intracardiac Procedures with and without MCC, respectively'' to better reflect the procedures assigned to them.

In the ICD–10 MS–DRGs Definitions Manual Version 39.1, procedure code 02K80ZZ is currently recognized as a non-O.R. procedure that affects the MS–DRG to which it is assigned. Our clinical advisors reviewed this grouping issue and stated that procedure code 02K80ZZ does not describe a percutaneous cardiovascular procedure. Our clinical advisors support the reassignment of code 02K80ZZ for clinical coherence, noting the procedure should be appropriately grouped along with other procedure codes that describe cardiac mapping currently assigned to MS–DRGs 273 and 274. Accordingly, because the procedure described by procedure code 02K80ZZ is not clinically consistent with percutaneous cardiovascular procedures

and it was initially assigned MS–DRGs 246, 247, 248, 249, 250 and 251 as a result of replication in the transition from ICD–9 to ICD–10 based MS–DRGs, we are proposing the reassignment of procedure code 02K80ZZ from MS–DRGs 246, 247, 248, 249, 250 and 251 to MS–DRGs 273 and 274 (Percutaneous and Other Intracardiac Procedures with and without MCC, respectively) in MDC 05 effective FY 2023.

As discussed in section II.D.1.b. of the preamble of this proposed rule, we are providing a test version of the ICD–10 MS–DRG GROUPER Software, Version 40, so that the public can better analyze and understand the impact of the proposals included in this proposed rule. We note that at the time of the development of the test software this issue was unable to be addressed and therefore, it does not reflect the proposed reassignment of procedure code 02K80ZZ from MS–DRGs 246, 247, 248, 249, 250 and 251 to MS–DRGs 273 and 274 (Percutaneous and Other Intracardiac Procedures with and without MCC, respectively) in MDC 05 for Version 40.

d. Surgical Ablation

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44836 through 44848), we discussed a two-part request we received to review the MS–DRG assignments for cases involving the surgical ablation procedure for atrial fibrillation. The first part of the request was to create a new classification of surgical ablation MS–DRGs to better accommodate the costs of open concomitant surgical ablations. The requestor identified the following potential procedure combinations that would comprise an ''open concomitant surgical ablation'' procedure.

- Open CABG + open surgical ablation
- Open MVR + open surgical ablation
- Open AVR + open surgical ablation
- Open MVR + open AVR + open surgical ablation
- Open MVR + open CABG + open surgical ablation
- Open MVR + open AVR + open CABG + open surgical ablation
- Open AVR + open CABG + open surgical ablation

As discussed in the FY 2022 IPPS/LTCH PPS final rule, we examined claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for cases reporting procedure code combinations describing open concomitant surgical ablations. We refer the reader to Table 6P.1o associated with the FY 2022 final rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for data analysis findings of cases reporting procedure code combinations describing open concomitant surgical ablations. We stated our analysis showed while the average lengths of stay and average costs of cases reporting procedure code combinations describing open concomitant surgical ablations are higher than all cases in their respective MS–DRG, we found variation in the volume, length of stay, and average costs of the cases. We also stated findings from our analysis indicated that MS–DRGs 216, 217, 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively) as well as approximately 31 other MS–DRGs would be subject to change based on the three-way severity level split criterion finalized in FY 2021. We refer the reader to section II.D.1.b. of this FY 2023 IPPS/LTCH PPS proposed rule, for related discussion regarding our proposal to continue to delay application of the NonCC subgroup criteria to existing MS–DRGs with three-way severity level split to maintain more stability in the current MS–DRG structure.

In the FY 2022 final rule, we finalized our proposal to revise the surgical hierarchy for the MS–DRGs in MDC 05 (Diseases and Disorders of the Circulatory System) to sequence MS–DRGs 231–236 (Coronary Bypass) above MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively), effective October 1, 2021. In addition, we also finalized the assignment of cases with a procedure code describing coronary bypass and a procedure code describing open ablation to MS–DRGs 233 and 234 and changed the titles of these MS–DRGs to ''Coronary Bypass with Cardiac Catheterization or Open Ablation with and without MCC, respectively'' to reflect this reassignment for FY 2022.

In response to this final policy, for this FY 2023 IPPS/LTCH PPS proposed rule, we received a request to again review the MS–DRG assignment of cases involving open concomitant surgical ablation procedures. The requestor stated they continue to believe that the average hospital costs for surgical ablation for atrial fibrillation demonstrates a cost disparity compared to all procedures within their respective MS–DRGs. The requestor asked that that when open surgical ablation is performed with MVR, or AVR or MVR/AVR + CABG that these procedures are either (1) assigned to a different family of MS–DRGs or (2) assigned to MS–DRGs 216 and 217 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC and with CC, respectively) similar to what CMS did with CABG and open ablation procedures in the FY 2022 rulemaking to better accommodate the added cost of open concomitant surgical ablation.

The change to the surgical hierarchy in MDC 05 and the assignment of cases with a procedure code describing coronary bypass and a procedure code describing open ablation to MS–DRGs 233 and 234 is recent, only becoming effective October 1, 2021. We believe more time is needed before considering to again review the MS–DRG assignment of cases reporting procedure code combinations describing open concomitant surgical ablations as the data from the September 2021 update of the FY 2021 MedPAR file does not reflect our FY 2022 finalization. In addition, our clinical advisors continue to state that in open concomitant surgical ablation procedures, the CABG, MVR, and AVR components of the procedure are more technically complex than the open surgical ablation procedure. They also state that the finalized revision to the surgical hierarchy leads to a grouping that is more coherent and better accounts for the resources expended to address the more complex procedures from other cases redistributed during the hierarchy change. As noted, we believe that additional time is needed to allow for further analysis of the claims data to reflect our FY 2022 finalization, and also to determine to what extent the patient's co-morbid conditions are also contributing to costs and to identify other contributing factors that might exist with respect to the increased length of stay and costs of this subset of cases in these MS–DRGs, as discussed in the FY 2022 IPPS/LTCH PPS final rule.

7. MDC 06 (Diseases and Disorders of the Digestive System): Appendicitis

We received a request to reconsider the MS–DRG assignment for diagnosis code K35.20 (Acute appendicitis with generalized peritonitis, without abscess). According to the requestor, when this code is reported in combination with any one of the corresponding procedure codes that describe an appendectomy, the case is grouping to MS–DRGs 341, 342, and 343 (Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). Alternatively, the requestor stated that when diagnosis code K35.32 (Acute

appendicitis with perforation and localized peritonitis, without abscess) is reported in combination with any one of the corresponding procedure codes that describe an appendectomy, the case is grouping to MS–DRGs 338, 339, and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

The requestor asserted that the difference in MS–DRG assignment suggests that localized peritonitis is more severe or requires an additional level of care over and above that for generalized peritonitis. The requestor stated that clinically, both localized and generalized peritonitis, when treated with an appendectomy require the same level of patient care, including extensive intraoperative irrigation at the surgical site, direct inspection or imaging of the abdomen to look for possible abscess, use of intravenous antibiotics, and prolonged inpatient monitoring. The requestor added that generalized peritonitis can be thought of as a progression of the localized peritonitis condition and that patients progress from localized to generalized peritonitis and not vice versa.

We note that this topic has been discussed previously in our FY 2019 (83 FR 41230) and FY 2021 rulemakings (85 FR 32500 through 32503) and (85 FR 58484 through 58488). Effective FY 2019 (October 1, 2018) diagnosis code K35.2 (Acute appendicitis with generalized peritonitis) was expanded to K35.20 (Acute appendicitis with generalized peritonitis, without abscess); and K35.21 (Acute appendicitis with generalized peritonitis, with abscess). In addition, code K35.3 (Acute appendicitis with localized peritonitis) was expanded to K35.30 (Acute appendicitis with localized peritonitis, without perforation or gangrene); K35.31 (Acute appendicitis with localized peritonitis and gangrene, without perforation); K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess); and K35.33 (Acute appendicitis with perforation and localized peritonitis, with abscess).

We finalized the severity level designations for these new diagnosis codes in the FY 2019 IPPS/LTCH PPS final rule and stated our clinical advisors believed that the new diagnosis codes for acute appendicitis described as ''with abscess'' or ''with perforation'' were clinically qualified for the MCC severity level designation, while acute appendicitis ''without abscess'' or ''without perforation'' were clinically qualified for the CC severity level designation because cases with abscess or perforation would be expected to require more clinical resources and time to treat while those cases ''without abscess'' or ''without perforation'' are not as severe clinical conditions.

As discussed in our FY 2021 rulemaking, we received the request to add K35.20 (Acute appendicitis with generalized peritonitis, without abscess) to the list of complicated principal diagnoses so that all ruptured/perforated appendicitis codes in MDC 06 group to MS–DRGs 338, 339, and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) as K35.20 is the only ruptured appendicitis code not included in the list of complicated principal diagnosis codes. At that time, we noted that the inclusion term at subcategory K35.2 (Acute appendicitis with generalized peritonitis) is: ''Appendicitis (acute) with generalized (diffuse) peritonitis following rupture or perforation of the appendix''. The requestor stated that code K35.20 (Acute appendicitis with generalized peritonitis, without abscess) describes a generalized, more extensive form of peritonitis than code K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess). We noted that our clinical advisors agreed that the presence of an abscess would clinically determine whether a diagnosis of acute appendicitis would be considered a complicated principal diagnosis. As diagnosis code K35.20 is described as ''without'' an abscess, our clinical advisors recommended that K35.20 not be added to the list of complicated principal diagnoses for MS–DRGS 338, 339, and 340. We also proposed to remove diagnosis code K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess) from the complicated principal diagnosis list.

In response to that proposal, some commenters disagreed. A commenter stated that when ruptured appendicitis results in generalized peritonitis, resources are greater because the infection is not walled off, not localized, and has spread to two or more compartments within the abdominal cavity. According to the commenter, clinical literature supports the statement that generalized peritonitis is a more morbid (severe) presentation than just perforation or localized abscess. After consideration of the comments received and for the reasons discussed in the FY 2021 final rule, we did not finalize our proposals in that final rule. We concurred that the expansion of diagnosis codes K35.2 and K35.3 to introduce additional clinical concepts effective October 1, 2018 significantly changed the scope and complexity of the diagnosis codes for this subset of patients. We also stated NCHS' staff acknowledged the clinical concerns based on the manner in which diagnosis codes K35.2 and K35.3 were expanded and confirmed that they would consider further review of these newly expanded codes with respect to the clinical concepts.

We communicated with the CDC/NCHS staff regarding this repeat request submitted for FY 2023 consideration. The CDC/NCHS staff included these codes describing appendicitis on the agenda and a proposal for further revisions was presented for discussion at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting. Specifically, the CDC/NCHS staff proposed to expand current diagnosis codes K35.20 and K35.21, making them sub-subcategories and creating new diagnosis codes to identify and describe acute appendicitis with generalized peritonitis, with perforation and without perforation, and unspecified as to perforation, as shown in the following table.

Proposed ICD-10-CM Code	Description
K35.200	Acute appendicitis with generalized peritonitis, without perforation or abscess
K35.201	Acute appendicitis with generalized peritonitis, with perforation, without abscess
K35.209	Acute appendicitis with generalized peritonitis, without abscess, unspecified as to perforation
K35.210	Acute appendicitis with generalized peritonitis, without perforation, with abscess
K35.211	Acute appendicitis with generalized peritonitis, with perforation and abscess
K35.219	Acute appendicitis with generalized peritonitis, with abscess, unspecified as to perforation

We refer the reader to the CDC website at *https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm* for additional detailed information regarding the proposal, including a recording of the discussion and the related meeting materials.

We note that the deadline for submitting public comments on the diagnosis code proposals discussed at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting is May 9, 2022 and according to the CDC/NCHS staff, the diagnosis code proposals are being considered for an October 1, 2023 implementation (FY 2024). Any future proposed changes to the MS–DRGs for Appendectomy would be dependent on the diagnosis code revisions that are finalized by the CDC/NCHS. Since it is not clear what code changes may be finalized, including whether public comments would support the proposed changes or provide alternative options for consideration, we believe it is appropriate to delay any possible MS–DRG modifications for future rulemaking. Therefore, we are not proposing a change to the MS–DRG assignment or the current structure for MS–DRGs 338, 339, 340, 341, 342, and 343 at this time. Although we are not proposing a change to the MS–DRG assignments for FY 2023, we are making available the findings from our data analysis for the listed MS–DRGs and the associated diagnosis codes which may help inform future comments. We refer the reader to Table 6P.4a (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*).

8. MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas): Laparoscopic Cholecystectomy with Common Bile Duct Exploration

We received a request to review the MS–DRG assignment when procedure code 0FC94ZZ (Extirpation of matter from common bile duct, percutaneous endoscopic approach) that describes a common bile duct exploration with gallstone removal procedure using a laparoscopic approach, is reported with a laparoscopic cholecystectomy. The procedure codes describing a laparoscopic cholecystectomy are

ICD-10-PCS Code	Description
0F544ZZ	Destruction of gallbladder, percutaneous endoscopic approach
0F548ZZ	Destruction of gallbladder, via natural or artificial opening endoscopic
0FB44ZZ	Excision of gallbladder, percutaneous endoscopic approach
0FB48ZZ	Excision of gallbladder, via natural or artificial opening endoscopic
0FT44ZZ	Resection of gallbladder, percutaneous endoscopic approach

According to the requestor, when a laparoscopic cholecystectomy is reported with any one of the listed procedure codes with a common bile duct exploration and gallstone removal procedure that is performed laparoscopically and reported with procedure code 0FC94ZZ, the resulting assignment is MS–DRGs 417, 418 and 419 (Laparoscopic Cholecystectomy without C.D.E. with MCC, with CC, and without CC/MCC, respectively). This MS–DRG assignment does not recognize that a common bile duct exploration (C.D.E.) was performed. However, the requestor stated that when procedure code 0FC90ZZ (Extirpation of matter from common bile duct, open approach) that describes a common bile duct exploration with gallstone removal procedure using an open approach is reported with any one of the listed procedure codes describing a laparoscopic cholecystectomy, the resulting assignment is MS–DRGs 411, 412, and 413 (Cholecystectomy with C.D.E. with MCC, with CC, and without CC/MCC, respectively). The requestor stated that this MS–DRG assignment appropriately recognizes that a common bile duct exploration was performed. The requestor questioned why only the common bile duct exploration with gallstone removal procedure performed using an open approach (code 0FC90ZZ) grouped appropriately when reported with the laparoscopic cholecystectomy.

We reviewed procedure code 0FC94ZZ and found that it is currently designated as a non-O.R. procedure, therefore, the GROUPER logic does not recognize this procedure for purposes of MS–DRG assignment. We also note that MS–DRGs 411, 412, and 413 include cholecystectomy procedures performed by either an open or a percutaneous endoscopic (laparoscopic) approach. We refer the reader to the V39.1 ICD–10 MS–DRG Definitions Manual, which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 411, 412, 413, 417, 418 and 419.

We analyzed claims data from the September 2021 update of the FY 2021 MedPAR file for all cases in MS–DRGs 411, 412, 413, 417, 418, and 419. Because the logic for MS–DRGs 411, 412, and 413 includes cholecystectomy

procedures performed by either an open or percutaneous endoscopic (laparoscopic) approach, we also analyzed the cases reported with each approach separately. The findings from our analysis are shown in the following tables.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
411	116	8.5	$29,332
412	152	6.8	$21,042
413	76	3.6	$12,427
417	10,448	6.3	$19,384
418	17,336	4.1	$13,627
419	9,479	2.7	$10,728

Number of Cases Reporting Open Cholecystectomy in MS-DRGs 411-413			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
411	56	10.73	$36,135
412	82	7.61	$23,390
413	28	4.3	$12,969
Total	**166**	**8.1**	**$25,932**

Number of Cases Reporting Laparoscopic Cholecystectomy in MS-DRGs 411-413			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
411	60	6.5	$22,982
412	70	5.8	$18,293
413	48	3.1	$12,110
Total	**178**	**5.3**	**$18,206**

In MS–DRG 411, we found a total of 116 cases with an average length of stay of 8.5 days and average costs of $29,332. Of those 116 cases, there were 56 cases reporting an open cholecystectomy, with an average length of stay of 10.7 days and average costs of $36,135 and 60 cases reporting a laparoscopic cholecystectomy, with an average length of stay of 6.5 days and average costs of $22,982. The data show that the cases reporting an open cholecystectomy have a longer average length of stay (10.7 days versus 6.5 days) and higher average costs ($36,135 versus $22,982) compared to the cases reporting a laparoscopic cholecystectomy. The data also show that the cases reporting an open cholecystectomy have a longer average length of stay (10.7 days versus 8.5 days) and higher average costs ($36,135 versus $29,332) compared to all the cases in MS–DRG 411. Similar findings are demonstrated for MS–DRGs 412 and 413, where the data show that the cases reporting an open cholecystectomy have a longer average length of stay and higher average costs compared to the cases reporting a laparoscopic cholecystectomy, and also, when compared to all the cases in their respective MS–DRGs.

We then analyzed claims data from the September 2021 update of the FY 2021 MedPAR file for cases reporting procedure code 0FC94ZZ in MS–DRGs 417, 418, and 419 to assess how often it was reported. The findings from our analysis are shown in the following table.

Number of Cases Reporting Procedure Code 0FC94ZZ in MS-DRGs 417-419			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
417	70	6.3	$17,685
418	96	4.4	$14,615
419	65	3.2	$13,914
Total	**231**	**4.6**	**$15,348**

We found a total of 231 cases across MS–DRGs 417, 418, and 419 with an average length of stay of 4.6 days and average costs of $15,348 reporting procedure code 0FC94ZZ. In our review of the cases reporting a laparoscopic cholecystectomy across MS–DRGs 411, 412, and 413, we found a total of 178 cases with an average length of stay of 5.3 days and average costs of $18,206.

We also examined claims data from the September 2021 update of the FY 2021 MedPAR file for cases reporting procedure code 0FC94ZZ across all the MS–DRGs without another O.R. procedure reported, to assess the number of cases and which MS–DRGs procedure code 0FC94ZZ was found. The findings from our analysis are shown in the following table.

Number of Cases Reporting Procedure Code 0FC94ZZ without another O.R. Procedure Across All MS-DRGs

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
438 - Disorders of Pancreas Except Malignancy with MCC	2	14	$26,092
441 - Disorders of Liver Except Malignancy Cirrhosis or Alcoholic Hepatitis with MCC	1	16	$30,076
444 - Disorders of the Biliary Tract with MCC	6	5.2	$10,237
445 - Disorders of the Biliary Tract with CC	11	4	$14,015
446 - Disorders of the Biliary Tract without CC/MCC	5	2.6	$15,036
871 - Septicemia or Severe Sepsis without MV >96 Hours with MCC	6	8.8	$22,737
872 - Septicemia or Severe Sepsis without MV >96 Hours without MCC	1	3	$5,322
Total	**32**	**5.9**	**$16,087**

The data analysis shows procedure code 0FC94ZZ was reported in a total of 32 cases across 7 MS–DRGs with an average length of stay of 5.9 days and average costs of $16,087. While procedure code 0FC94ZZ is designated as non-O.R., we also analyzed the average length of stay and average costs of the cases found within each of the 7 MS–DRGs reporting procedure code 0FC94ZZ against all the cases in their respective MS–DRGs, to determine if there was any indication that the performance of the procedure described by procedure code 0FC94ZZ may have had any impact. For instance, as shown in the table, for MS–DRG 438 we found 2 cases reporting procedure code 0FC94ZZ with an average length of stay of 14 days and average costs of $26,092. In the September 2021 update of the FY 2021 MedPAR file, the total number of cases for MS–DRG 438 is 10,240 with an average length of stay of 6.4 days and average costs of $13,341. The 2 cases reporting procedure code 0FC94ZZ have approximately twice the average length of stay (14 days versus 6.4 days) and approximately twice the average costs ($26,092 versus $13,341) compared to all the cases for MS–DRG 438. In the absence of additional analysis, it is unknown if these differences can be attributed to other factors, such as the MCCs that were reported in these cases. Similar findings were found for MS–DRGs 441, 445, 446, and 871. We will consider if further detailed analysis may be warranted for these cases.

Our clinical advisors agreed that procedure code 0FC94ZZ describes a common bile duct exploration procedure with removal of a gallstone and should be added to the logic for case assignment to MS–DRGs 411, 412, and 413 for clinical coherence with the other procedures that describe a common bile duct exploration. Therefore, for FY 2023, we are proposing to redesignate procedure code 0FC94ZZ from a non-O.R. procedure to an O.R. procedure and add it to the logic list for common bile duct exploration (CDE) in MS–DRGs 411, 412, and 413 (Cholecystectomy with C.D.E. with MCC, with CC, and without CC/MCC, respectively) in MDC 07 to appropriately reflect when this procedure is performed and improve the clinical coherence of the patients assigned to these MS–DRGs.

In addition, we note that MS–DRGs 414, 415, and 416 (Cholecystectomy Except By Laparoscope without C.D.E. with MCC, with CC and without CC/MCC, respectively) also reflect cholecystectomy procedures, however, the logic is specifically defined for open cholecystectomy procedures *without* a common bile duct exploration procedure performed. Since MS–DRGs 411, 412, and 413 reflect cases where an open or laparoscopic cholecystectomy is performed *with* a common bile duct exploration procedure, MS–DRGs 414, 415, and 416 reflect cases where only an open cholecystectomy is performed *without* a common bile duct exploration procedure, and MS–DRGs 417, 418, and 419 reflect cases where only a laparoscopic cholecystectomy is performed *without* a common bile duct exploration procedure, we believe there may be an opportunity to further refine these MS–DRGs once additional analysis is performed for consideration in future rulemaking. For example, we could consider proposing to restructure these cholecystectomy MS–DRGs to reflect the following two concepts, if supported by the data, and relatedly, to determine if severity levels are also supported according to the existing criteria.

- Open Cholecystectomy with or without C.D.E.; and
- Laparoscopic Cholecystectomy with or without C.D.E.

We are interested in receiving feedback from the public on this and any alternative recommendations or options to further refine these MS–DRGs by October 20, 2022 for future consideration. Feedback and other suggestions should be directed to the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™), discussed in section II.D.1.b. of the preamble of this proposed rule at *https://mearis.cms.gov/public/home.*

9. MDC 10 (Diseases and Disorders of the Endocrine System): Eladocagene Exuparvovec Gene Therapy

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44895), we finalized the redesignation of code XW0Q316 (Introduction of eladocagene exuparvovec into cranial cavity and brain, percutaneous approach, new technology group 6) from a Non-O.R. procedure to an O.R. procedure, assigned to MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders) and to MS–DRGs 987, 988,

and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without MCC/CC, respectively). We received a request to reconsider this assignment for FY 2023. According to the requestor, the clinical characteristics and costs of cases assigned to MS–DRGs 628 through 630 are significantly different from those associated with the administration of eladocagene exuparvovec. The requestor performed its own analysis, using deep brain stimulation for epilepsy and selective dorsal rhizotomy for cerebral palsy as proxies, and stated that based on its findings for the initial cost analysis and clinical comparison, that MS–DRG 23 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator), MS–DRG 24 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC) and MS–DRGs 25, 26, and 27 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively) may be more appropriate. However, the requestor also stated that while the clinical aspects of eladocagene exuparvovec cases are similar to those of MS–DRGs 23 through 27, the costs are much higher and neither MS–DRGs 628, 629, 630 or MS–DRGs 23 through 27 are appropriate. Therefore, the requestor stated its belief that assigning eladocagene exuparvovec cases to new MS–DRGs is warranted.

Eladocagene exuparvovec is a gene therapy for the treatment of patients with aromatic L-amino acid decarboxylase (AADC) deficiency, a rare genetic and fatal condition identified with ICD–10–CM diagnosis code E70.81. Patients with AADC deficiency are generally observed to have onset of symptoms in the first year of life, most notably hypotonia (muscle weakness), followed by movement disorders, developmental delay and autonomic signs, such as hyperhidrosis (profuse sweating unrelated to heat or exercise). It is understood that the long-term implications of this disease are severe, resulting in severe deficits and limitations in life expectancy. Because the condition is primarily diagnosed in the pediatric population, we would not expect to find any meaningful volume of cases in the MedPAR data.

We analyzed claims data from the September 2021 update of the FY 2021 MedPAR file for MS–DRGs 628, 629, and 630 for cases reporting procedure code XW0Q316 and did not find any cases. We then extended our analysis to all MS–DRGs and found 1 case reporting the administration of this therapy in MS–DRG 829 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures with CC/MCC) with an average length of stay of 2 days and average costs of $1,544. As we have discussed elsewhere we generally prefer not to create a new MS–DRG unless it would include a substantial number of cases. However, as discussed in section II.D.19.b. of the preamble of this proposed rule, we are seeking public comment on possible mechanisms through which we can address rare diseases and conditions that are represented by low volumes in our claims data. We believe this topic, relating to the administration of treatment to address the rare genetic and fatal condition of AADC deficiency, is appropriately aligned with and should be considered as part of that effort. Therefore, we are maintaining the current structure for MS–DRGs 628, 629, and 630 for FY 2023, but will continue to consider this request in connection with our evaluation of possible mechanisms to address rare diseases and conditions in the MS–DRG structure, as discussed later in this rule.

10. MDC 15 Newborns and Other Neonates With Conditions Originating in Perinatal Period: MS–DRG 795 Normal Newborn

We received a request to review the MS–DRG assignment of newborn encounters with diagnosis codes describing contact with and (suspected) exposure to COVID–19 when the condition is ruled out after clinical evaluation and negative workup. The requestor expressed concern that a newborn encounter coded with a principal diagnosis code from category Z38 (Liveborn infants according to place of birth and type of delivery), followed by codes Z05.1 (Observation and evaluation of newborn for suspected infectious condition ruled out) and Z20.822 (Contact with and (suspected) exposure to COVID–19) is assigned to MS–DRG 794 (Neonate with Other Significant Problems). The requestor stated that this assignment appears to be in error and that the assignment should instead be to MS–DRG 795 (Normal Newborn).

Our analysis of this grouping issue confirmed that, when a principal diagnosis code from category Z38 (Liveborn infants according to place of birth and type of delivery), followed by codes Z05.1 (Observation and evaluation of newborn for suspected infectious condition ruled out) and Z20.822 (Contact with and (suspected) exposure to COVID–19), the case is assigned to MS–DRG 794.

As we examined the GROUPER logic that would determine an assignment of cases to MS–DRG 795, we note the ''only secondary diagnosis'' list under MS–DRG 795 includes the following five ICD–10–CM diagnosis codes from ICD–10–CM category Z20. We refer the reader to the ICD–10 MS–DRG Version 39.1 Definitions Manual (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for the MS–DRG 795.

ICD-10-CM Code	Description
Z20.09	Contact with and (suspected) exposure to other intestinal infectious diseases
Z20.7	Contact with and (suspected) exposure to pediculosis, acariasis and other infestations
Z20.810	Contact with and (suspected) exposure to anthrax
Z20.818	Contact with and (suspected) exposure to other bacterial communicable diseases
Z20.89	Contact with and (suspected) exposure to other communicable diseases

In reviewing the ICD–10–CM diagnosis code classification and the GROUPER logic list, we note that the 13 ICD–10–CM diagnosis codes, also from category Z20, listed in the following table were inadvertently omitted from the ''only secondary diagnosis'' list under MS–DRG 795.

ICD-10-CM Code	Description
Z20.01	Contact with and (suspected) exposure to intestinal infectious diseases due to Escherichia coli (E. coli)
Z20.1	Contact with and (suspected) exposure to tuberculosis
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
Z20.3	Contact with and (suspected) exposure to rabies
Z20.4	Contact with and (suspected) exposure to rubella
Z20.5	Contact with and (suspected) exposure to viral hepatitis
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus [HIV]
Z20.811	Contact with and (suspected) exposure to meningococcus
Z20.820	Contact with and (suspected) exposure to varicella
Z20.821	Contact with and (suspected) exposure to Zika virus
Z20.822	Contact with and (suspected) exposure to COVID-19
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases
Z20.9	Contact with and (suspected) exposure to unspecified communicable disease

We reviewed section I.C.21.c.1 of the 2022 ICD–10–CM Official Guidelines for Coding and Reporting which state ''category Z20 indicates contact with, and suspected exposure to, communicable diseases. These codes are for patients who are suspected to have been exposed to a disease by close personal contact with an infected individual or are in an area where a disease is epidemic . . . Contact/exposure codes may be used as a first-listed code to explain an encounter for testing, or, more commonly, as a secondary code to identify a potential risk.'' Per the Excludes1 note at category Z20, when applicable, diagnoses of current infectious or parasitic disease are coded instead of codes from category Z20.

Our clinical advisors reviewed this issue and agree that patients exposed to communicable diseases that are worked up or treated prophylactically or both, and for whom those conditions are later determined after study to not be present, are distinct from patients with identified signs or symptoms of a suspected problem or diagnosed with having that communicable disease. Our clinical advisors supported adding the 13 diagnosis codes listed previously to the logic of MS–DRG 795 for clinical consistency with the five other diagnosis codes describing contact with, and suspected exposure to, communicable diseases currently assigned to the ''only secondary diagnosis'' list under MS–DRG 795.

After review of the coding guidelines and conventions, and discussion with our clinical advisors, we agree with the requestor that in these circumstances, these encounters should not map to MS–DRG 794 (Neonate with Other Significant Problems) and should instead be assigned to MS–DRG 795 (Normal Newborn). Therefore, we are proposing to add the 13 diagnosis codes listed previously that describe contact with and (suspected) exposure to communicable diseases to the ''only secondary diagnosis'' list under MS–DRG 795 (Normal Newborn). Under this proposal, cases with a principal diagnosis described by an ICD–10–CM code from category Z38 (Liveborn infants according to place of birth and type of delivery), following by codes Z05.1 (Observation and evaluation of newborn for suspected infectious condition ruled out) and Z20.822 (Contact with and (suspected) exposure to COVID–19) will be assigned to MS–DRG 795.

As we examined the GROUPER logic that would determine an assignment of cases to MS–DRGs in MDC 15, we noted the logic for MS–DRG 790 (Extreme Immaturity or Respiratory Distress Syndrome Neonate) includes ICD–10–CM diagnosis codes that describe extremely low birth weight newborn, extreme immaturity of newborn and respiratory distress syndrome of newborn. We refer the reader to the ICD–10 MS–DRG Version 39.1 Definitions Manual (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*) for complete documentation of the GROUPER logic for MS–DRG 790. During our review of the diagnosis codes assigned to these MS–DRGs, we identified three diagnosis codes that do not exist in the logic for MS–DRG 790. The three diagnosis codes and their current MS–DRG assignments are listed in the following table.

ICD-10-CM Code	Description	MS-DRG
P07.00	Extremely low birth weight newborn, unspecified weight	791 and 792 (Prematurity with and without Major Problems, respectively)
P07.20	Extreme immaturity of newborn, unspecified weeks of gestation	795 (Normal Newborn)
P07.26	Extreme immaturity of newborn, gestational age 27 completed weeks	791 and 792 (Prematurity with and without Major Problems, respectively)

Our clinical advisors reviewed this grouping issue and noted that while virtually every neonate under 1000 grams, which is the definition of extremely low birth weight (ELBW), will have a weight documented somewhere

in the medical record, in the rare instance that it is not, if the diagnosis documented by the provider is ''ELBW'' the neonate would be in a higher risk category. Our clinical advisors also note that whereas weight is measured with high precision, gestational age is more complicated. With the exception of in vitro fertilization, gestational age is an estimate. Our clinical advisors state similar to documentation of ''ELBW'', if the diagnosis documented by the provider is ''extreme immaturity of newborn'' the neonate would be in a higher risk category. These diagnoses describe conditions that require advanced care and resources similar to other conditions already assigned to the logic of MS–DRG 790 even in cases where the birth weight, or weeks of gestation, are unspecified.

For clinical consistency, our clinical advisors supported the addition of these three diagnosis codes to the GROUPER logic list for MS–DRG 790. Therefore, we are proposing to reassign ICD–10–CM diagnosis codes P07.00, P07.20 and P07.26 to MS–DRG 790, effective October 1, 2022 for FY 2023.

11. Review of Procedure Codes in MS–DRGs 981 Through 983 and 987 Through 989

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move cases reporting these procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC. We use this information to determine which procedure codes and diagnosis codes to examine.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. We also consider whether it would be more appropriate to move the principal diagnosis codes into the MDC to which the procedure is currently assigned.

In addition to this internal review, we also consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate to add procedure codes to one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls or to move the principal diagnosis to the surgical MS–DRGs to which the procedure codes are assigned.

Based on the results of our review of the claims data from the September 2021 update of the FY 2021 MedPAR file, as well as our review of the requests that we received to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, we are proposing to move the cases reporting the procedures and/or principal diagnosis codes described in this section of this rule from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis or procedure is assigned.

a. Embolization of Portal and Hepatic Veins

We received a request to reassign cases with a principal diagnosis from MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas) when reported with procedures involving the embolization of a hepatic or portal vein from MS–DRGs 981, 982 and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 423, 424, and 425 (Other Hepatobiliary or Pancreas Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 07.

In ICD–10–PCS, the root operation selected to code embolization procedures is dependent on the objective of the procedure. If the objective of an embolization procedure is to completely close a vessel, the root operation Occlusion is coded. ICD–10–PCS procedure codes 06L43DZ (Occlusion of hepatic vein with intraluminal device, percutaneous approach) or 06L83DZ (Occlusion of portal vein with intraluminal device, percutaneous approach) may be reported to describe embolization procedures to completely close off a hepatic or portal vein with an intraluminal device. If the objective of an embolization procedure is to narrow the lumen of a vessel, the root operation Restriction is coded. ICD–10–PCS procedure codes 06V43DZ (Restriction of hepatic vein with intraluminal device, percutaneous approach) or 06V83DZ (Restriction of portal vein with intraluminal device, percutaneous approach) may be reported to describe embolization procedures to narrow or partially occlude a hepatic or portal vein with an intraluminal device.

These four ICD–10–PCS procedure codes, as well as their MDC assignments, are listed in the table:

ICD-10-PCS Code	Description	MDC
06L43DZ	Occlusion of hepatic vein with intraluminal device, percutaneous approach	05, 06, 21, 24
06L83DZ	Occlusion of portal vein with intraluminal device, percutaneous approach	05, 06, 21, 24
06V43DZ	Restriction of hepatic vein with intraluminal device, percutaneous approach	05, 21, 24
06V83DZ	Restriction of portal vein with intraluminal device, percutaneous approach	05, 21, 24

Our analysis of this grouping issue confirmed that when a procedure code describing the percutaneous occlusion or restriction of the hepatic or portal vein with intraluminal device is reported with a principal diagnosis from MDC 07, these cases group to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). Whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

To understand the resource use for the subset of cases reporting procedure codes 06L43DZ, 06L83DZ, 06V43DZ or 06V83DZ with a principal diagnosis from MDC 07 that are currently

grouping to MS–DRGs 981, 982, and 983, we examined claims data from the September 2021 update of the FY 2021 MedPAR file for the average length of stay and average costs for these cases. Our findings are shown in the following table:

MS-DRGs 981-983: Cases Reporting Procedure Describing Percutaneous Occlusion or Restriction of Hepatic or Portal Vein with Intraluminal Device with Principal Diagnosis from MDC 07				
MS-DRG		Number of Cases	Average Length of Stay	Average Costs
981	All cases	22,967	12.1	$35,790
	Cases reporting 06L43DZ; 06L83DZ; 06V43DZ or 06V83DZ with a principal diagnosis from MDC 07	23	13.9	$45,634
982	All cases	10,465	5.9	$19,803
	Cases reporting 06L43DZ; 06L83DZ; 06V43DZ or 06V83DZ with a principal diagnosis from MDC 07	10	8.6	$16,772
983	All cases	1,905	2.7	$13,877
	Cases reporting 06L43DZ; 06L83DZ; 06V43DZ or 06V83DZ with a principal diagnosis from MDC 07	1	1	$15,140

We also examined the data for cases in MS–DRGs 423, 424, and 425, and our findings are shown in the following table:

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
423 – All cases	1,222	10.9	$32,145
424 – All cases	547	6	$19,514
425 – All cases	98	2.9	$12,113

While the claims analysis based on the September 2021 update of the FY 2021 MedPAR file identified only 34 cases for which these procedures were reported with a principal diagnosis from MDC 07 resulting in assignment to MS–DRGs 981 through 983, and the average length of stay and average costs for these cases vary in comparison to the average length of stay and average costs of all cases in MS–DRGs 423, 424, and 425, given the clinical indications for hepatic or portal vein embolization procedures, such as to induce regrowth on one side of the liver in advance of a planned hepatic resection on the other side, we believe it is clinically appropriate to add these procedure codes describing the percutaneous occlusion or restriction of the hepatic or portal vein with intraluminal device to MS–DRGs 423, 424, and 425 in MDC 07. Our clinical advisors state that these procedures are clearly related to the principal diagnoses as they are procedures performed for hepatobiliary diagnoses, namely hepatocellular carcinoma and liver metastases, so it is clinically appropriate for the procedures to group to the same MDC as the principal diagnoses. Our clinical advisors also stated the procedures describing the percutaneous occlusion or restriction of the hepatic or portal vein with intraluminal device are consistent with the existing procedure codes included in the logic for case assignment to MS–DRGs 423, 424, and 425.

Therefore, we are proposing to add ICD–10–PCS procedure codes 06L43DZ, 06L83DZ, 06V43DZ and 06V83DZ to MDC 07 in MS–DRGs 423, 424 and 425. Under this proposal, cases reporting procedure codes 06L43DZ, 06L83DZ, 06V43DZ or 06V83DZ in conjunction with a principal diagnosis code from MDC 07 would group to MS–DRGs 423, 424 and 425.

b. Percutaneous Excision of Hip Muscle

We received a request to examine cases reporting a procedure describing percutaneous biopsies of muscle. The requestor stated that when procedures describing the percutaneous excision of the left hip muscle for diagnostic purposes are reported with a principal diagnosis from MDC 06 (Diseases and Disorders of the Digestive System) such as K68.12 (Psoas muscle abscess), the cases are assigned to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). However, when procedures describing the percutaneous excision of the retroperitoneum for diagnostic purposes are reported with the same principal diagnosis of psoas muscle abscess, the cases are assigned to medical MS–DRGs 371, 372, and 373 (Major Gastrointestinal Disorders and Peritoneal Infections with MCC, with CC, and without CC/MCC, respectively).

The requestor stated the cases at their facility with a principal diagnosis of psoas muscle abscess when reported with a procedure describing a biopsy of the left muscle had an average length of stay comparable to other cases assigned to MS–DRGs 371, 372, and 373. The requestor provided ICD–10–PCS procedure code 0KBP3ZX (Excision of left hip muscle, percutaneous approach, diagnostic) in its request and asked that CMS evaluate the assignment of procedure code 0KBP3ZX because procedures describing the percutaneous excision of the left hip muscle for diagnostic purposes appear to be related to a diagnosis of psoas muscle abscess.

To analyze this request, we first identified the similar ICD–10–PCS procedure codes that also describe the excision of hip muscle. We note that under the ICD–10–PCS procedure classification, biopsy procedures are identified by the 7th digit qualifier value ''diagnostic'' in the code description. The four ICD–10–PCS procedure codes that describe the excision of hip muscle, as well as their MDC assignments, are listed in the table:

ICD-10-PCS Code	Description	MDC
0KBN3ZX	Excision of right hip muscle, percutaneous approach, diagnostic	08
0KBN3ZZ	Excision of right hip muscle, percutaneous approach	01; 08; 09; 21; 24
0KBP3ZX	Excision of left hip muscle, percutaneous approach, diagnostic	08
0KBP3ZZ	Excision of left hip muscle, percutaneous approach	01; 08; 09; 21; 24

Our analysis of this grouping issue confirmed that when procedure codes 0KBN3ZX, 0KBN3ZZ, 0KBP3ZX or 0KBP3ZZ are reported with a principal diagnosis from MDC 06, such as K68.12, these cases group to MS–DRGs 981, 982, and 983. As noted in the previous discussion, whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in a MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

We examined the claims data from the September 2021 update of the FY 2021 MedPAR file to identify cases reporting procedure codes 0KBN3ZX, 0KBN3ZZ, 0KBP3ZX, or 0KBP3ZZ with a principal diagnosis of K68.12 (Psoas muscle abscess) that are currently grouping to MS–DRGs 981, 982, and 983. Our findings are shown in this table:

MS-DRGs 981-983: Cases Reporting Procedures Describing Excision of Hip Muscle with a Principal Diagnosis of Psoas Muscle Abscess

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
981	All cases	22,967	12.1	$35,790
	Cases reporting excision of hip muscle with principal diagnosis of K68.12	2	7.5	$12,388
982	All cases	10,465	5.9	$19,803
	Cases reporting excision of hip muscle with principal diagnosis of K68.12	4	9.8	$13,810
983	All cases	1,905	2.7	$13,877
	Cases reporting excision of hip muscle with principal diagnosis of K68.12	1	2	$7,781

As shown, in our analyses of the claims data for MS–DRGs 981 through 983, we found a total of seven cases reporting procedures describing excision of hip muscle with a principal diagnosis of K68.12 in the September 2021 update of the FY 2021 MedPAR file.

To further evaluate this issue, we examined claims data from the September 2021 update of the FY 2021 MedPAR file for cases reporting any one of the four procedure codes (0KBN3ZX, 0KBN3ZZ, 0KBP3ZX, or 0KBP3ZZ) in MS–DRGs 981 through 983 with a principal diagnosis from MDC 06. Our findings are shown in the following table.

MS-DRGs 981-983: Cases Reporting Procedures Describing Excision of Hip Muscle with Principal Diagnosis from MDC 06				
MS-DRG		Number of Cases	Average Length of Stay	Average Costs
981	All cases	22,967	12.1	$35,790
	Cases reporting excision of hip muscle with any principal diagnosis from MDC 06	5	9.6	$15,599
982	All cases	10,465	5.9	$19,803
	Cases reporting excision of hip muscle with any principal diagnosis from MDC 06	8	8.5	$12,346
983	All cases	1,905	2.7	$13,877
	Cases reporting excision of hip muscle with any principal diagnosis from MDC 06	1	2	$7,781

As shown, in our analyses of the claims data for MS–DRGs 981 through 983, we found a total of 14 cases reporting procedures describing excision of hip muscle with a principal diagnosis from MDC 06 in the September 2021 update of the FY 2021 MedPAR file.

We also examined the data for cases in MS–DRGs 371, 372, and 373, and our findings are shown in the following table:

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
371 – All cases	11,415	6.9	$13,284
372 – All cases	15,680	4.6	$8,072
373 – All cases	3,090	3.3	$5,860

We reviewed these procedures and our clinical advisors state that procedures that describe the percutaneous excision of hip muscle are not surgical in nature and would not be the main reason for inpatient hospitalization or be considered the principal driver of resource expenditure. Our clinical advisors state although a correlation cannot usually be made between procedures performed in general anatomic regions, such as the retroperitoneum, and procedures performed in specific body parts, such as muscle, because procedures coded with general anatomic region body parts represent a broader range of procedures that cannot be coded to a specific body part, they agree that in this instance procedures that describe the percutaneous excision of hip muscle should have the same designation as the ICD–10–PCS procedure codes that describe the percutaneous excision of the retroperitoneum that are currently designated as non-O.R. procedures.

Our clinical advisors reviewed this analysis and believe that, for clinical coherence and consistency, it would be appropriate to designate ICD–10–PCS codes 0KBN3ZX, 0KBN3ZZ, 0KBP3ZX, and 0KBP3ZZ as non-O.R. procedures.

Therefore, we are proposing to remove codes 0KBN3ZX, 0KBN3ZZ, 0KBP3ZX, and 0KBP3ZZ from the FY 2023 ICD–10 MS–DRGs Version 40 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. Under this proposal, these procedures would no longer impact MS–DRG assignment. Cases reporting procedure codes 0KBN3ZX, 0KBN3ZZ, 0KBP3ZX, and 0KBP3ZZ in conjunction with a principal diagnosis code from MDC 06 would group to MS–DRGs 371, 372, and 373.

In addition, we also conduct an internal review and consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate for the cases to be reassigned from one of the MS–DRG groups to the other. Based on the results of our review of the claims data from the September 2021 update of the FY 2021 MedPAR file we did not identify any cases for reassignment. We also did not receive any requests suggesting reassignment. Therefore, for FY 2023 we are not proposing to move any cases reporting procedure codes from MS–DRGs 981 through 983 to MS–DRGs 987 through 989 or vice versa.

12. Operating Room (O.R.) and Non-O.R. Issues

a. Background

Under the IPPS MS–DRGs (and former CMS MS–DRGs), we have a list of procedure codes that are considered operating room (O.R.) procedures. Historically, we developed this list using physician panels that classified each procedure code based on the procedure and its effect on consumption of hospital resources. For example, generally the presence of a surgical procedure which required the use of the operating room would be expected to have a significant effect on the type of hospital resources (for example, operating room, recovery room, and anesthesia) used by a patient, and therefore, these patients were considered surgical. Because the claims data generally available do not precisely indicate whether a patient was taken to

the operating room, surgical patients were identified based on the procedures that were performed. Generally, if the procedure was not expected to require the use of the operating room, the patient would be considered medical (non-O.R.).

Currently, each ICD–10–PCS procedure code has designations that determine whether and in what way the presence of that procedure on a claim impacts the MS–DRG assignment. First, each ICD–10–PCS procedure code is either designated as an O.R. procedure for purposes of MS–DRG assignment (''O.R. procedures'') or is not designated as an O.R. procedure for purposes of MS–DRG assignment (''non-O.R. procedures''). Second, for each procedure that is designated as an O.R. procedure, that O.R. procedure is further classified as either extensive or non-extensive. Third, for each procedure that is designated as a non-O.R. procedure, that non-O.R. procedure is further classified as either affecting the MS–DRG assignment or not affecting the MS–DRG assignment. We refer to these designations that do affect MS–DRG assignment as ''non O.R. affecting the MS–DRG.'' For new procedure codes that have been finalized through the ICD–10 Coordination and Maintenance Committee meeting process and are proposed to be classified as O.R. procedures or non-O.R. procedures affecting the MS–DRG, our clinical advisors recommend the MS–DRG assignment which is then made available in association with the proposed rule (Table 6B.—New Procedure Codes) and subject to public comment. These proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes. For example, we generally examine the MS–DRG assignment for similar procedures, such as the other approaches for that procedure, to determine the most appropriate MS–DRG assignment for procedures proposed to be newly designated as O.R. procedures. As discussed in section II.D.14. of the preamble of this proposed rule, we are making Table 6B.—New Procedure Codes—FY 2023 available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* We also refer readers to the ICD–10 MS–DRG Version 39.1 Definitions Manual at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* for detailed information regarding the designation of procedures as O.R. or non-O.R. (affecting the MS–DRG) in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index.

In the FY 2020 IPPS/LTCH PPS proposed rule, we stated that, given the long period of time that has elapsed since the original O.R. (extensive and non-extensive) and non-O.R. designations were established, the incremental changes that have occurred to these O.R. and non-O.R. procedure code lists, and changes in the way inpatient care is delivered, we plan to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes. This will be a multiyear project during which we will also review the process for determining when a procedure is considered an operating room procedure. For example, we may restructure the current O.R. and non O.R. designations for procedures by leveraging the detail that is now available in the ICD–10 claims data. We refer readers to the discussion regarding the designation of procedure codes in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38066) where we stated that the determination of when a procedure code should be designated as an O.R. procedure has become a much more complex task. This is, in part, due to the number of various approaches available in the ICD–10–PCS classification, as well as changes in medical practice. While we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room, we believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10.

We discussed in the FY 2020 IPPS/LTCH PPS proposed rule that as a result of this planned review and potential restructuring, procedures that are currently designated as O.R. procedures may no longer warrant that designation, and conversely, procedures that are currently designated as non-O.R. procedures may warrant an O.R. type of designation. We intend to consider the resources used and how a procedure should affect the MS–DRG assignment. We may also consider the effect of specific surgical approaches to evaluate whether to subdivide specific MS DRGs based on a specific surgical approach. We plan to utilize our available MedPAR claims data as a basis for this review and the input of our clinical advisors. As part of this comprehensive review of the procedure codes, we also intend to evaluate the MS–DRG assignment of the procedures and the current surgical hierarchy because both of these factor into the process of refining the ICD–10 MS–DRGs to better recognize complexity of service and resource utilization.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58540 through 58541), we provided a summary of the comments we had received in response to our request for feedback on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system for future consideration. In consideration of the ongoing PHE, we continue to believe it may be appropriate to allow additional time for the claims data to stabilize prior to selecting the timeframe to analyze for this review. Additional time is also necessary as we continue to develop our process and methodology. Therefore, we will provide more detail on this analysis and the methodology for conducting this review in future rulemaking.

We received the following requests regarding changing the designation of specific ICD–10–PCS procedure codes from non-O.R. to O.R. procedures. We summarize these requests in this section of this rule and address why we are not considering a change to the designation of these codes at this time.

- We received a request to change the designation of all ICD–10–PCS procedure codes that describe diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs, from non-O.R. to O.R. According to the requestor, thoracoscopic and laparoscopic procedures are always performed in the operating room under general anesthesia. We believe additional time is needed to fully examine the numerous ICD–10–PCS codes in the classification that describe diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs as there are over 19,000 ICD–10–PCS codes in the classification that describe procedures performed using a percutaneous endoscopic approach. As we have signaled in prior rulemaking, the designation of an O.R. procedure encompasses more than the physical location of the hospital in which the procedure may be performed. We also examine if, and in what way, the performance of the procedure affects the resource expenditure in those admissions in the inpatient setting, in addition to examining other clinical factors such as procedure complexity, and need for anesthesia administration as well as other types of sedation. We will continue to evaluate the ICD–10–PCS procedure codes that describe diagnostic and therapeutic percutaneous endoscopic procedures performed on

thoracic and abdominal organs as we conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes.

• In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44892 through 44895), CMS finalized the proposal to remove the 22 codes that describe the open drainage of subcutaneous tissue and fascia listed in the following table from the ICD–10 MS–DRGs Version 39.1 Definitions Manual in Appendix E–Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. Under this finalization, these procedures no longer impact MS–DRG assignment.

ICD-10-PCS Code	Description
0J900ZZ	Drainage of scalp subcutaneous tissue and fascia, open approach
0J910ZZ	Drainage of face subcutaneous tissue and fascia, open approach
0J940ZZ	Drainage of right neck subcutaneous tissue and fascia, open approach
0J950ZZ	Drainage of left neck subcutaneous tissue and fascia, open approach
0J960ZZ	Drainage of chest subcutaneous tissue and fascia, open approach
0J970ZZ	Drainage of back subcutaneous tissue and fascia, open approach
0J980ZZ	Drainage of abdomen subcutaneous tissue and fascia, open approach
0J990ZZ	Drainage of buttock subcutaneous tissue and fascia, open approach
0J9B0ZZ	Drainage of perineum subcutaneous tissue and fascia, open approach
0J9C0ZZ	Drainage of pelvic region subcutaneous tissue and fascia, open approach
0J9D0ZZ	Drainage of right upper arm subcutaneous tissue and fascia, open approach
0J9F0ZZ	Drainage of left upper arm subcutaneous tissue and fascia, open approach
0J9G0ZZ	Drainage of right lower arm subcutaneous tissue and fascia, open approach
0J9H0ZZ	Drainage of left lower arm subcutaneous tissue and fascia, open approach
0J9J0ZZ	Drainage of right hand subcutaneous tissue and fascia, open approach
0J9K0ZZ	Drainage of left hand subcutaneous tissue and fascia, open approach
0J9L0ZZ	Drainage of right upper leg subcutaneous tissue and fascia, open approach
0J9M0ZZ	Drainage of left upper leg subcutaneous tissue and fascia, open approach
0J9N0ZZ	Drainage of right lower leg subcutaneous tissue and fascia, open approach
0J9P0ZZ	Drainage of left lower leg subcutaneous tissue and fascia, open approach
0J9Q0ZZ	Drainage of right foot subcutaneous tissue and fascia, open approach
0J9R0ZZ	Drainage of left foot subcutaneous tissue and fascia, open approach

In the FY 2022 final rule, we noted that the designation of the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia as O.R. procedures was a result of a replication error in transitioning to ICD–10. This replication error led to ICD–10–PCS procedure codes that describe the open drainage of subcutaneous tissue and fascia being listed as comparable translations for ICD–9–CM code 83.09 (Other incision of soft tissue), which was designated as a non-extensive O.R. procedure under the ICD–9–CM MS–DRGs Version 32, as opposed to being listed as comparable translations for ICD–9–CM code 86.04 (Other incision with drainage of skin and subcutaneous tissue) which was designated as a non-O.R. procedure under the ICD–9–CM MS–DRGs Version 32. We stated in the FY 2022 final rule that designating the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia as non-O.R. procedures would result in a more accurate replication of the comparable procedure, under the ICD–9–CM MS–DRGs Version 32 which was 86.04, not 83.09 and is more aligned with current shifts in treatment practices.

For this FY 2023 IPPS/LTCH PPS proposed rule, we received a request to re-examine this change in designation. According to the requestor, open procedures for the drainage of subcutaneous tissue and fascia are indeed typically performed in the operating room under general anesthesia and involve making incisions through the subcutaneous tissue into fascia for therapeutic drainage, breaking up of loculations, and irrigation. While our clinical advisors do not disagree with the requestor that these procedures can involve making incisions through the subcutaneous tissue into fascia, they continue to state procedures describing the open drainage of subcutaneous tissue and fascia can now be safely performed in the outpatient setting and when performed during a hospitalization, they are typically performed in conjunction with another O.R. procedure. For the reasons discussed in the FY 2022 final rule, our clinical advisors state that the non-O.R. designation of the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia as finalized in the FY 2022 final rule better reflects the associated technical complexity and hospital resource use of these procedures.

13. Proposed Changes to the MS–DRG Diagnosis Codes for FY 2023

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses

that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length-of-stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (NonCC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. Of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. Overview of Comprehensive CC/MCC Analysis

In the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes. The categorization of diagnoses as a MCC, a CC, or a NonCC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our approach. Since the comprehensive analysis was completed for FY 2008, we have evaluated diagnosis codes individually when assigning severity levels to new codes and when receiving requests to change the severity level of specific diagnosis codes.

We noted in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235 through 19246) that with the transition to ICD–10–CM and the significant changes that have occurred to diagnosis codes since the FY 2008 review, we believed it was necessary to conduct a comprehensive analysis once again. Based on this analysis, we proposed changes to the severity level designations for 1,492 ICD–10–CM diagnosis codes and invited public comments on those proposals. As summarized in the FY 2020 IPPS/LTCH PPS final rule, many commenters expressed concern with the proposed severity level designation changes overall and recommended that CMS conduct further analysis prior to finalizing any proposals. After careful consideration of the public comments we received, as discussed further in the FY 2020 final rule, we generally did not finalize our proposed changes to the severity designations for the ICD–10–CM diagnosis codes, other than the changes to the severity level designations for the diagnosis codes in category Z16- (Resistance to antimicrobial drugs) from a NonCC to a CC. We stated that postponing adoption of the proposed comprehensive changes in the severity level designations would allow further opportunity to provide additional background to the public on the methodology utilized and clinical rationale applied across diagnostic categories to assist the public in its review. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42150 through 42152) for a complete discussion of our response to public comments regarding the proposed severity level designation changes for FY 2020.

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32550), to provide the public with more information on the CC/MCC comprehensive analysis discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules, CMS hosted a listening session on October 8, 2019. The listening session included a review of this methodology utilized to mathematically measure the impact on resource use. We refer readers to *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/Downloads/10082019ListingSessionTrasncriptandQandAsandAudioFile.zip* for the transcript and audio file of the listening session. We also refer readers to *https://www.cms.gov/Medicare/MedicareFee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* for the supplementary file containing the mathematical data generated using claims from the FY 2018 MedPAR file describing the impact on resource use of specific ICD–10–CM diagnosis codes when reported as a secondary diagnosis that was made available for the listening session.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58550 through 58554), we discussed our plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of nine guiding principles and plan to present the findings and proposals in future rulemaking. The nine guiding principles are as follows:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.
- Denotes organ system instability or failure.
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.
- Serves as a marker for advanced disease states across multiple different comorbid conditions.
- Reflects systemic impact.
- Post-operative/post-procedure condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).
- Impedes patient cooperation or management of care or both.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

We refer readers to the FY 2021 IPPS/LTCH PPS final rule for a complete discussion of our response to public comments regarding the nine guiding principles.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25175 through 25180), as another interval step in our comprehensive review of the severity designations of ICD–10–CM diagnosis codes, we requested public comments on a potential change to the severity level designations for ''unspecified'' ICD–10–CM diagnosis codes that we were considering adopting for FY 2022. Specifically, we noted we were considering changing the severity level designation of ''unspecified'' diagnosis codes to a NonCC where there are other codes available in that code subcategory that further specify the anatomic site. As summarized in the FY 2022 IPPS/LTCH PPS final rule, many commenters expressed concern with the potential severity level designation changes overall and recommended that CMS delay any possible change to the designation of these codes to give hospitals and their physicians time to prepare. After careful consideration of the public comments we received, we maintained the severity level designation of the ''unspecified'' diagnosis codes currently designated as a CC or MCC where there are other codes available in that code subcategory that further specify the anatomic site for

FY 2022. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44916 through 44926) for a complete discussion of our response to public comments regarding the potential severity level designation changes. Instead, for FY 2022, we finalized a new Medicare Code Editor (MCE) code edit for ''unspecified'' codes, effective with discharges on and after April 1, 2022. We stated we believe finalizing this new edit would provide additional time for providers to be educated while not affecting the payment the provider is eligible to receive. We refer the reader to section II.D.14.e. of the FY 2022 IPPS/LTCH PPS final rule (86 FR 44940 through 44943) for the complete discussion.

As this new edit will be effective beginning with discharges on and after April 1, 2022, our clinical advisors believe at this time, it is appropriate to not propose to change the designation of any ICD–10–CM diagnosis codes, including the unspecified codes that are subject to the ''Unspecified Code'' edit, as we continue our comprehensive CC/MCC analysis to allow stakeholders the time needed to become acclimated to the new edit.

We continue to solicit feedback regarding the guiding principles, as well as other possible ways we can incorporate meaningful indicators of clinical severity. We have made available on the CMS website updated impact on resource use files so that the public can review the mathematical data for the impact on resource use generated using claims from the FY 2019 MedPAR file, the FY 2020 MedPAR file and the FY 2021 MedPAR files. The link to these files is posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.* When providing additional feedback or comments, we encourage the public to provide a detailed explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code. We also continue to be interested in receiving feedback on how we might otherwise foster the documentation and reporting of the most specific diagnosis codes supported by the available medical record documentation and clinical knowledge of the patient's health condition to more accurately reflect each health care encounter and improve the reliability and validity of the coded data.

For new diagnosis codes approved for FY 2023, consistent with our annual process for designating a severity level (MCC, CC or NonCC) for new diagnosis codes, we first review the predecessor code designation, followed by review and consideration of other factors that may be relevant to the severity level designation, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis or treatment of the condition. We note that this process does not automatically result in the new diagnosis code having the same designation as the predecessor code. We refer the reader to section II.D.14 of this proposed rule for the discussion of the proposed changes to the ICD–10–CM and ICD–10–PCS coding systems for FY 2023.

c. Requested Changes to Severity Levels

For this FY 2023 IPPS/LTCH PPS proposed rule, we received several requests to change the severity level designations of specific ICD–10–CM diagnosis codes, including a request to analyze a subset of the social determinants of health (SDOH) diagnosis codes. Our clinical advisors believe it is appropriate to consider these requests in connection with our continued comprehensive CC/MCC analysis in future rulemaking, rather than proposing to change the designation of individual ICD–10–CM diagnosis codes at this time. However, we refer the reader to section II.D.13.d for further discussion related to the diagnosis codes describing social determinants of health. As stated earlier in this section, we plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data and the application of nine guiding principles. We will consider these individual requests received for changes to severity level designations as we continue our comprehensive CC/MCC analysis and will provide more detail in future rulemaking.

d. Request for Information on Social Determinants of Health Diagnosis Codes

For this FY 2023 IPPS/LTCH PPS proposed rule, we are soliciting public comments on how the reporting of diagnosis codes in categories Z55–Z65 may improve our ability to recognize severity of illness, complexity of illness, and/or utilization of resources under the MS–DRGs as described further in this section. Consistent with the Administration's goal of advancing health equity for all, including members of historically underserved and under-resourced communities, as described in the President's January 20, 2021 Executive Order 13985 on ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' [10] we are also interested in receiving feedback on how we might otherwise foster the documentation and reporting of the diagnosis codes describing social and economic circumstances to more accurately reflect each health care encounter and improve the reliability and validity of the coded data including in support of efforts to advance health equity.

Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.[11] These circumstances or determinants influence an individual's health status and can contribute to wide health disparities and inequities. While SDOH do not describe current illnesses or injuries at the individual level, they are widely recognized as important potential predictors of risk for developing medical conditions like heart disease, diabetes, and obesity. In ICD–10–CM, the Z codes found in Chapter 21 represent reasons for encounters, and are provided for occasions when circumstances other than a disease, injury or external cause classifiable to categories A00–Y89 are recorded as 'diagnoses' or 'problems'. The subset of Z codes that describe the social determinants of health are found in categories Z55–Z65 (Persons with potential health hazards related to socioeconomic and psychosocial circumstances). These codes describe a range of issues related—but not limited—to education and literacy, employment, housing, ability to obtain adequate amounts of food or safe drinking water, and occupational exposure to toxic agents, dust, or radiation. Effective October 1, 2021, the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS) added 11 new diagnosis codes describing SDOH to provide additional information regarding determinants such as housing, food insecurity, and transportation. In addition, section I.B.14 of the FY 2022 ICD–10–CM Official Guidelines for Coding and Reporting was updated to provide clarification of the term ''clinician'' in reporting codes related to social determinants of health and clarified the documentation that can be

[10] 86 FR 7009 (January 25, 2021). *Available at: https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[11] *Available at: https://health.gov/healthypeople/objectives-and-data/social-determinants-health.*

utilized to assign SDOH codes when included in the official medical record. In this context, ''clinicians'' other than the patient's provider refer to ''healthcare professionals permitted, based on regulatory or accreditation requirements or internal hospital policies, to document in a patient's official medical record.'' [12]

Reporting SDOH Z codes in inpatient claims data could enhance quality improvement activities, track factors that influence people's health, and provide further insight into existing health inequities. [13] [14] [15] More routine collection of SDOH Z codes could also likely improve coordination within hospitals to utilize the data across their clinical care and discharge planning teams, including with post-acute partners. CMS has heard from stakeholders about a number of reasons for why there may be less routine documentation and reporting of SDOH in the inpatient setting. First, Z codes are not required to be reported by inpatient hospitals and generally do not affect MS–DRG assignment. Rather, these codes are currently reported voluntarily by providers when and if supported in the medical record documentation. As such, consistent protocols may not be in place for documenting and reporting. Second, many of the circumstances captured through SDOH Z codes are dependent on the willingness of patients to discuss personal social, economic, or environmental conditions. Providers may or may not be able to reliably document certain circumstances,[16] as a result, in the medical records. There are also questions of how bias can play into screening for SDOH and how systemic bias within the health care system can play a role in this process.[17] CMS has also heard of the significant pressures on provider time, and whether providers have access to comprehensive care and coordination teams, including social workers, who may be more appropriately skilled to assess certain SDOH.

Given that SDOH diagnosis codes describe economic and environmental circumstances faced by patients and often correlate with substantial variance in health outcomes,[18] more widely adopted consistent documentation and reporting in the inpatient setting could better identify non-medical factors affecting health and track progress toward addressing them. Doing so could also aid in work toward formulating more comprehensive and actionable policies to address health equity and promote the highest quality, best-value care for all beneficiaries.

As we discuss more fully later in this section, we believe reporting of SDOH Z codes may also better determine the resource utilization for treating patients experiencing these circumstances to help inform whether a change to the severity designation of these codes would be clinically warranted as we continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of nine guiding principles.

There are 96 diagnosis codes that describe the social determinants of health found in categories Z55–Z65. These 96 diagnosis codes for which we are soliciting comments as described in this proposed rule are shown in Table 6P.5a (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*). We note we are also making available the data describing the impact on resource use when reported as a secondary diagnosis for all 96 ICD–10–CM Z codes that describe the social determinants of health from categories Z55–Z65. These data are consistent with data historically used to mathematically measure impact on resource use for secondary diagnoses, and the data which we plan to use in combination with application of the nine guiding principles as we continue the comprehensive CC/MCC analysis.

In Table 6P.5a associated with this proposed rule, column C displays the FY 2021 severity level designation for these diagnosis codes in MS–DRG GROUPER Version 38.1. Column D displays CMS's current FY 2022 severity level designation in MS–DRG GROUPER Version 39.1. Columns E—N show data on the impact on resource use generated using discharge claims from the September 2021 update of the FY 2021 MedPAR file and MS–DRG GROUPER Version 39.1. For further information on the data on the impact on resource use as displayed in Columns E—N, we refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of the methodology utilized to mathematically measure the impact on resource use. Also, as discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32550), to provide the public with more information on the CC/MCC comprehensive analysis discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules, CMS hosted a listening session on October 8, 2019. The listening session included a review of this methodology utilized to mathematically measure the impact on resource use. We refer readers to *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/Downloads/10082019ListingSessionTrasncriptandQandAsandAudioFile.zip* for the transcript and audio file of the listening session. We also refer readers to *https://www.cms.gov/Medicare/MedicareFee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* for the supplementary file containing the data describing the impact on resource use of specific ICD–10–CM diagnosis codes when reported as a secondary diagnosis that was made available for the listening session. We note that the supplementary file that was made available for the listening session contains the mathematical data for the impact on resource use generated using claims from the FY 2018 MedPAR file. We have also made available on the CMS website updated impact on resource use files so that the public can review the mathematical data for the impact on resource use generated using claims from the FY 2019 MedPAR file, FY 2020 MedPAR file and the FY 2021 MedPAR files.

In the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described the categorization of diagnoses as an MCC, a CC, or a NonCC, accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a

[12] *Available at: https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2022/10cmguidelines-FY2022-April%201%20update%202-3-22.pdf.*

[13] Maksut JL, Hodge C, Van CD, Razmi, A, & Khau MT. Utilization of Z Codes for Social Determinants of Health among Medicare Fee-For-Service Beneficiaries, 2019. Office of Minority Health (OMH) Data Highlight No. 24. Centers for Medicare & Medicaid Services (CMS), Baltimore, MD, 2021.

[14] Truong HP, Luke AA, Hammond G, Wadhera RK, Reidhead M, Joynt Maddox KE. Utilization of Social Determinants of Health ICD–10 Z-Codes Among Hospitalized Patients in the United States, 2016–2017. Med Care. 2020;58(12):1037–1043. doi:10.1097/MLR.0000000000001418.

[15] Wark K, Cheung K, Wolter E, Avey JP. Engaging stakeholders in integrating social determinants of health into electronic health records: A scoping review. International Journal of Circumpolar Health. 2021 Jan 1;80(1):1943983.

[16] Garg A, Boynton-Jarrett R, Dworkin PH. Avoiding the Unintended Consequences of Screening for Social Determinants of Health. JAMA. 2016;316(8):813–814. doi:10.1001/jama.2016.9282

[17] Egede LE, Walker RJ, Williams JS. Intersection of Structural Racism, Social Determinants of Health, and Implicit Bias With Emergency Physician Admission Tendencies. JAMA Netw Open. 2021;4(9):e2126375. doi:10.1001/jamanetworkopen.2021.26375

[18] Commission on Social Determinants of Health. *Closing the gap in a generation: Health equity through action on the social determinants of health: Final report of the commission on social determinants of health.* World Health Organization, 2008.

secondary diagnosis resulted in increased hospital resource use. As such, the designation of CC or MCC is intended to account for the increased resources required to address a condition as a secondary diagnosis. In Version 39.1, the 96 diagnosis codes that describe the social determinants of health from categories Z55–Z65 have a severity designation of NonCC.

If SDOH Z codes are not consistently reported in inpatient claims data, our methodology utilized to mathematically measure the impact on resource use, as described previously, may not adequately reflect what additional resources were expended by the hospital to address these SDOH circumstances in terms of requiring clinical evaluation, extended length of hospital stay, increased nursing care or monitoring or both, and comprehensive discharge planning. We seek public comment on whether CMS should consider requiring more robust documentation and claims data reporting to inform the impact on resource use these determinants have on caring for patients affected by these circumstances in an inpatient setting and inform our decision-making in a future year in determining the most appropriate CC subclass (NonCC, CC, or MCC) assignment for each SDOH Z code as a secondary diagnosis. We also seek public comment on developing protocols to standardize the screening for SDOH for all patients, and then consistently document and report such codes and on whether such protocols should vary based on certain factors, such as hospital size and type. For instance, we recognize that hospitals have different mixes of patients and volume of patients, and as such, may have different staffing resources to devote to proper documentation and coding of SDOH. In particular, we are interested in hearing the perspectives of different sized hospitals in both urban and rural settings, and hospitals disproportionately serving members of historically underserved and under-resourced communities in regard to their experience with reporting of SDOH. We are additionally interested in learning how reporting SDOH Z codes may be used to inform community health need assessment activities required by non-profit hospitals.

We also recognize that there is a potential for different uses and complexity in appropriately determining and reporting the full range of Z codes. For instance, certain code categories like Z62 (Problems related to upbringing) and Z63 (Other problems related to principal support group, including family circumstances) may require specialized clinical training to diagnose and document, which may not be the primary purpose of the inpatient admission. Category Z57 describes occupational exposure to risk factors, which also may not be apparent in most inpatient admissions and would rely upon the patient providing this information voluntarily. Category Z60 (Problems related to social environment) also describes problems of adjustment to life-cycle transitions, which also may or may not be readily apparent or discussed by the patient in relation to the inpatient admission.

Thus, we are seeking comment on which specific SDOH Z codes are most likely to influence (that is, increase) hospital resource utilization related to inpatient care, including any supporting information that correlates inpatient hospital resource use to specific SDOH Z codes. CMS believes a potential starting point for discussion is consideration of the SDOH Z diagnosis codes describing homelessness. Homelessness can be reasonably expected to have an impact on hospital utilization.[19] Healthcare needs for patients experiencing homelessness may be associated with increased resource utilization compared to other patients due to difficulty finding discharge destinations to meet the patient's multifaceted needs which can result in longer inpatient stays and can have financial impacts for hospitals.[20] Longer hospital stays for these patients [21] can also be associated with increased costs because patients experiencing homelessness are less able to access care at early stages of illness, and also may be exposed to communicable disease and harsh climate conditions, resulting in more severe and complex symptoms by the time they are admitted to hospitals, potentially leading to worse health outcomes. Patients experiencing homelessness can also be disproportionately affected by mental health diagnoses and issues with substance use disorders. In addition, patients experiencing homelessness may have limited or no access to prescription medicines or over-the-counter medicines, including adequate locations to store medications away from the heat or cold,[22] and studies have shown difficulties adhering to medication regimens among persons experiencing homeless.[23] Patients experiencing homelessness may also face challenges in accessing transplants and clinicians may defer care because of the uncertain post-acute discharge.

To further examine the diagnosis codes that describe SDOH, we reviewed the data on the impact on resource use for diagnosis code Z59.0 (Homelessness) when reported as a secondary diagnosis to facilitate discussion for the purposes of this comment solicitation. We note that prior to FY 2022, homelessness was one of the more frequently reported codes that describe social determinants of health. We also note that effective FY 2022, this subcategory has been expanded and now includes codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and code Z59.02 (Unsheltered homelessness).

In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19243 through 19244), as part of our proposal to change the severity level designations for 1,492 ICD–10–CM diagnosis codes, we proposed to change the severity level designation of code Z59.0 (Homelessness) from NonCC to CC. We stated that because the C1 value (C1 = 1.5964) in the table was generally close to 2, the data suggested that when reported as a secondary diagnosis, the resources involved in caring for a patient experiencing homelessness supported increasing the severity level from a NonCC to a CC. In the FY 2020 IPPS/LTCH PPS proposed rule, we also stated our clinical advisors reviewed these data and believed the resources involved in caring for these patients are more aligned with a CC. As noted in section II.D.13.b of this proposed rule, many commenters expressed concern with the proposed severity level designation changes overall and consequently we generally did not finalize our proposed changes to the severity designations for the 1,492 ICD–10–CM diagnosis codes, at that time.

[19] Koh HK, O'Connell JJ. Improving Health Care for Homeless People. JAMA. 2016;316(24):2586–2587. doi:10.1001/jama.2016.18760.

[20] Canham SL, Custodio K, Mauboules C, Good C, Bosma H. Health and Psychosocial Needs of Older Adults Who Are Experiencing Homelessness Following Hospital Discharge. Gerontologist. 2020 May 15;60(4):715–724. doi: 10.1093/geront/gnz078. PMID: 31228238. *https://pubmed.ncbi.nlm.nih.gov/31228238/.*

[21] Hwang SW, Weaver J, Aubry T. Hospital costs and length of stay among homeless patients admitted to medical, surgical, and psychiatric services. Med Care. 2011;49:350–354. *https://journals.lww.com/lww-medicalcare/Fulltext/2019/01000/Trends,_Causes,_and_Outcomes_of_Hospitalizations.4.aspx.*

[22] Sun R (AHRQ), Karaca Z (AHRQ), Wong HS (AHRQ). Characteristics of Homeless Individuals Using Emergency Department Services in 2014. HCUP Statistical Brief #229. October 2017. Agency for Healthcare Research and Quality, Rockville, MD. *www.hcup-us.ahrq.gov/reports/statbriefs/sb229-Homeless-ED-Visits-2014.pdf.*

[23] Coe, Antoinette B. Coe et al. ''Medication Adherence Challenges Among Patients Experiencing Homelessness in a Behavioral Health Clinic. *https://journals.lww.com/lww-medicalcare/Fulltext/2019/01000/Trends,_Causes,_and_Outcomes_of_Hospitalizations.4.aspx.*

However, the proposal to change the severity designation of code Z59.0 specifically did receive mostly supportive comments. Many commenters stated that a patient experiencing homelessness requires significant coordination of social services along with their health care. One commenter also recommended that CMS expand the change in designation to all the codes in category Z59, not just code Z59.0. Another commenter, while indicating their support of the proposal, noted that it is unclear that the status/condition would result in increased hospital resource use.

Our proposal in FY 2020 was based on the data for the impact on resource use generated using claims from the FY 2018 MedPAR file. The following table reflects the impact on resource use data generated using claims from the FY 2019 MedPAR file, FY 2020 MedPAR file and the FY 2021 MedPAR file, respectively, for the diagnosis code that describes homelessness as a NonCC. We note there is currently no data for codes Z59.01 (Sheltered homelessness) and code Z59.02 (Unsheltered homelessness) as these codes became effective on October 1, 2021. Again, we refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our historical approach to mathematically evaluate the extent to which the presence of an ICD–10–CM code as a secondary diagnosis resulted in increased hospital resource use, and the explanation of the columns in the table.

FY	ICD-10-CM Code	Description	Tota1 Count	Cnt1	C1	Cnt2	C2	Cnt3	C3
2019	Z59.0	Homelessness	43,405	7,022	1.6723	22,336	2.2963	14,047	3.1374
2020	Z59.0	Homelessness	44,609	6,393	1.8374	22,416	2.1964	15,800	3.0879
2021	Z59.00	Homelessness, unspecified	37,919	5,225	1.4299	18,158	2.0823	14,536	3.0710

As shown in the table, we examined data for the diagnosis code(s) that describe homelessness as a NonCC in FY 2019 through FY 2021. When examining diagnosis code Z59.0 (Homelessness), the value in column C1 is closer to 2.0 than to 1.0 in FY 2019 and FY 2020, though we note that we did not use FY 2020 data for rate setting purposes in light of impacts related to the PHE for COVID–19 as described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44778). The data suggests that when homelessness is reported as a secondary diagnosis, the resources involved in caring for these patients are more aligned with a CC than a NonCC or an MCC, as explained in the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159). However, in FY 2021, the C1 value is generally closer to 1, which suggest the resources involved in caring for patients experiencing homelessness are more aligned with a NonCC severity level than a CC or an MCC severity level. We also note fluctuations in the C1 values year to year. We are uncertain if the data from FY 2021, in particular, reflect fluctuations that may be a result of the public health emergency or even reduced hospitalizations of certain conditions. We also are uncertain if homelessness may be underreported when there is not an available field on the claim when other diagnoses are reported instead. We seek public comment on these possibilities, particularly to inform our understanding of the trend of the C1 value.

As we have stated in prior rulemaking, these mathematical constructs are used in conjunction with the judgment of our clinical advisors to classify each secondary diagnosis reviewed. We present these data to highlight that the resources expended in caring for patients reported to be affected by a SDOH such as homelessness during an inpatient hospitalization may not be consistently expressed in the inpatient claims data and to demonstrate how reporting the SDOH Z codes could more accurately reflect the health care encounter and improve the reliability and validity of the coded data.

In summary, we appreciate public comment on these issues, including on the following questions:

- How the reporting of certain Z codes—and if so, which Z codes [24]—may improve our ability to recognize severity of illness, complexity of illness, and utilization of resources under the MS–DRGs?
- Whether CMS should require the reporting of certain Z codes—and if so, which ones—to be reported on hospital inpatient claims to strengthen data analysis?
- The additional provider burden and potential benefits of documenting and reporting of certain Z codes, including potential benefits to beneficiaries.
- Whether codes in category Z59 (Homelessness) have been underreported and if so, why? In particular, we are interested in hearing the perspectives of large urban hospitals, rural hospitals, and other hospital types in regard to their experience. We also seek comments on how factors such as hospital size and type might impact a hospital's ability to develop standardized consistent protocols to better screen, document and report homelessness.

The comments we receive on these issues may also be informative as we evaluate whether to develop a proposal in future rulemaking to change the severity level designation of the diagnosis codes describing homelessness from NonCC to CC and whether other SDOH, as described by Z codes, are also appropriate candidates to be proposed for designation as CCs.

We note that examining the severity level designation of diagnosis codes is just one area to possibly support documentation and reporting of SDOH in the inpatient setting. We are also interested in ideas from the public on how the MS–DRG classification can be utilized in agency wide efforts to advance health equity, expand access, drive high-quality, person-centered care, and promote affordability and sustainability in the Medicare program. Specifically, we invite public comment on ways the MS–DRG classification can be useful in addressing the challenges of defining and collecting accurate and standardized self-identified socioeconomic information for the purposes of reporting, measure stratification, and other data collection efforts. We are interested in learning more about the potential benefits and challenges associated with the collection of SDOH data in the inpatient setting. Feedback on the limitations and barriers providers could experience as they consider more robust documentation and reporting would also help inform our development of appropriately tailored efforts that address and mitigate barriers for all hospital types across communities and patient mixes. We will take

[24] *https://www.cms.gov/files/document/zcodes-infographic.pdf.*

commenters' feedback into consideration in future policy development.

e. Proposed Additions and Deletions to the Diagnosis Code Severity Levels for FY 2023

The following tables identify the proposed additions and deletions to the diagnosis code MCC severity levels list and the proposed additions and deletions to the diagnosis code CC severity levels list for FY 2023 and are available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

Table 6I.1—Proposed Additions to the MCC List—FY 2023;

Table 6I.2—Proposed Deletions to the MCC List—FY 2023;

Table 6J.1—Proposed Additions to the CC List—FY 2023; and

Table 6J.2—Proposed Deletions to the CC List—FY 2023.

f. Proposed CC Exclusions List for FY 2023

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another.
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another.
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another.
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another.
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541 through 50544) for detailed information regarding revisions that were made to the CC and CC Exclusion Lists under the ICD–9–CM MS–DRGs.

The ICD–10 MS–DRGs Version 39.1 CC Exclusion List is included as Appendix C in the ICD–10 MS–DRG Definitions Manual, which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html,* and includes two lists identified as Part 1 and Part 2. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. For all diagnosis codes on the list, a link is provided to a collection of diagnosis codes which, when reported as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a NonCC. Part 2 is the list of diagnosis codes designated as a MCC only for patients discharged alive; otherwise, they are assigned as a NonCC.

We are proposing additional changes to the ICD–10 MS–DRGs Version 40 CC Exclusion List based on the diagnosis and procedure code updates as discussed in section II.D.14. of this FY 2023 IPPS/LTCH PPS proposed rule. Therefore, we have developed Table 6G.1.–Proposed Secondary Diagnosis Order Additions to the CC Exclusions List–FY 2023; Table 6G.2.–Proposed Principal Diagnosis Order Additions to the CC Exclusions List–FY 2023; Table 6H.1.–Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List–FY 2023; and Table 6H.2.–Proposed Principal Diagnosis Order Deletions to the CC Exclusions List–FY 2023. For Table 6G.1, each secondary diagnosis code proposed for addition to the CC Exclusion List is shown with an asterisk and the principal diagnoses proposed to exclude the secondary diagnosis code are provided in the indented column immediately following it. For Table 6G.2, each of the principal diagnosis codes for which there is a CC exclusion is shown with an asterisk and the conditions proposed for addition to the CC Exclusion List that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. For Table 6H.1, each secondary diagnosis code proposed for deletion from the CC Exclusion List is shown with an asterisk followed by the principal diagnosis codes that currently exclude it. For Table 6H.2, each of the principal diagnosis codes is shown with an asterisk and the proposed deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis. Tables 6G.1., 6G.2., 6H.1., and 6H.2. associated with this proposed rule are available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

14. Proposed Changes to the ICD–10–CM and ICD–10–PCS Coding Systems

To identify new, revised and deleted diagnosis and procedure codes, for FY 2023, we have developed Table 6A.–New Diagnosis Codes, Table 6B.–New Procedure Codes, Table 6C.–Invalid Diagnosis Codes, and Table 6E.–Revised Diagnosis Code Titles for this proposed rule. These tables are not published in the Addendum to this proposed rule, but are available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. Of the Addendum to this proposed rule. As discussed in section II.D.17. of the preamble of this proposed rule, the code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

We are proposing the MDC and MS–DRG assignments for the new diagnosis codes and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes. In addition, the proposed severity level designations for the new diagnosis codes are set forth in Table 6A. and the proposed O.R. status for the new procedure codes are set forth in Table 6B. Consistent with our established process, we examined the MS–DRG assignment and the attributes (severity level and O.R. status) of the predecessor diagnosis or procedure code, as applicable, to inform our proposed assignments and designations. Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the

severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis or treatment of the condition. We note that this process does not automatically result in the new diagnosis or procedure code being proposed for assignment to the same MS–DRG or to have the same designation as the predecessor code.

We are making available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* the following tables associated with this proposed rule:

- Table 6A.—New Diagnosis Codes–FY 2023
- Table 6B.—New Procedure Codes–FY 2023
- Table 6C.—Invalid Diagnosis Codes–FY 2023
- Table 6E.—Revised Diagnosis Code Titles–FY 2023
- Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List–FY 2023
- Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List–FY 2023
- Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List–FY 2023
- Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2023
- Table 6I.1.—Proposed Additions to the MCC List–FY 2023
- Table 6I.2.—Proposed Deletions to the MCC List–FY 2023
- Table 6J.1.—Proposed Additions to the CC List–FY 2023
- Table 6J.2.—Proposed Deletions to the CC List–FY 2023.

15. Proposed Changes to the Medicare Code Editor (MCE)

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44936), we made available the FY 2022 ICD–10 MCE Version 39 manual file. The manual contains the definitions of the Medicare code edits, including a description of each coding edit with the corresponding diagnosis and procedure code edit lists. The link to this MCE manual file, along with the link to the mainframe and computer software for the MCE Version 39 (and ICD–10 MS–DRGs) are posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

For this FY 2023 IPPS/LTCH PPS proposed rule, we discuss the proposals we are making based on our internal review and analysis. We did not receive any specific MCE requests by the November 1, 2021 deadline.

a. External Causes of Morbidity Codes as Principal Diagnosis

In the MCE, the external cause codes (V, W, X, or Y codes) describe the circumstance causing an injury, not the nature of the injury, and therefore should not be used as a principal diagnosis.

As discussed in section II.D.14. of the preamble of this proposed rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2022. Included in this table are codes currently subject to the External causes of morbidity codes as principal diagnosis edit. We are proposing to delete the ICD–10–CM diagnosis codes shown in Table 6P.6a associated with this proposed rule and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* that are currently subject to the External causes of morbidity codes as principal diagnosis edit since they will no longer be valid for reporting purposes.

b. Age Conflict Edit

In the MCE, the Age conflict edit exists to detect inconsistencies between a patient's age and any diagnosis on the patient's record; for example, a 5-year-old patient with benign prostatic hypertrophy or a 78-year-old patient coded with a delivery. In these cases, the diagnosis is clinically and virtually impossible for a patient of the stated age. Therefore, either the diagnosis or the age is presumed to be incorrect. Currently, in the MCE, the following four age diagnosis categories appear under the Age conflict edit and are listed in the manual and written in the software program:

- Perinatal/Newborn—Age 0 years only; a subset of diagnoses which will only occur during the perinatal or newborn period of age 0 (for example, tetanus neonatorum, health examination for newborn under 8 days old).
- Pediatric—Age is 0–17 years inclusive (for example, Reye's syndrome, routine child health exam).
- Maternity—Age range is 9–64 years inclusive (for example, diabetes in pregnancy, antepartum pulmonary complication).
- Adult—Age range is 15–124 years inclusive (for example, senile delirium, mature cataract).

(1) Maternity Diagnoses

Under the ICD–10 MCE, the Maternity diagnoses category for the Age conflict edit considers the age range of 9 to 64 years inclusive. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

As discussed in section II.D.14. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes, lists the diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2022. We are proposing to add new ICD–10–CM diagnosis codes to the edit code list for the Maternity diagnoses category as shown in Table 6P.6b associated with this proposed rule and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* under the Age conflict edit.

In addition, as discussed in section II.D.14. of the preamble of this proposed rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2022. Included in this table are the following ICD–10–CM diagnosis codes that are currently listed on the edit code list for the Maternity diagnoses category under the Age conflict edit. We are proposing to delete these codes from the Maternity diagnoses edit code list.

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ICD-10-CM Code	Description
O35.0XX0	Maternal care for (suspected) central nervous system malformation in fetus, not applicable or unspecified
O35.0XX1	Maternal care for (suspected) central nervous system malformation in fetus, fetus 1
O35.0XX2	Maternal care for (suspected) central nervous system malformation in fetus, fetus 2
O35.0XX3	Maternal care for (suspected) central nervous system malformation in fetus, fetus 3
O35.0XX4	Maternal care for (suspected) central nervous system malformation in fetus, fetus 4
O35.0XX5	Maternal care for (suspected) central nervous system malformation in fetus, fetus 5
O35.0XX9	Maternal care for (suspected) central nervous system malformation in fetus, other fetus
O35.1XX0	Maternal care for (suspected) chromosomal abnormality in fetus, not applicable or unspecified
O35.1XX1	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 1
O35.1XX2	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 2
O35.1XX3	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 3
O35.1XX4	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 4
O35.1XX5	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 5
O35.1XX9	Maternal care for (suspected) chromosomal abnormality in fetus, other fetus

(2) Adult Diagnoses

Under the ICD–10 MCE, the Adult diagnoses category for the Age conflict edit considers the age range of 15 to 124 years inclusive. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

As discussed in section II.D.14. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes, lists the diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2022. We are proposing to add the following new ICD–10–CM diagnosis codes to the edit code list for the Adult diagnoses category under the Age conflict edit.

ICD-10-CM Code	Description
F01.511	Vascular dementia, unspecified severity, with agitation
F01.518	Vascular dementia, unspecified severity, with other behavioral disturbance
F01.52	Vascular dementia, unspecified severity, with psychotic disturbance
F01.53	Vascular dementia, unspecified severity, with mood disturbance
F01.54	Vascular dementia, unspecified severity, with anxiety
F01.A0	Vascular dementia, mild, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F01.A11	Vascular dementia, mild, with agitation
F01.A18	Vascular dementia, mild, with other behavioral disturbance
F01.A2	Vascular dementia, mild, with psychotic disturbance
F01.A3	Vascular dementia, mild, with mood disturbance
F01.A4	Vascular dementia, mild, with anxiety
F01.B0	Vascular dementia, moderate, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F01.B11	Vascular dementia, moderate, with agitation
F01.B18	Vascular dementia, moderate, with other behavioral disturbance
F01.B2	Vascular dementia, moderate, with psychotic disturbance
F01.B3	Vascular dementia, moderate, with mood disturbance
F01.B4	Vascular dementia, moderate, with anxiety
F01.C0	Vascular dementia, severe, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F01.C11	Vascular dementia, severe, with agitation
F01.C18	Vascular dementia, severe, with other behavioral disturbance
F01.C2	Vascular dementia, severe, with psychotic disturbance
F01.C3	Vascular dementia, severe, with mood disturbance
F01.C4	Vascular dementia, severe, with anxiety
F03.911	Unspecified dementia, unspecified severity, with agitation
F03.918	Unspecified dementia, unspecified severity, with other behavioral disturbance
F03.92	Unspecified dementia, unspecified severity, with psychotic disturbance
F03.93	Unspecified dementia, unspecified severity, with mood disturbance
F03.94	Unspecified dementia, unspecified severity, with anxiety
F03.A0	Unspecified dementia, mild, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F03.A11	Unspecified dementia, mild, with agitation
F03.A18	Unspecified dementia, mild, with other behavioral disturbance
F03.A2	Unspecified dementia, mild, with psychotic disturbance
F03.A3	Unspecified dementia, mild, with mood disturbance
F03.A4	Unspecified dementia, mild, with anxiety
F03.B0	Unspecified dementia, moderate, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F03.B11	Unspecified dementia, moderate, with agitation
F03.B18	Unspecified dementia, moderate, with other behavioral disturbance
F03.B2	Unspecified dementia, moderate, with psychotic disturbance
F03.B3	Unspecified dementia, moderate, with mood disturbance
F03B4	Unspecified dementia, moderate, with anxiety
F03.C0	Unspecified dementia, severe, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F03.C11	Unspecified dementia, severe, with agitation
F03.C18	Unspecified dementia, severe, with other behavioral disturbance
F03.C2	Unspecified dementia, severe, with psychotic disturbance
F03.C3	Unspecified dementia, severe, with mood disturbance
F03.C4	Unspecified dementia, severe, with anxiety
I25.112	Atherosclerotic heart disease of native coronary artery with refractory angina pectoris
I25.702	Atherosclerosis of coronary artery bypass graft(s), unspecified, with refractory angina pectoris
I25.712	Atherosclerosis of autologous vein coronary artery bypass graft(s) with refractory angina pectoris
I25.722	Atherosclerosis of autologous artery coronary artery bypass graft(s) with refractory angina pectoris
I25.732	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with refractory angina pectoris
I25.752	Atherosclerosis of native coronary artery of transplanted heart with refractory angina pectoris
I25.762	Atherosclerosis of bypass graft of coronary artery of transplanted heart with refractory angina pectoris
I25.792	Atherosclerosis of other coronary artery bypass graft(s) with refractory angina pectoris

In addition, as discussed in section II.D.14. of the preamble of this proposed rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2022. Included in this table are the following ICD–10–CM diagnosis codes that are currently listed on the edit code list for the Adult diagnoses category under the Age conflict edit. We are proposing to delete these codes from the Adult diagnoses edit code list.

ICD-10-CM Code	Description
F01.51	Vascular dementia with behavioral disturbance
F03.91	Unspecified dementia with behavioral disturbance

c. Sex Conflict Edit

In the MCE, the Sex conflict edit detects inconsistencies between a patient's sex and any diagnosis or procedure on the patient's record; for example, a male patient with cervical cancer (diagnosis) or a female patient with a prostatectomy (procedure). In both instances, the indicated diagnosis or the procedure conflicts with the stated sex of the patient. Therefore, the patient's diagnosis, procedure, or sex is presumed to be incorrect.

(1) Diagnoses for Females Only Edit

As discussed in section II.D.14. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2022. We are proposing to add new ICD–10–CM diagnosis codes to the edit code list for the Diagnoses for females only category as shown in Table 6P.6c associated with this proposed rule and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* under the Sex conflict edit.

In addition, as discussed in section II.D.14. of the preamble of this proposed rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2022. Included in this table are the following ICD–10–CM diagnosis codes that are currently listed on the edit code list for the Diagnoses for females only category under the Sex conflict edit. We are proposing to delete these codes from the Diagnoses for females only edit code list.

ICD-10-CM Code	Description
B37.3	Candidiasis of vulva and vagina
N80.0	Endometriosis of uterus
N80.1	Endometriosis of ovary
N80.2	Endometriosis of fallopian tube
N80.3	Endometriosis of pelvic peritoneum
N80.4	Endometriosis of rectovaginal septum and vagina
N80.5	Endometriosis of intestine
O35.0XX0	Maternal care for (suspected) central nervous system malformation in fetus, not applicable or unspecified
O35.0XX1	Maternal care for (suspected) central nervous system malformation in fetus, fetus 1
O35.0XX2	Maternal care for (suspected) central nervous system malformation in fetus, fetus 2
O35.0XX3	Maternal care for (suspected) central nervous system malformation in fetus, fetus 3
O35.0XX4	Maternal care for (suspected) central nervous system malformation in fetus, fetus 4
O35.0XX5	Maternal care for (suspected) central nervous system malformation in fetus, fetus 5
O35.0XX9	Maternal care for (suspected) central nervous system malformation in fetus, other fetus
O35.1XX0	Maternal care for (suspected) chromosomal abnormality in fetus, not applicable or unspecified
O35.1XX1	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 1
O35.1XX2	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 2
O35.1XX3	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 3
O35.1XX4	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 4
O35.1XX5	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 5
O35.1XX9	Maternal care for (suspected) chromosomal abnormality in fetus, other fetus

(2) Procedures for Males Only

As discussed in section II.D.14. of the preamble of this proposed rule, Table 6B.—New Procedure Codes, lists the new procedure codes that have been approved to date which will be effective with discharges on and after October 1, 2022. Included in this table are the following procedure codes we are proposing to add to the edit code list for the Procedures for males only category under the Sex conflict edit.

ICD-10-PCS Code	Code Description
04LE0CV	Occlusion of right prostatic artery with extraluminal device, open approach
04LE0DV	Occlusion of right prostatic artery with intraluminal device, open approach
04LE0ZV	Occlusion of right prostatic artery, open approach
04LE3CV	Occlusion of right prostatic artery with extraluminal device, percutaneous approach
04LE3DV	Occlusion of right prostatic artery with intraluminal device, percutaneous approach
04LE3ZV	Occlusion of right prostatic artery, percutaneous approach
04LE4CV	Occlusion of right prostatic artery with extraluminal device, percutaneous endoscopic approach
04LE4DV	Occlusion of right prostatic artery with intraluminal device, percutaneous endoscopic approach
04LE4ZV	Occlusion of right prostatic artery, percutaneous endoscopic approach
04LF0CW	Occlusion of left prostatic artery with extraluminal device, open approach
04LF0DW	Occlusion of left prostatic artery with intraluminal device, open approach
04LF0ZW	Occlusion of left prostatic artery, open approach
04LF3CW	Occlusion of left prostatic artery with extraluminal device, percutaneous approach
04LF3DW	Occlusion of left prostatic artery with intraluminal device, percutaneous approach
04LF3ZW	Occlusion of left prostatic artery, percutaneous approach
04LF4CW	Occlusion of left prostatic artery with extraluminal device, percutaneous endoscopic approach
04LF4DW	Occlusion of left prostatic artery with intraluminal device, percutaneous endoscopic approach
04LF4ZW	Occlusion of left prostatic artery, percutaneous endoscopic approach

d. Manifestation Code as Principal Diagnosis Edit

In the ICD–10–CM classification system, manifestation codes describe the manifestation of an underlying disease, not the disease itself, and therefore should not be used as a principal diagnosis.

As discussed in section II.D.14. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2022. Included in this table are the following new ICD–10–CM diagnosis codes that we are proposing to add to the edit code list for the Manifestation code as principal diagnosis edit, because the disease itself would be required to be reported first.

ICD-10-CM Code	Description
F02.811	Dementia in other diseases classified elsewhere, unspecified severity, with agitation
F02.818	Dementia in other diseases classified elsewhere, unspecified severity, with other behavioral disturbance
F02.82	Dementia in other diseases classified elsewhere, unspecified severity, with psychotic disturbance
F02.83	Dementia in other diseases classified elsewhere, unspecified severity, with mood disturbance
F02.84	Dementia in other diseases classified elsewhere, unspecified severity, with anxiety
F02.A0	Dementia in other diseases classified elsewhere, mild, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F02.A11	Dementia in other diseases classified elsewhere, mild, with agitation
F02.A18	Dementia in other diseases classified elsewhere, mild, with other behavioral disturbance
F02.A2	Dementia in other diseases classified elsewhere, mild, with psychotic disturbance
F02.A3	Dementia in other diseases classified elsewhere, mild, with mood disturbance
F02.A4	Dementia in other diseases classified elsewhere, mild, with anxiety
F02.B0	Dementia in other diseases classified elsewhere, moderate, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F02.B11	Dementia in other diseases classified elsewhere, moderate, with agitation
F02.B18	Dementia in other diseases classified elsewhere, moderate, with other behavioral disturbance
F02.B2	Dementia in other diseases classified elsewhere, moderate, with psychotic disturbance
F02.B3	Dementia in other diseases classified elsewhere, moderate, with mood disturbance
F02.B4	Dementia in other diseases classified elsewhere, moderate, with anxiety
F02.C0	Dementia in other diseases classified elsewhere, severe, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F02.C11	Dementia in other diseases classified elsewhere, severe, with agitation
F02.C18	Dementia in other diseases classified elsewhere, severe, with other behavioral disturbance
F02.C2	Dementia in other diseases classified elsewhere, severe, with psychotic disturbance
F02.C3	Dementia in other diseases classified elsewhere, severe, with mood disturbance
F02.C4	Dementia in other diseases classified elsewhere, severe, with anxiety
I31.31	Malignant pericardial effusion in diseases classified elsewhere

In addition, as discussed in section II.D.14. of the preamble of this proposed rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2022. Included in this table is ICD–10–CM diagnosis code F02.81 (Dementia in other diseases classified elsewhere with behavioral disturbance), that is currently listed on the edit code list for the Manifestation code as principal diagnosis edit. We are proposing to delete this code from the Manifestation code as principal diagnosis edit code list.

e. Unacceptable Principal Diagnosis Edit

In the MCE, there are select codes that describe a circumstance which influences an individual's health status but does not actually describe a current illness or injury. There also are codes that are not specific manifestations but may be due to an underlying cause. These codes are considered unacceptable as a principal diagnosis. In limited situations, there are a few codes on the MCE Unacceptable Principal Diagnosis edit code list that are considered ''acceptable'' when a specified secondary diagnosis is also coded and reported on the claim.

As discussed in section II.D.14. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2022. We are proposing to add the following new ICD–10–CM diagnosis codes to the Unacceptable Principal Diagnosis edit code list.

As discussed in section II.D.1.b. of the preamble of this proposed rule, we are providing a test version of the ICD–10 MS–DRG GROUPER Software, Version 40, so that the public can better analyze and understand the impact of the proposals included in this proposed rule. We note that at the time of the development of the test software, a subset of the listed codes (F01.511 through F01.C4) proposed for this edit were unable to be included and therefore, the test software does not reflect these codes.

ICD-10-CM Code	Description
F01.511	Vascular dementia, unspecified severity, with agitation
F01.518	Vascular dementia, unspecified severity, with other behavioral disturbance
F01.52	Vascular dementia, unspecified severity, with psychotic disturbance
F01.53	Vascular dementia, unspecified severity, with mood disturbance
F01.54	Vascular dementia, unspecified severity, with anxiety
F01.A0	Vascular dementia, mild, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F01.A11	Vascular dementia, mild, with agitation
F01.A18	Vascular dementia, mild, with other behavioral disturbance
F01.A2	Vascular dementia, mild, with psychotic disturbance
F01.A3	Vascular dementia, mild, with mood disturbance
F01.A4	Vascular dementia, mild, with anxiety
F01.B0	Vascular dementia, moderate, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F01.B11	Vascular dementia, moderate, with agitation
F01.B18	Vascular dementia, moderate, with other behavioral disturbance
F01.B2	Vascular dementia, moderate, with psychotic disturbance
F01.B3	Vascular dementia, moderate, with mood disturbance
F01.B4	Vascular dementia, moderate, with anxiety

ICD-10-CM Code	Description
F01.C0	Vascular dementia, severe, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F01.C11	Vascular dementia, severe, with agitation
F01.C18	Vascular dementia, severe, with other behavioral disturbance
F01.C2	Vascular dementia, severe, with psychotic disturbance
F01.C3	Vascular dementia, severe, with mood disturbance
F01.C4	Vascular dementia, severe, with anxiety
F06.70	Mild neurocognitive disorder due to known physiological condition without behavioral disturbance
F06.71	Mild neurocognitive disorder due to known physiological condition with behavioral disturbance
T43.655A	Adverse effect of methamphetamines, initial encounter
T43.655D	Adverse effect of methamphetamines, subsequent encounter
T43.655S	Adverse effect of methamphetamines, sequela
T43.656A	Underdosing of methamphetamines, initial encounter
T43.656D	Underdosing of methamphetamines, subsequent encounter
T43.656S	Underdosing of methamphetamines, sequela
Z03.83	Encounter for observation for suspected conditions related to home physiologic monitoring device ruled out
Z59.82	Transportation insecurity
Z59.86	Financial insecurity
Z59.87	Material hardship
Z71.87	Encounter for pediatric-to-adult transition counseling
Z71.88	Encounter for counseling for socioeconomic factors
Z72.823	Risk of suffocation (smothering) under another while sleeping
Z79.60	Long term (current) use of unspecified immunomodulators and immunosuppressants
Z79.61	Long term (current) use of immunemodulator
Z79.620	Long term (current) use of immunosuppressive biologic
Z79.621	Long term (current) use of calcineurin inhibitor
Z79.622	Long term (current) use of Janus kinase inhibitor
Z79623	Long term (current) use of mammalian target of rapamycin (mTOR) inhibitor
Z79.624	Long term (current) use of inhibitors of nucleotide synthesis
Z79.630	Long term (current) use of alkylating agent
Z79.631	Long term (current) use of antimetabolite agent
Z79.632	Long term (current) use of antitumor antibiotic
Z79.633	Long term (current) use of mitotic inhibitor
Z79.634	Long term (current) use of topoisomerase inhibitor
Z79.64	Long term (current) use of myelosuppressive agent
Z79.69	Long term (current) use of other immunomodulators and immunosuppressants
Z79.85	Long-term (current) use of injectable non-insulin antidiabetic drugs
Z87.61	Personal history of (corrected) necrotizing enterocolitis of newborn
Z87.68	Personal history of other (corrected) conditions arising in the perinatal period
Z87.731	Personal history of (corrected) tracheoesophageal fistula or atresia
Z87.732	Personal history of (corrected) persistent cloaca or cloacal malformations
Z87.760	Personal history of (corrected) congenital diaphragmatic hernia or other congenital diaphragm malformations
Z87.761	Personal history of (corrected) gastroschisis
Z87.762	Personal history of (corrected) prune belly malformation
Z87.763	Personal history of other (corrected) congenital abdominal wall malformations
Z87.768	Personal history of other specified (corrected) congenital malformations of integument, limbs and musculoskeletal system
Z91.110	Patient's noncompliance with dietary regimen due to financial hardship
Z91.118	Patient's noncompliance with dietary regimen for other reason
Z91.119	Patient's noncompliance with dietary regimen due to unspecified reason
Z91.190	Patient's noncompliance with other medical treatment and regimen due to financial hardship
Z91.198	Patient's noncompliance with other medical treatment and regimen for other reason
Z91.199	Patient's noncompliance with other medical treatment and regimen due to unspecified reason
Z91.A10	Caregiver's noncompliance with patient's dietary regimen due to financial hardship

In addition, as discussed in section II.D.14. of the preamble of this proposed rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2022. Included in this table are the following

ICD–10–CM diagnosis codes that are currently listed on the Unacceptable Principal Diagnosis edit code list. We are proposing to delete these codes from the Unacceptable Principal Diagnosis edit code list.

ICD-10-CM Code	Description
Z91.A18	Caregiver's noncompliance with patient's dietary regimen for other reason
Z91.A20	Caregiver's intentional underdosing of patient's medication regimen due to financial hardship
Z91.A28	Caregiver's intentional underdosing of medication regimen for other reason
Z91.A3	Caregiver's unintentional underdosing of patient's medication regimen
Z91.A4	Caregiver's other noncompliance with patient's medication regimen
Z91.A5	Caregiver's noncompliance with patient's renal dialysis
Z91.A9	Caregiver's noncompliance with patient's other medical treatment and regimen

f. Unspecified Code

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44940 through 44943), we finalized the implementation of a new Unspecified code edit, effective with discharges on and after April 1, 2022. Unspecified codes exist in the ICD–10–CM classification for circumstances when documentation in the medical record does not provide the level of detail needed to support reporting a more specific code. However, in the inpatient setting, there should generally be very limited and rare circumstances for which the laterality (right, left, bilateral) of a condition is unable to be documented and reported.

As discussed in section II.D.14. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2022. We are proposing to add the following new ICD–10–CM diagnosis codes to the Unspecified code edit code list.

ICD-10-CM Code	Description
Z87.76	Personal history of (corrected) congenital malformations of integument, limbs and musculoskeletal system
Z91.11	Patient's noncompliance with dietary regimen
Z91.19	Patient's noncompliance with other medical treatment and regimen

g. Future Enhancement

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38053 through 38054), we noted the importance of ensuring accuracy of the coded data from the reporting, collection, processing, coverage, payment and analysis aspects. Subsequently, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20235), we stated that we engaged a contractor to assist in the review of the limited coverage and non-covered procedure edits in the MCE that may also be present in other claims processing systems that are utilized by our MACs. The MACs must adhere to criteria specified within the National Coverage Determinations (NCDs) and may implement their own edits in addition to what is already incorporated into the MCE, resulting in duplicate edits. The objective of this review is to identify where duplicate edits may exist and to determine what the impact might be if these edits were to be removed from the MCE.

We have also noted that the purpose of the MCE is to ensure that errors and inconsistencies in the coded data are recognized during Medicare claims processing. As we indicated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41228), we are considering whether the inclusion of coverage edits in the MCE necessarily aligns with that specific goal because the focus of coverage edits is on whether or not a particular service is covered for payment purposes and not whether it was coded correctly.

As we continue to evaluate the purpose and function of the MCE with respect to ICD–10, we encourage public input for future discussion. As we have discussed in prior rulemaking, we recognize a need to further examine the current list of edits and the definitions of those edits.

ICD-10-CM Code	Description
S06.33AA	Contusion and laceration of cerebrum, unspecified, with loss of consciousness status unknown, initial encounter
S06.36AA	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness status unknown, initial encounter

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We continue to encourage public comments on whether there are additional concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data. Comments should be directed to the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™), discussed in section II.D.1.b. of the preamble of this

proposed rule at *https://mearis.cms.gov/public/home* by October 20, 2022.

16. Proposed Changes to Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single MS–DRG (MS–DRG 652) and the class ''major bladder procedures'' consists of three MS–DRGs (MS–DRGs 653, 654, and 655). Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005 are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed in this proposed rule.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the ''other O.R. procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The ''other O.R. procedures'' class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

Based on the changes that we are proposing to make for FY 2023, as discussed in section II.D. of the preamble of this proposed rule, we are proposing to maintain the existing surgical hierarchy for FY 2023.

17. Maintenance of the ICD–10–CM and ICD–10–PCS Coding Systems

In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with the March 19–20, 2014 meeting. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM and ICD–10–PCS coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS website at *https://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html.* The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS website at *https://www.cms.gov/Medicare/Coding/ICD10/index.html.*

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The ICD–10 Coordination and Maintenance Committee holds its meetings in the spring and fall to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the Committee meeting if the request is received at least 3 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS website.

The Committee encourages participation in the previously mentioned process by health- related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed during the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

A complete addendum describing details of all diagnosis and procedure coding changes, both tabular and index, is published on the CMS and NCHS websites in June of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers.

The Committee presented proposals for coding changes for implementation in FY 2023 at a public meeting held on September 14–15, 2021, and finalized the coding changes after consideration of comments received at the meetings and in writing by November 15, 2021.

The Committee held its 2022 meeting on March 8–9, 2022. The deadline for submitting comments on the procedure code proposals that are being considered for an October 1, 2022 implementation was April 8, 2022. The deadline for submitting comments on the diagnosis code proposals that are being considered for an October 1, 2023 implementation is May 9, 2022. It was announced at this meeting that any new diagnosis and procedure codes for which there was consensus of public support and for which complete tabular and indexing changes would be made by June 2022 would be included in the October 1, 2022, update to the ICD–10–CM diagnosis and ICD–10–PCS procedure code sets. It was also announced at this meeting that we are changing the process for submitting requested updates to the ICD–10–PCS classification, beginning with the procedure code request submitted for consideration for the September 13–14, 2022 ICD–10 Coordination and Maintenance Committee Meeting. As stated in section II.D.1.b. of the preamble of this proposed rule, CMS is in the process of implementing a new electronic application intake system, MEARIS™. Effective January 5, 2022, MEARIS™ became available as an initial release for users to begin gaining familiarity with a new approach and process to submit ICD–10–PCS procedure code requests. Information on this new approach for submitting an ICD–10–PCS code request can be accessed at *https://mearis.cms.gov.* Effective March 1, 2022, the full release of MEARIS™ became active for ICD–10–PCS code request submissions. ICD–10–PCS code request submissions are due no later than June 10, 2022, to be considered for the September 13–14, 2022, ICD–10 Coordination and Maintenance Committee Meeting. Moving forward, CMS will only accept ICD–10–PCS code requests submitted via MEARIS™. Requests submitted through the ICDProcedureCodeRequest mailbox will no longer be considered. Within MEARIS™, we have built in several resources to support users, including a ''Resources'' section (available at *https://mearis.cms.gov/public/resources*) and technical support available under ''Useful Links'' at the bottom of the MEARIS™ site. Questions regarding MEARIS™ can be submitted to CMS using the form available under ''Contact'' at *https://mearis.cms.gov/public/resources.*

As discussed in earlier sections of the preamble of this proposed rule, there are new, revised, and deleted ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that are captured in Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, and Table 6E.—Revised Diagnosis Code Titles for this proposed rule, which are available via the internet on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps.* The code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee process. Therefore, although we make the code titles available through tables in association with the IPPS proposed rule, they are not subject to comment in the proposed rule. Because of the length of these tables, they are not published in the Addendum to the proposed rule. Rather, they are available via the internet as discussed in section VI. of the Addendum to the proposed rule.

Recordings for the virtual meeting discussions of the procedure codes at the Committee's September 14–15, 2021, meeting and the March 8–9, 2022, meeting can be obtained from the CMS website at *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.* The materials for the discussions relating to diagnosis codes at the September 14–15, 2021, meeting and March 8–9, 2022, meeting can be found at *https://www.cdc.gov/nchs/icd/icd10cm_maintenance.html.* These websites also provide detailed information about the Committee, including information on requesting a new code, participating in a Committee meeting, timeline requirements and meeting dates.

We encourage commenters to submit questions and comments on coding issues involving diagnosis codes via Email to *nchsicd10cm@cdc.gov.*

Questions and comments concerning the procedure codes should be submitted via Email to *ICDProcedureCodeRequest@cms.hhs.gov.*

As a result of the ongoing COVID–19 public health emergency, the CDC implemented three new diagnosis codes describing immunization status related to COVID–19 into the ICD–10–CM effective with discharges on and after April 1, 2022. The diagnosis codes are as follows:

ICD-10-CM Code	Description
Z28.310	Unvaccinated for COVID-19
Z28.311	Partially vaccinated for COVID-19
Z28.39	Other under immunization status

We refer the reader to the CDC web page at *https://www.cdc.gov/nchs/icd/icd10cm.htm* for additional details regarding the implementation of these new diagnosis codes.

We provided the MS–DRG assignments for the three diagnosis codes effective with discharges on and after April 1, 2022, consistent with our established process for assigning new diagnosis codes. Specifically, we review the predecessor diagnosis code and MS–DRG assignment most closely associated with the new diagnosis code, and consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, and the resources utilized for the specific condition/diagnosis. We note that this process does not automatically result in the new diagnosis code being assigned to the same MS–DRG as the predecessor code. The assignments for the previously listed diagnosis codes are reflected in Table 6A.—New Diagnosis Codes (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*). As with the other new diagnosis codes and MS–DRG assignments included in Table 6A of this proposed

rule, we are soliciting public comments on the most appropriate MDC, MS–DRG, and severity level assignments for these codes for FY 2023, as well as any other options for the GROUPER logic.

In addition, CMS implemented nine new procedure codes describing the introduction or infusion of therapeutics, including vaccines for COVID–19 treatment, into the ICD–10–PCS effective with discharges on and after April 1, 2022. The nine procedure codes listed in this section of this rule are designated as non-O.R. and do not affect any MDC or MS–DRG assignment as shown in the following table.

ICD-10-PCS Code	Description	O.R.	MDC	MS-DRG
XW013V7	Introduction of COVID-19 vaccine dose 3 into subcutaneous tissue, percutaneous approach, new technology group 7	N		
XW013W7	Introduction of COVID-19 vaccine booster into subcutaneous tissue, percutaneous approach, new technology group 7	N		
XW023V7	Introduction of COVID-19 vaccine dose 3 into muscle, percutaneous approach, new technology group 7	N		
XW023W7	Introduction of COVID-19 vaccine booster into muscle, percutaneous approach, new technology group 7	N		
XW023X7	Introduction of tixagevimab and cilgavimab monoclonal antibody into muscle, percutaneous approach, new technology group 7	N		
XW023Y7	Introduction of other new technology monoclonal antibody into muscle, percutaneous approach, new technology group 7	N		
XW0DXR7	Introduction of fostamatinib into mouth and pharynx, external approach, new technology group 7	N		
XW0G7R7	Introduction of fostamatinib into upper GI, via natural orartificial opening, new technology group 7	N		
XW0H7R7	Introduction of fostamatinib into lower GI, via natural or artificial opening, new technology group 7	N		

The ICD–10 MS–DRG assignment for cases reporting any one of the nine procedure codes is dependent on the reported principal diagnosis, any secondary diagnoses defined as a CC or MCC, procedures or services performed, age, sex, and discharge status. The nine procedure codes are reflected in Table 6B—New Procedure Codes (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*). As with the other new procedure codes and MS–DRG assignments included in Table 6B of this proposed rule, we are soliciting public comments on the most appropriate MDC, MS–DRG, and operating room status assignments for these codes for FY 2023, as well as any other options for the GROUPER logic.

We note that Change Request (CR) 12578, Transmittal 11174, titled ''April 2022 Update to the Medicare Severity—Diagnosis Related Group (MS–DRG) Grouper and Medicare Code Editor (MCE) Version 39.1 for the International Classification of Diseases, Tenth Revision (ICD–10) Diagnosis Codes for 2019 Novel Coronavirus (COVID–19) Vaccination Status and ICD–10 Procedure Coding System (PCS) Codes for Introduction or Infusion of Therapeutics and Vaccines for COVID–19 Treatment'', was issued on January 14, 2022 (available via the internet on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r11174cp*) regarding the release of an updated version of the ICD–10 MS–DRG GROUPER and Medicare Code Editor software, Version 39.1, effective with discharges on and after April 1, 2022, reflecting the new diagnosis and procedure codes. The updated software, along with the updated ICD–10 MS–DRG V39.1 Definitions Manual and the Definitions of Medicare Code Edits V39.1 manual is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of Public Law 108–173 included a requirement for updating

diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) of Public Law 108–173 amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making those determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting were considered for an April 1 update if a strong and convincing case was made by the requestor during the Committee's public meeting. The request needed to identify the reason why a new code was needed in April for purposes of the new technology process. Meeting participants and those reviewing the Committee meeting materials were provided the opportunity to comment on the expedited request. We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950) for further discussion of the implementation of this prior April 1 update for purposes of the new technology add-on payment process.

However, as discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950 through 44956), we adopted an April 1 implementation date, in addition to the annual October 1 update, beginning with April 1, 2022. We noted that the intent of this April 1 implementation date is to allow flexibility in the ICD–10 code update process. With this new April 1 update, CMS now uses the same process for consideration of all requests for an April 1 implementation date, including for purposes of the new technology add-on payment process (that is, the prior process for consideration of an April 1 implementation date only if a strong and convincing case was made by the requestor during the meeting no longer applies). We are continuing to use several aspects of our existing established process to implement new codes through the April 1 code update, which includes presenting proposals for April 1 consideration at the September ICD–10 Coordination and Maintenance Committee meeting, requesting public comments, reviewing the public comments, finalizing codes, and announcing the new codes with their assignments consistent with the new GROUPER release information. We note that under our established process, requestors indicate whether they are submitting their code request for consideration for an April 1 implementation date or an October 1 implementation date. The ICD–10 Coordination and Maintenance Committee makes efforts to accommodate the requested implementation date for each request submitted. However, the Committee determines which requests are to be presented for consideration for an April 1 implementation date or an October 1 implementation date. As discussed earlier in this section of the preamble of this proposed rule, there were code proposals presented for an expedited April 1, 2022, implementation at the September 14–15, 2021, Committee meetings that involved treatments related to the COVID–19 PHE. One of these code proposals was also in connection with a request for a new technology add-on payment application. Following the receipt of public comments, the code proposals were approved and finalized, therefore, there were new codes implemented April 1, 2022.

Consistent with the process we outlined for the April 1 implementation date, we announced the new codes in November 2021 and provided the updated code files and ICD–10–CM Official Guidelines for Coding and Reporting in December 2021. In the January 24, 2022, **Federal Register** (87 FR 3549), notice for the March 8–9, 2022, ICD–10 Coordination and Maintenance Committee Meeting was published that includes the tentative agenda and identifies which topics are related to a new technology add-on payment application. By February 1, 2022, we made available the updated V39.1 ICD–10 MS–DRG Grouper software and related materials via the internet on CMS web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

ICD–9–CM addendum and code title information is published on the CMS website at *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/addendum.* ICD–10–CM and ICD–10–PCS addendum and code title information is published on the CMS website at *https://www.cms.gov/medicare/coding/icd10.* CMS also sends electronic files containing all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their systems and providing education to providers. Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can be found on the CDC website at *https://www.cdc.gov/nchs/icd/icd10cm.htm.* Additionally, information on new, revised, and deleted ICD–10–CM diagnosis and ICD–10–PCS procedure codes is provided to the AHA for publication in the Coding Clinic for ICD–10. The AHA also distributes coding update information to publishers and software vendors.

For FY 2022, there are currently 72,750 diagnosis codes and 78,229 procedure codes. As displayed in Table 6A.—New Diagnosis Codes and in Table 6B.—New Procedure Codes associated with this proposed rule (and available via the internet on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps,* there are 1,176 new diagnosis codes and 45 new procedure codes that have been finalized for FY 2023 at the time of the development of this proposed rule. The code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee process. Thus, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules. We will continue to provide the October updates in this manner in the IPPS proposed and final rules.

18. Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the

implantation of a device that subsequently failed or was recalled determined the base MS–DRG assignment. At that time, we specified that we will reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Proposed Changes for FY 2023

For FY 2023 we are proposing not to add any MS–DRGs to the policy for replaced devices offered without cost or with a credit. We are proposing to continue to include the existing MS–DRGs currently subject to the policy as displayed in the following table.

MDC	MS-DRG	MS-DRG Title
Pre-MDC	001	Heart Transplant or Implant of Heart Assist System with MCC
Pre-MDC	002	Heart Transplant or Implant of Heart Assist System without MCC
01	023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator
01	024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC
01	025	Craniotomy and Endovascular Intracranial Procedures with MCC
01	026	Craniotomy and Endovascular Intracranial Procedures with CC
01	027	Craniotomy and Endovascular Intracranial Procedures without CC/MCC
01	040	Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC
01	041	Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator
01	042	Peripheral, Cranial Nerve and Other Nervous System Procedures without CC/MCC
03	140	Major Head and Neck Procedures with MCC
03	141	Major Head and Neck Procedures with CC
03	142	Major Head and Neck Procedures without CC/MCC
05	215	Other Heart Assist System Implant
05	216	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC
05	217	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC
05	218	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC
05	219	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC
05	220	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC
05	221	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC
05	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock with MCC
05	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock without MCC
05	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock with MCC
05	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock without MCC
05	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC
05	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC
05	242	Permanent Cardiac Pacemaker Implant with MCC
05	243	Permanent Cardiac Pacemaker Implant with CC
05	244	Permanent Cardiac Pacemaker Implant without CC/MCC
05	245	AICD Generator Procedures
05	258	Cardiac Pacemaker Device Replacement with MCC
05	259	Cardiac Pacemaker Device Replacement without MCC
05	260	Cardiac Pacemaker Revision Except Device Replacement with MCC
05	261	Cardiac Pacemaker Revision Except Device Replacement with CC
05	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC
05	265	AICD Lead Procedures
05	266	Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC
05	267	Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC
05	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC
05	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC
05	270	Other Major Cardiovascular Procedures with MCC
05	271	Other Major Cardiovascular Procedures with CC
05	272	Other Major Cardiovascular Procedures without CC/MCC
05	319	Other Endovascular Cardiac Valve Procedures with MCC
05	320	Other Endovascular Cardiac Valve Procedures without MCC
08	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC
08	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC
08	466	Revision of Hip or Knee Replacement with MCC
08	467	Revision of Hip or Knee Replacement with CC
08	468	Revision of Hip or Knee Replacement without CC/MCC
08	469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement
08	470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC
08	521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC
08	522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC

The final list of MS–DRGs subject to the IPPS policy for replaced devices offered without cost or with a credit will be included in the FY 2023 IPPS/LTCH PPS final rule and also will be issued to providers in the form of a Change Request (CR).

19. Other Policy Issues

a. Comment Solicitation on Possible Mechanisms To Address Rare Diseases and Conditions Represented by Low Volumes Within the MS–DRG Structure

As discussed in section II.D.13.d. of the preamble of this proposed rule, we are soliciting public comments involving how the reporting of certain diagnosis codes may improve our ability to recognize severity of illness, complexity of illness, and utilization of resources under the MS–DRGs, as well as feedback on mechanisms to improve the reliability and validity of the coded data as part of an ongoing effort across CMS to evaluate and develop policies to reduce health disparities. In concert with that effort, we are also soliciting comments to explore possible mechanisms through which we can address rare diseases and conditions that are represented by low volumes in our claims data.

One subset of our beneficiary population for which we are seeking comment on potential issues related to patient access in the inpatient setting are patients diagnosed with rare diseases and conditions that are represented by low volumes in our claims data. The Orphan Drug Act (ODA) added section 526(a)(2)(B) to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)(2)(B)), defining a rare disease or condition as ''any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug.'' Most rare diseases, however, affect far fewer people. The Genetic and Rare Diseases Information Center (GARD), which was created in 2002 by the National Institutes of Health (NIH) Office of Rare Diseases Research, estimates that there are as many as 7,000 distinct rare diseases. Rare diseases, which can include genetic diseases, autoimmune conditions, some cancers, and uncommon infections, are highly diverse, may affect many organ systems and have wide variations in the rates and patterns of manifestations and progression.

The ODA created a process for the U.S. Food and Drug Administration (FDA) to identify a drug as a drug developed for the treatment of a rare disease or condition called ''orphan-drug designation''. The sponsor of a drug that has orphan drug designation may be eligible for certain financial incentives, such as tax credits and potentially seven years of market exclusivity after approval, all of which are intended to incentivize developing drugs for small numbers of patients. We have heard from some stakeholders, however, that there may be a number of barriers to providers in treating these patients with these orphan designated drugs in the Medicare hospital inpatient setting.

According to these stakeholders, one significant barrier that continues to present challenges to manufacturers is accessing formulary coverage for potentially high cost therapeutics for rare diseases. These stakeholders have stated that hospitals utilize formularies for inpatient drugs as a cost-management tool that strongly incentivizes physicians to use on-formulary drugs over off-formulary drugs, whenever clinically appropriate to do so. A drug formulary is defined as a list of medications and continually updated related information, that represents the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and treatment of disease or promotion of health. It is often described as a list of medications routinely stocked by the health care system. These stakeholders stated that although certain therapeutics can be associated with better outcomes for patients with rare diseases, the lack of access to hospital formularies represents a hurdle under the IPPS MS–DRGs. According to these stakeholders, when Medicare reimbursement is insufficient to cover the costs of certain therapeutics that treat patients with rare diseases, a disincentive can be created in addressing these conditions.

For the purposes of this comment solicitation we describe in this section three selected requests we have received relating to the MS–DRG classification of rare diseases and conditions that are represented by low volumes in our claims data.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53311), the FY 2015 IPPS/LTCH PPS final rule (79 FR 49901), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41200), we discussed requests we received to revise the MS–DRG classification for cases of patients diagnosed with porphyria to recognize the resource requirements in caring for these patients, to ensure appropriate payment for these cases, and to preserve patient access to necessary treatments. Porphyria is defined as a group of rare disorders (''porphyrias'') that interfere with the production of hemoglobin that is needed for red blood cells. While some of these disorders are genetic (inborn) and others are acquired, they all result in the abnormal accumulation of hemoglobin building blocks, called porphyrins, which can be deposited in the tissues where they particularly interfere with the functioning of the nervous system and the skin. Treatment for patients suffering from disorders of porphyrin metabolism consists of an intravenous injection of Panhematin® (hemin for injection).

In the FY 2019 proposed rule, we stated our data analysis showed that cases reporting diagnosis code E80.21 (Acute intermittent (hepatic) porphyria) as the principal diagnosis in MS–DRG 642 (Inborn and Other Disorders of Metabolism) had higher average costs and longer average lengths of stay compared to the average costs and length of stay for all other cases in MS–DRG 642. However, after considering these findings in the context of the current MS–DRG structure, we stated that we were unable to identify an MS–DRG that would more closely parallel these cases with respect to average costs and length of stay that would also be clinically aligned. We further stated that our clinical advisors believed that, in the current MS–DRG structure, the clinical characteristics of patients in these cases are most closely aligned with the clinical characteristics of patients in all cases in MS–DRG 642. Moreover, given the small number of porphyria cases, we stated we did not believe there was justification for creating a new MS–DRG and did not propose to revise the MS–DRG classification for porphyria cases.

In response, some commenters described significant difficulties encountered by patients with acute porphyria attacks in obtaining Panhematin® when presenting to an inpatient hospital, which they attributed to the strong financial disincentives faced by facilities to treat these cases on an inpatient basis. The commenters stated that, based on the lower than expected average cost per case and longer than expected length of stay for acute porphyria attacks, it appeared that facilities were frequently not providing Panhematin® to patients in this condition, and instead attempting to provide symptom relief and transferring patients to an outpatient setting to receive the drug where they can be adequately paid. The commenters stated that this is in contrast to the standard of

care for acute porphyria attacks and could result in devastating long-term health consequences.

In the FY 2019 final rule (83 FR 41200), as we have stated in prior rulemaking, we noted it is not appropriate for facilities to deny treatment to beneficiaries needing a specific type of therapy or treatment that involves increased costs. We further noted the MS–DRG system is a system of averages and it is expected that across the diagnostic related groups that within certain groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. While we recognized the average costs of the small number of porphyria cases were greater than the average costs of the cases in MS–DRG 642 overall, we also noted that an averaged payment system depends on aggregation of similar cases with a range of costs, and that we seek to identify sufficiently large sets of claims data with a resource/cost similarity and clinical similarity in developing diagnostic-related groups rather than smaller subsets of diagnoses. We further stated that we were sensitive to the commenters' concerns about access to treatment for beneficiaries who have been diagnosed with this condition and we would continue to explore mechanisms through which to address rare diseases and low volume DRGs.

Similarly, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44869), we discussed a request we received to review potential access issues in the inpatient setting for the administration of ANDEXXA®. ANDEXXA® (coagulation factor Xa (recombinant), inactivated-zhzo) is a recombinant decoy protein that rapidly reverses the anticoagulant effects of two direct oral anticoagulants, apixaban and rivaroxaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding in indications such as intracranial hemorrhages (ICHs) and gastrointestinal bleeds (GIBs). We noted that while our data findings demonstrated the average costs for the cases reporting the intravenous administration of ANDEXXA® were higher when compared to all cases in their respective MS–DRG, these cases represented a very small percentage of the total number of cases reported in those MS–DRGs. We stated we were unable to identify another MS–DRG that would be a more appropriate MS–DRG assignment for these cases based on the indication for this therapeutic drug. We also stated that while we were sensitive to the requestors' concerns about continued access to treatment for beneficiaries who require the reversal of anticoagulation due to life-threatening or uncontrolled bleeding, we indicated additional time was needed to explore options and other mechanisms through which to address low volume, high-cost drugs outside of the MS–DRGs.

Lastly, we received a request to reconsider how cases reporting the administration of Zulresso® (brexanolone) are recognized for payment under the ICD–10 MS–DRGs in an effort to improve access to treatment for maternal mental health. On March 19, 2019 Zulresso® (brexanolone) became the first Food and Drug Administration (FDA) approved drug, specifically for postpartum depression (PPD) in adults. According to the requestor, PPD is one of the most common complications during and after pregnancy. The requestor stated PPD is a serious but manageable disorder and that with early treatment, the life of the mother, baby, and the entire family could be positively impacted. The requestor indicated it shares CMS's goals of addressing disparities in access to care, and urged CMS to take additional steps to address inequities in women's health by permitting separate payment for Zulresso® (brexanolone), in addition to the MS–DRG payment.

Effective with discharges on and after October 1, 2020, cases reporting the administration of Zulresso® in the inpatient setting are identified by ICD–10–PCS procedure codes XW03306 (Introduction of brexanolone into peripheral vein, percutaneous approach, new technology group 6) or XW04306 (Introduction of brexanolone into central vein, percutaneous approach, new technology group 6). These procedure codes are designated as non-O. R. procedures and do not affect the MS–DRG assignment when reported on an inpatient claim. We note that an application for new technology add-on payment for Zulresso® (brexanolone) was discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32672 through 32676) and was not approved, as discussed in the final rule (85 FR 58709 through 58715).

We analyzed claims from the September 2021 update of the FY 2021 MedPAR file for cases reporting the administration of Zulresso® (brexanolone). Our analysis of the claims data identified only one case reporting the administration of Zulresso® (brexanolone) in MS–DRG 870 (Septicemia or Severe Sepsis with MV >96 Hours) with an average length of stay of 22 days and average costs of $67,812. For all cases in MS–DRG 870, the average costs are $55,459 and the average length of stay is 15.9 days. While the average length of stay for the case reporting the administration of Zulresso® (brexanolone) is greater (22 days versus 15.9 days) and the average costs are higher ($67,812 versus $55,459), than all cases in MS–DRG 870 it is unclear if treatment with Zulresso® (brexanolone) is the underlying reason for these factors, given that the MS–DRG assigned is for sepsis and it is not uncommon for sepsis patients to have multiple co-morbidities and intensive treatment strategies to address this severe, often life threatening condition.

We appreciate the requestor's interest in sharing CMS's goal of advancing women's health, however, we note that the population in which Zulresso® (brexanolone) is indicated generally does not include our inpatient Medicare population. As we have stated in prior rulemaking, (83 FR 41210), we have not adopted the same approach to refine the maternity and newborn MS–DRGs because of the extremely low volume of Medicare patients there are in these MS–DRGs. When there is not a high volume of these cases (for example, maternity and newborn) represented in the Medicare data, we generally advise that other payers should develop DRGs to address the needs of their patients. We believe the same would apply with respect to administration of Zulresso® (brexanolone) for which, as noted, we identified only one case in the FY 2021 MedPAR file.

As discussed in prior rulemaking, the MS–DRGs are a classification system intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources. Rare diseases and conditions that are represented by low volumes in our claims data however, pose a unique challenge to this methodology as these conditions by definition affect small subsets of the population. It has been difficult to identify other MS–DRGs that would be more appropriate MS–DRG assignments for these rare conditions based on the wide variance in the clinical characteristics and utilization of resources for each condition, depending on the diagnosis. Creating a new MS–DRG for these conditions as a distinct ''related'' group is also challenging for the same reasons.

As previously noted, we generally seek to identify sufficiently large sets of claims data with a resource/cost similarity and clinical similarity in developing diagnostic-related groups rather than smaller subsets. We have been concerned that basing MS–DRG reclassification decisions on small numbers of cases could lead to complexities in establishing the relative payment weights for the MS–DRGs

because several expensive cases could impact the overall relative payment weight. Having larger clinical cohesive groups within an MS–DRG provides greater stability and thus predictability for hospitals for annual updates to the relative payment weights.

As also previously noted, the MS–DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. However, as noted, cases involving treatment of rare diseases may involve more resource use than other cases in their respective MS–DRG. Section 1886(d)(5)(A) of the Act provides for Medicare payments to Medicare-participating hospitals in addition to the basic prospective payments for cases incurring extraordinarily high costs, however we are soliciting feedback on other mechanisms we can explore through which we could address concerns relating to payment for patients with rare diseases and conditions that are represented by low volumes in our claims data. We are also interested in receiving comments on other meaningful ways in which we may potentially improve access to treatment for postpartum depression in certain populations, including through activities pursuant to Vice President Harris's Call to Action to Reduce Maternal Mortality and Morbidity.[25]

To inform decision making, we are also looking for feedback on how to mitigate any unintended negative payment impacts to providers serving patients with rare diseases or conditions that are represented by low volumes in our claims data. In particular, we are interested in hearing the perspectives of large urban hospitals, rural hospitals, and other hospital types in regard to their experience. We also seek comments on how factors such as hospital size and type might impact a hospital's ability to develop protocols to better address these conditions. We will take commenters' feedback into consideration in future policy development.

[25] *Available at: https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/07/fact-sheet-vice-president-kamala-harris-announces-call-to-action-to-reduce-maternal-mortality-and-morbidity/.*

II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

E. Recalibration of the FY 2023 MS–DRG Relative Weights

1. Data Sources for Developing the Relative Weights

Consistent with our established policy, in developing the MS–DRG relative weights for FY 2023, we are proposing to use two data sources: Claims data and cost report data. The claims data source is the MedPAR file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2021 MedPAR data used in this proposed rule include discharges occurring on October 1, 2020, through September 30, 2021, based on bills received by CMS through December 31, 2021, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS).

The FY 2021 MedPAR file used in calculating the proposed relative weights includes data for approximately 7,417,999 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the December 31, 2021 update of the FY 2021 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the proposed relative weights for FY 2023 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. We note that the proposed FY 2023 relative weights are based on the ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes from the FY 2021 MedPAR claims data, grouped through the ICD–10 version of the proposed FY 2023 GROUPER (Version 40).

The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. In general, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, for this proposed rule, we used the December 31, 2021 update of the FY 2020 HCRIS for calculating the proposed FY 2023 cost-based relative weights. Consistent with our historical practice, for this FY 2023 proposed rule, we are providing the version of the HCRIS from which we calculated these proposed 19 CCRs on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.* Click on the link on the left side of the screen titled ''FY 2023 IPPS Proposed Rule Home Page'' or ''Acute Inpatient Files for Download.''

2. Methodology for Calculation of the Relative Weights

a. General

We continued to calculate the proposed FY 2023 relative weights based on 19 CCRs. The methodology we are proposing to use to calculate the FY 2023 MS–DRG cost-based relative weights based on claims data in the FY 2021 MedPAR file and data from the FY 2020 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2023 MS–DRG classifications discussed in sections II.B. and II.D. of the preamble of this proposed rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2021 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average

cost for each MS–DRG and before eliminating statistical outliers.

Section 108 of the Further Consolidated Appropriations Act, 2020 provides that, for cost reporting periods beginning on or after October 1, 2020, costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant shall be paid on a reasonable cost basis. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for further discussion of the reasonable cost basis payment for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842). For FY 2022 and subsequent years, we subtract the hematopoietic stem cell acquisition charges from the total charges on each transplant bill that showed hematopoietic stem cell acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $30.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, implantable devices charges, supplies and equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood and blood products charges, anesthesia charges, cardiac catheterization charges, CT scan charges, and MRI charges were also deleted.
- At least 92.9 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.
- Effective October 1, 2008, because hospital inpatient claims include a POA indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a ''Y'' indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to ''Y'' only for relative weight-setting purposes for all claims that otherwise have an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

In addition, in the FY 2013 IPPS/LTCH PPS final rule, for FY 2013 and subsequent fiscal years, we finalized a policy to treat hospitals that participate in the Bundled Payments for Care Improvement (BPCI) initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to hospitals' participation within these bundled payment models (77 FR 53341 through 53343). Specifically, because acute care hospitals participating in the BPCI Initiative still receive IPPS payments under section 1886(d) of the Act, we include all applicable data from these subsection (d) hospitals in our IPPS payment modeling and ratesetting calculations as if the hospitals were not participating in those models under the BPCI initiative. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI initiative in our ratesetting process. For additional information on the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's website at *https://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343).

The participation of hospitals in the BPCI initiative concluded on September 30, 2018. The participation of hospitals in the BPCI Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 1115A of the Act, is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in BPCI Advanced in one of two capacities: As a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals will continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at *https://innovation.cms.gov/initiatives/bpci-advanced/*. Consistent with our policy for FY 2022, and consistent with how we have treated hospitals that participated in the BPCI Initiative, for FY 2023, we continue to believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because, as noted previously, these

hospitals are still receiving IPPS payments under section 1886(d) of the Act. Consistent with the FY 2022 IPPS/LTCH PPS final rule, we are also proposing to include all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

The charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 19 cost groups so that each MS–DRG had 19 standardized charge totals. Statistical outliers were then removed. These charges were then adjusted to cost by applying the proposed national average CCRs developed from the FY 2020 cost report data, consistent with our proposed FY 2023 ratesetting discussed in section II.A.4. of the Addendum of this proposed rule.

The 19 cost centers that we used in the proposed relative weight calculation are shown in a supplemental data file, Cost Center HCRIS Lines Supplemental Data File, posted via the internet on the CMS website for this proposed rule and available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.* The supplemental data file shows the lines on the cost report and the corresponding revenue codes that we used to create the proposed 19 national cost center CCRs. If we receive comments about the groupings in this supplemental data file, we may consider these comments as we finalize our policy.

Consistent with historical practice, we account for rare situations of non-monotonicity in a base MS–DRG and its severity levels, where the mean cost in the higher severity level is less than the mean cost in the lower severity level, in determining the relative weights for the different severity levels. If there are initially non-monotonic relative weights in the same base DRG and its severity levels, then we combine the cases that group to the specific non-monotonic MS–DRGs for purposes of relative weight calculations. For example, if there are two non-monotonic MS–DRGs, combining the cases across those two MS–DRGs results in the same relative weight for both MS–DRGs. The relative weight calculated using the combined cases for those severity levels is monotonic, effectively removing any non-monotonicity with the base DRG and its severity levels. For this FY 2023 proposed rule, this calculation was applied to address non-monotonicity for cases that grouped to MS–DRG 504 and MS–DRG 505, as well as MS–DRG 793 and MS–DRG 794. In the supplemental file titled AOR/BOR File, we include statistics for the affected MS–DRGs both separately and with cases combined.

We are inviting public comments on our proposals related to recalibration of the proposed FY 2023 relative weights and the changes in relative weights from FY 2022.

b. Relative Weight Calculation for MS–DRG 018

As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58599 through 58600), we created MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, which were reported using ICD–10–PCS procedure codes XW033C3 or XW043C3. Effective for FY 2022, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106). We refer the reader to section II.D.17. of this proposed rule for discussion of the agenda items for the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting relating to new procedure codes to describe the administration of a CAR T-cell or another type of gene or cellular therapy product, as well as our established process for determining the MS–DRG assignment for codes approved at the March meeting.

For MS–DRG 018, we include a modification to our existing relative weight methodology to ensure that the relative weight for MS–DRG 018 appropriately reflects the relative resources required for providing CAR T-cell and non-CAR T-cell therapies and other immunotherapies outside of a clinical trial, while still accounting for the clinical trial cases in the overall average cost for all MS–DRGs. For cases that group to MS–DRG 018, we do not include claims determined to be clinical trial claims that group to MS–DRG 018 when calculating the average cost for MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, with the additional refinements that (a) when the CAR T-cell, non-CAR T-cell or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, we include the claim when calculating the average cost for MS–DRG 018 to the extent such claims can be identified in the historical data, and (b) when there is expanded access use of the CAR T-cell, non-CAR T-cell or other immunotherapy product, these cases will not be included when calculating the average cost for new MS–DRG 018 to the extent such claims can be identified in the historical data (85 FR 58600). We also calculate an adjustment to account for the CAR T-cell, non-CAR T-cell and other immunotherapy cases determined to be clinical trial cases, as described later in this proposed rule and include revenue center 891 in our calculation of standardized drug charges for MS–DRG 018. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for further discussion of our modifications to the relative weight calculation for MS–DRG 018.

We are proposing to continue to use the same process to identify clinical trial claims in the FY 2021 MedPAR for purposes of calculating the FY 2023 relative weights. We continue to use the proxy of standardized drug charges of less than $373,000, which was the average sales price of KYMRIAH and YESCARTA, which are the two CAR T-cell biological products in the FY 2021 MedPAR data used for this proposed rule. (As previously noted, effective beginning FY 2022, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106).) Using the same methodology from the FY 2021 IPPS/LTCH PPS final rule, we are proposing to apply an adjustment to account for the CAR T cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs:

- Calculate the average cost for cases to be assigned to MS–DRG 018 that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000.
- Calculate the average cost for all other cases to be assigned to MS–DRG 018
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply the adjustor calculated in step 3 to the cases identified in step 1 as clinical trial cases, then add this adjusted case count to the non-clinical trial case count prior to calculating the average cost across all MS–DRGs.

Additionally, we are continuing our finalized methodology for calculating this payment adjustment, such that: (a)

When the CAR T-cell, non-CAR T-cell or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for cases not determined to be clinical trial cases and (b) when there is expanded access use of immunotherapy, these cases will be included when calculating the average cost for cases determined to be clinical trial cases. However, we continue to believe to the best of our knowledge there are no claims in the historical data (FY 2021 MedPAR) used in the calculation of the adjustment for cases involving a clinical trial of a different product, and to the extent the historical data contain claims for cases involving expanded access use of immunotherapy we believe those claims would have drug charges less than $373,000.

Applying this previously finalized methodology, based on the December 2021 update of the FY 2021 MedPAR file used for this proposed rule, we estimated that the average costs of cases assigned to MS–DRG 018 that are identified as clinical trial cases ($61,356) were 20 percent of the average costs of the cases assigned to MS–DRG 018 that are identified as non-clinical trial cases ($299,460). Accordingly, as we did for FY 2022, we are proposing to adjust the transfer-adjusted case count for MS–DRG 018 by applying the proposed adjustor of .20 to the applicable clinical trial and expanded access use immunotherapy cases, and to use this adjusted case count for MS–DRG 018 in calculating the national average cost per case, which is used in the calculation of the relative weights. Therefore, in calculating the national average cost per case for purposes of this proposed rule, each case identified as an applicable clinical trial or expanded access use immunotherapy case was adjusted by .20. As we did for FY 2022, we are applying this same adjustor for the applicable cases that group to MS–DRG 018 for purposes of budget neutrality and outlier simulations. We are also proposing to update the value of the adjustor based on more recent data for the final rule.

c. Proposed Averaging of Relative Weights for FY 2023

In section I.F. of this proposed rule, we discuss our proposal to use the FY 2021 MedPAR data for purposes of FY 2023 IPPS ratesetting, with certain proposed modifications to our usual methodologies, including a proposed averaging approach for calculating the FY 2023 relative weights. As discussed, we observed that COVID–19 cases were impacting the relative weights as calculated using the FY 2021 claims data for a few COVID–19-related MS–DRGs. For example, for MS–DRG 870 (Septicemia or Severe Sepsis with MV >96 hours), the relative weight calculated using the FY 2021 MedPAR data was approximately 9 percent higher than the relative weight calculated excluding the COVID–19 cases in the FY 2021 data. As also discussed in that section, we believe it is reasonable to assume that there will be fewer COVID–19 hospitalizations among Medicare beneficiaries in FY 2023 than there were in FY 2021. However, we cannot know the precise number of COVID–19 hospitalizations among Medicare beneficiaries in FY 2023. To account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries as compared to FY 2021, we are proposing to determine the MS–DRG relative weights for FY 2023 by averaging the relative weights as calculated with and without COVID–19 cases in the FY 2021 data, as described in greater detail below. Given the uncertainty in the number of COVID–19 hospitalizations in FY 2023, we are proposing to use 50 percent of the relative weights calculated using all applicable cases in the FY 2021 claims data and 50 percent of the relative weights calculated without the COVID–19 cases in the FY 2021 claims data. We believe this proposed approach would appropriately reduce, but not remove entirely, the effect of COVID–19 cases on the relative weight calculations, consistent with our expectation that Medicare inpatient hospitalizations for COVID–19 will continue in FY 2023 at a lower level as compared to FY 2021. By averaging the relative weights in this manner, we believe the result would reflect a reasonable estimation of the case mix for FY 2023 based on the information available at this time, as discussed in section I.F. of the preamble to this proposed rule, and more accurately estimate the relative resource use for the cases treated in FY 2023 than if we were to calculate the proposed relative weights based on 100% of the relative weights as calculated for all applicable cases in the FY 2021 data. For this proposed rule, our proposed calculation is as follows:

- *Step 1:* Calculate a set of relative weights using all applicable cases in the December 2021 update of the FY 2021 MedPAR data, using the methodology as described earlier in this section, and then applying a normalization adjustment factor as described later in this section.
- *Step 2:* Calculate a set of relative weights using the December 2021 update of the FY 2021 MedPAR data excluding cases with a principal or secondary diagnosis of COVID–19 (ICD–10–CM diagnosis code U07.1), and otherwise using the methodology as described earlier in this section, and then applying a normalization adjustment factor as described later in this section.
- *Step 3:* Average the results of step 1 and step 2 to calculate a set of averaged relative weights, geometric mean length of stays, and arithmetic mean length of stays.
- *Step 4:* Calculate the proposed FY 2023 relative weights by applying an additional normalization factor to these averaged relative weights. This additional normalization factor is necessary to ensure that the average case weight as calculated in step 3 of this proposed averaging methodology for recalibration of the FY 2023 relative weights is equal to the average case weight before recalibration. We note that this factor is very close to 1 and is described later in this section.

We note that in Step 5 of this proposed calculation, we apply the proposed 10 percent cap to the relative weights for those MS–DRGs for which the relative weight as calculated in Step 4 would otherwise have declined by more than 10 percent from the FY 2022 relative weight, as discussed more fully later in this section. We also note that we intend to update this calculation for the final rule using the March 2022 update of the FY 2021 MedPAR file.

The proposed relative weights, geometric mean length of stay, and average length of stay as calculated using this proposed methodology are set forth in Table 5 associated with this proposed rule, which is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.* We are also making available the relative weights, geometric mean length of stay, and average length of stay as calculated in steps 1 and 2 of this proposed methodology on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.*

As discussed in section I.O. of Appendix A of this proposed rule, as an alternative to our proposed approach, we also considered calculating the FY 2023 MS–DRG relative weights based on all applicable cases in the FY 2021 MedPAR data, without the averaging approach we are proposing to account for COVID–19 cases. We note, as an example, that the proposed relative weight for MS–DRG 871 (Septicemia Or Severe Sepsis Without MV >96 Hours with MCC) as calculated using our

proposed averaging of the relative weights as calculated with and without the COVID–19 cases in the FY 2021 data is 1.9549, while the relative weight as calculated without this proposed averaging would be 1.9954. We are making available supplemental information, including the relative weights, average length of stay, and geometric mean length of stay, calculated both with and without COVID–19 cases as noted previously. We refer the reader to section I.O. of Appendix A of this proposed rule for a discussion of the files that we are making available with regard to our alternative approach.

d. Proposed Cap for Relative Weight Reductions

In the FY 2018 IPPS/LTCH PPS final rule, we summarized comments we had received requesting a transition period for substantial reductions in relative weights in order to facilitate payment stability. Specifically, some commenters asked CMS to establish a cap on the decline in a relative weight from FY 2017 to FY 2018, or a phase-in or multi-year transition period in cases of substantial fluctuation of payment rates (82 FR 38103).

After consideration of these comments, and for the reasons discussed in the FY 2018 final rule, we adopted a temporary one-time measure for FY 2018 for MS–DRGs where the relative weight would have declined by more than 20 percent from the FY 2017 relative weight, consistent with our general authority to assign and update appropriate weighting factors under sections 1886(d)(4)(B) and (C) of the Act (82 FR 38103). Specifically, for these MS–DRGs, the relative weight for FY 2018 was set at 80 percent of the FY 2017 relative weight. In the FY 2019 IPPS/LTCH PPS final rule, in response to similar comments, we adopted a temporary one-time measure for FY 2019 for an MS–DRG where the FY 2018 relative weight declined by 20 percent from the FY 2017 relative weight and the FY 2019 relative weight would have declined by 20 percent or more from the FY 2018 relative weight (83 FR 41273). Specifically, for an MS–DRG meeting this criterion, we set the FY 2019 relative weight equal to the FY 2018 relative weight. In the FY 2020 IPPS/LTCH PPS final rule, in response to similar comments, we adopted a temporary one-time measure for FY 2020 for an MS–DRG where the FY 2018 relative weight declined by 20 percent from the FY 2017 relative weight and the FY 2020 relative weight would have declined by 20 percent or more from the FY 2019 relative weight, which was maintained at the FY 2018 relative weight (84 FR 42167). Specifically, for an MS–DRG meeting this criterion, we set the FY 2020 relative weight equal to the FY 2019 relative weight, which was in turn set equal to the FY 2018 relative weight.

In the FY 2021 IPPS/LTCH PPS proposed rule, we noted the one-time measure adopted for FY 2020 and sought comment on whether we should consider a similar policy for FY 2021, or an alternative approach such as averaging the FY 2020 relative weight and the otherwise applicable FY 2021 relative weight for MS–DRG 215, which was the only MS–DRG impacted by the FY 2020 policy setting the FY 2020 relative weight equal to the FY 2019 relative weight. Commenters generally supported either setting the FY 2021 weight for MS–DRG 215 equal to the FY 2020 relative weight or an averaging approach. Some commenters requested that CMS consider such an approach when the relative weight for an MS–DRG is drastically reduced in a given year, particularly when it follows a significant decline in prior years. After consideration of comments received, and for the reasons discussed in the FY 2021 final rule, we set the FY 2021 relative weight for MS–DRG 215 equal to the average of the FY 2020 relative weight and the otherwise applicable FY 2021 weight. With regard to the concerns raised about other MS–DRGs with significant reductions relative to FY 2020, we noted that these other MS–DRGs were low volume in our claims data, and therefore typically experience a greater degree of year-to-year variation. We acknowledged the longstanding concerns related to low volume MS–DRGs and stated that we would take into consideration the unique issues relating to such MS–DRGs and the stability of their weights for future rulemaking.

We have continued to consider the comments we received in response to prior rulemaking recommending that CMS limit significant declines in the relative weights for the MS–DRGs more broadly, including by establishing a cap on the degree to which the relative weight for an MS–DRG may decline from one fiscal year to the next. For prior fiscal years, as previously discussed, we have adopted limited, temporary measures to address potentially substantial declines in the relative weights in certain outlier circumstances to mitigate the impacts of such declines. However, we have also acknowledged commenters' concerns related to significant reductions in the weights for other MS–DRGs, in particular low volume MS–DRGs. For these low volume MS–DRGs, fluctuations in the volume or mix of cases and/or the presence of a few high cost or low cost cases can have a disproportionate impact on the calculated relative weight, thus resulting in greater year-to-year variation in the relative weights for these MS–DRGs. This variation may reduce the predictability and stability of an individual hospital's Medicare payments from year-to-year. We also recognize that significant declines in the relative weights may occur for higher-volume MS–DRGs, with such fluctuations likewise affecting the predictability and stability of hospital payments.

In light of these concerns, we have further considered requests made by commenters that we address year-to-year fluctuations in relative weights, particularly for low volume MS–DRGs, and to mitigate the financial impacts of significant fluctuations. In consideration of the concerns that commenters have raised about year-to-year fluctuations in relative weights and the financial impacts of significant fluctuations, we believe it would be appropriate to limit such fluctuations by applying a cap on reductions in the relative weight for an MS–DRG for a given fiscal year. Therefore, consistent with our statutory authority under section 1886(d)(4)(B) and (C) of the Act to assign and update appropriate weighting factors, we are proposing a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. This proposal is consistent with our general authority to assign and update appropriate weighting factors as part of our annual reclassification of the MS–DRGs and recalibration of the relative weights under sections 1886(d)(4)(B) and (C)(i) of the Act, as well as the requirements of section 1886(d)(4)(C)(iii) of the Act, which specifies that the annual DRG reclassification and recalibration of the relative weights be made in a manner that ensures that aggregate payments to hospitals are not affected. In addition, we have authority to implement this proposed cap and the associated budget neutrality adjustment under our special exceptions and adjustments authority at section 1886(d)(5)(I)(i) of the Act, which similarly gives the Secretary broad authority to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate. As discussed, we believe this cap on declines in the relative weights would be appropriate in order to promote predictability and

stability in hospital payments and to mitigate the financial impacts of significant fluctuations in the weights. That is, by smoothing year-to-year changes in the MS–DRG relative weights, this proposed policy would provide greater predictability to hospitals, allowing time to adjust to significant changes to relative weights. Moreover, consistent with the budget neutrality requirement for annual updates to the relative weights, including our implementation of similar caps on significant declines in the relative weight for prior fiscal years, we believe that application of this proposed 10-percent cap on relative weight reductions should not increase estimated aggregate Medicare payments beyond the payments that would be made had we never applied this cap. Accordingly, we are proposing to apply a budget neutrality adjustment to the standardized amount for all hospitals to ensure that application of the proposed 10-percent cap does not result in an increase or decrease of estimated aggregate payments. For a further discussion of the proposed budget neutrality adjustment, we refer readers to the Addendum of this proposed rule.

Under this proposal, in cases where the relative weight for a MS–DRG would decrease by more than 10 percent in a given fiscal year, we propose to limit the reduction to 10 percent for that fiscal year. For example, if the relative weight for an MS–DRG in FY 2022 is 1.100 and the relative weight for FY 2023 would otherwise be 0.9350, which would represent a decrease of 15 percent from FY 2022, the reduction would be limited to 10 percent, such that the proposed relative weight for FY 2023 for MS–DRG XYZ would be 0.9900 (that is, 0.90 x FY 2022 weight of 1.100). The proposed relative weights for FY 2023 as set forth in Table 5 associated with this proposed rule and available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* reflect the application of this proposed cap.

As previously summarized, in the past, we have adopted a temporary cap of 20 percent on the decline in an MS–DRG's relative weight to address certain outlier circumstances. However, as also previously discussed, we recognize that hospitals may benefit from the phase-in of smaller declines in the relative weight that may nonetheless contribute to less stability and predictability in hospital payment rates. Accordingly, for purposes of this proposed permanent cap, we considered that a higher cap, such as the twenty percent cap that we have applied previously (see, for example, 82 FR 38103), would limit declines in the relative weights for fewer MS–DRGs (5 MS–DRGs in our analysis of FY 2021 claims), while a lower cap, such as a five percent cap, would limit declines in the relative weights for more MS–DRGs (89 MS–DRGs in our analysis of FY 2021 claims), but with a larger associated budget neutrality adjustment to the standardized amount. On balance, we believe that a 10-percent cap would mitigate financial impacts resulting from significant fluctuations in the relative weights, particularly for low volume MS–DRGs, without the larger budget neutrality adjustment associated with a smaller cap. We note that this proposed policy would limit declines in the relative weight for 27 MS–DRGs, based on the FY 2021 claims data used for this proposed rule.

We note that this proposed 10-percent cap on reductions to a MS–DRG's relative weight would apply only to a given MS–DRG with its current MS–DRG number. In cases where CMS creates new MS–DRGs or modifies the MS–DRGs as part of its annual reclassifications resulting in renumbering of one or more MS–DRGs, we are proposing that this limit on the reduction in the relative weight would not apply to any MS–DRGs affected by the renumbering (that is, the proposed 10 percent cap would not apply to the relative weight for any new or renumbered MS–DRGs for the fiscal year). We propose to modify the regulations at § 412.60(b) to reflect this proposed permanent cap on relative weight reductions. We are seeking comments on our proposal to apply a 10-percent cap on decreases in a MS–DRG relative weight from one fiscal year to the next.

3. Development of Proposed National Average CCRs

We developed the proposed national average CCRs as follows:

Using the FY 2020 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. Then we created CCRs for each provider for each cost center (see the supplemental data file for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. Then we took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost per case to determine the proposed relative weight.

As discussed earlier in this section, we are proposing to (a) use 50 percent of the relative weights calculated using all cases in the FY 2021 MedPAR data and 50 percent of the relative weights calculated without COVID–19 cases in the FY 2021 MedPAR data to calculate the relative weights for FY 2023 and (b) apply a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, beginning in FY 2023.

In developing the proposed relative weights consistent with these proposals, we first created a set of relative weights using all applicable cases in the December 2021 update of the FY 2021 MedPAR data, using the methodology as described earlier in this section (Step 1). These relative weights were then normalized by an adjustment factor of 1.947540 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

Next, we created a set of relative weights using the December 2021 update of the FY 2021 MedPAR data

excluding cases with a principal or secondary diagnosis of COVID–19 (ICD–10–CM diagnosis code U07.1), and otherwise using the methodology as described earlier in this section (Step 2). These relative weights were then normalized by an adjustment factor of 1.915575.

We then averaged the results of Step 1 and Step 2 (Step 3), and normalized these relative weights by applying an adjustment factor of 1.000308 (Step 4). This normalization adjustment is intended to ensure that this proposed averaging methodology for recalibration of the FY 2023 relative weights neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

Finally, we applied the proposed 10 percent cap to the relative weights for those MS–DRGs for which the relative weight as calculated in Step 4 would otherwise have declined by more than 10 percent from the FY 2022 relative weight (Step 5). Specifically, for those MS–DRGs for which the relative weight as calculated in Step 4 declined by more than 10 percent from the FY 2022 relative weight, we set the proposed FY 2023 relative weight equal to 90 percent of the FY 2022 relative weight. The proposed relative weights for FY 2023 as set forth in Table 5 associated with this proposed rule and available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* reflect the application of this proposed cap. We are also making available a supplemental file setting forth the relative weights as calculated with all cases (Step 1), excluding cases with a principal or secondary diagnosis of COVID–19 (Step 2), following application of the normalization factor and prior to the application of this proposed cap (Step 4), and with the application of this proposed cap (Step 5) along with the other supplemental files for this proposed rule, on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.* The proposed 19 national average CCRs for FY 2023 are as follows:

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Group	CCR
Routine Days	0.421
Intensive Days	0.342
Drugs	0.187
Supplies & Equipment	0.307
Implantable Devices	0.286
Inhalation Therapy	0.15
Therapy Services	0.286
Anesthesia	0.076
Labor & Delivery	0.347
Operating Room	0.168
Cardiology	0.095
Cardiac Catheterization	0.104
Laboratory	0.108
Radiology	0.138
MRIs	0.072
CT Scans	0.035
Emergency Room	0.155
Blood and Blood Products	0.265
Other Services	0.362

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We are proposing to use that same case threshold in recalibrating the proposed MS–DRG relative weights for FY 2023. Using data from the FY 2021 MedPAR file, there were 7 MS–DRGs that contain fewer than 10 cases. For FY 2023, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, we are proposing to compute relative weights for the low-volume MS–DRGs by adjusting their final FY 2022 relative weights by the percentage change in the average weight of the cases in other MS–DRGs from FY 2022 to FY 2023. The crosswalk table is as follows.

Low-Volume MS-DRG	MS-DRG Title	Crosswalk to MS-DRG
789	Neonates, Died or Transferred to Another Acute Care Facility	Final FY 2022 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate	Final FY 2022 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
791	Prematurity with Major Problems	Final FY 2022 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
792	Prematurity without Major Problems	Final FY 2022 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
793	Full-Term Neonate with Major Problems	Final FY 2022 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
794	Neonate with Other Significant Problems	Final FY 2022 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
795	Normal Newborn	Final FY 2022 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)

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F. Add-On Payments for New Services and Technologies for FY 2023

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. The regulations at 42 CFR 412.87 implement these provisions and § 412.87(b) specifies three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. In addition, certain transformative new devices and antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway, as set forth in the regulations at § 412.87(c) and (d). We note that section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services. The system of payment for capital costs is established under section 1886(g) of the Act. Therefore, as discussed in prior rulemaking (72 FR 47307 through 47308), we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs.

In this rule, we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria, as well as other information. For further discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42300), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58736 through 58742).

a. New Technology Add-On Payment Criteria

(1) Newness Criterion

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will no longer be considered ''new'' for purposes of new medical service or technology add-on payments after CMS has recalibrated the MS–DRGs, based on available data, to reflect the cost of the technology. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a medical product receives a new FDA approval or clearance, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to another medical product that was approved or cleared by FDA and has been on the market for more than 2 to 3 years. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically whether: (1) A product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) a product is assigned to the same or a different MS–DRG; and (3) the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all

three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352) and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

(2) Cost Criterion

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to discharges involving the new medical service or technology must be assessed for adequacy. Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation beyond the geometric mean standardized charge for all cases in the MS–DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant MS–DRGs if the new medical service or technology occurs in many different MS–DRGs). The MS–DRG threshold amounts generally used in evaluating new technology add-on payment applications for FY 2023 are presented in a data file that is available, along with the other data files associated with the FY 2022 IPPS/LTCH PPS final rule and correction notice, on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*.

We note that, under the policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58603 through 58605), beginning with FY 2022, we use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for all applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS–DRG for that same fiscal year.

As finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41275), beginning with FY 2020, we include the thresholds applicable to the next fiscal year (previously included in Table 10 of the annual IPPS/LTCH PPS proposed and final rules) in the data files associated with the prior fiscal year. Accordingly, the proposed thresholds for applications for new technology add-on payments for FY 2024 are presented in a data file that is available on the CMS website, along with the other data files associated with the FY 2023 proposed rule, by clicking on the FY 2023 IPPS proposed rule home page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*.

In the FY 2022 IPPS/LTCH PPS final rule, we finalized our proposal to use the FY 2019 MedPAR claims data where we ordinarily would have used the FY 2020 MedPAR claims data for purposes of FY 2022 ratesetting. Consistent with that final policy, we finalized our proposal to use the FY 2019 claims data to set the thresholds for applications for new technology add-on payments for FY 2023. We note that, for the reasons discussed in section I.F. of the preamble of this proposed rule, we are proposing to use the FY 2021 MedPAR claims data for FY 2023 ratesetting, with certain proposed modifications to our relative weight setting and outlier methodologies. Consistent with this proposal, for the FY 2024 proposed threshold values, we are proposing to use the FY 2021 claims data to set the proposed thresholds for applications for new technology add-on payments for FY 2024. In addition, as discussed in section III.E.1.c. of this proposed rule, we are proposing to use an averaging approach for calculating the FY 2023 relative weights, to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries as compared to FY 2021. Specifically, we are proposing to average the relative weights as calculated with and without COVID–19 cases in the FY 2021 data to determine the MS–DRG relative weights for FY 2023. Certain steps of calculating the thresholds for applications for new technology add-on payments use the same charge data that is used to calculate the MS–DRG weights. As a result, different average charges per MS–DRG are calculated using the charge data for the relative weights as calculated with and without COVID–19 cases. Therefore, for purposes of calculating the FY 2024 thresholds, we are also proposing to average the data in the steps of the calculation that use charge data from the calculation of the MS–DRG weights. In addition, as discussed in section III.E.1.c. of this proposed rule, we are also considering, as an alternative to our proposal, calculating the FY 2023 MS–DRG relative weights without this proposed averaging approach to account for COVID–19 cases. In connection with this alternative approach, we are making available the threshold values as calculated without this averaged data on the ''FY 2023 Proposed Rule Homepage'' at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps,* as well as other supplemental files as discussed further in section I.O. of Appendix A of this proposed rule.

In the September 7, 2001, final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed that applicants should submit a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Specifically, applicants should submit a sample of sufficient size to enable us to undertake an initial validation and analysis of the data. We also discussed in the September 7, 2001, final rule (66 FR 46917) the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR parts 160 and 164 applies to claims information that providers submit with applications for new medical service or technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for further information on this issue.

(3) Substantial Clinical Improvement Criterion

Under the third criterion at § 412.87(b)(1), a medical service or technology must represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292), we prospectively codified in our regulations at § 412.87(b) the following aspects of how we evaluate substantial clinical improvement for purposes of new technology add-on payments under the IPPS:

- The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- A determination that a new medical service or technology represents an advance that substantially improves,

relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means—

++ The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;

++ The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient;

++ The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following: A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance; or

++ The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

• Evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

• The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.

• The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for additional discussion of the evaluation of substantial clinical improvement for purposes of new technology add-on payments under the IPPS.

We note, consistent with the discussion in the FY 2003 IPPS final rule (67 FR 50015), that although we do not question FDA's regulatory responsibility for decisions related to marketing authorization (for example, approval, clearance, etc.), we do not rely upon FDA criteria in our evaluation of substantial clinical improvement for purposes of determining what drugs, devices, or technologies qualify for new technology add-on payments under Medicare. This criterion does not depend on the standard of safety and effectiveness on which FDA relies but on a demonstration of substantial clinical improvement in the Medicare population.

b. Alternative Inpatient New Technology Add-on Payment Pathway

Beginning with applications for FY 2021 new technology add-on payments, under the regulations at § 412.87(c), a medical device that is part of FDA's Breakthrough Devices Program may qualify for the new technology add-on payment under an alternative pathway. Additionally, under the regulations at § 412.87(d) for certain antimicrobial products, beginning with FY 2021, a drug that is designated by FDA as a Qualified Infectious Disease Product (QIDP), and, beginning with FY 2022, a drug that is approved by FDA under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD), may also qualify for the new technology add-on payment under an alternative pathway. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for further discussion on this policy. We note that a technology is not required to have the specified FDA designation at the time the new technology add-on payment application is submitted. CMS reviews the application based on the information provided by the applicant only under the alternative pathway specified by the applicant at the time of application submission. However, to receive approval for the new technology add-on payment under that alternative pathway, the technology must have the applicable FDA designation and meet all other requirements in the regulations in § 412.87(c) and (d), as applicable.

(1) Alternative Pathway for Certain Transformative New Devices

For applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, if a medical device is part of FDA's Breakthrough Devices Program and received FDA marketing authorization, it will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement under § 412.87(b)(1) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this alternative pathway, a medical device that has received FDA marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by, FDA) and that is part of FDA's Breakthrough Devices Program will need to meet the requirements of § 412.87(c). We note that in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736), we clarified our policy that a new medical device under this alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736) for further discussion regarding this clarification.

(2) Alternative Pathway for Certain Antimicrobial Products

For applications received for new technology add-on payments for certain antimicrobial products, beginning with FY 2021, if a technology is designated by FDA as a QIDP and received FDA marketing authorization, and, beginning with FY 2022, if a drug is approved under FDA's LPAD pathway and used for the indication approved under the LPAD pathway, it will be considered not substantially similar to an existing technology for purposes of new technology add-on payments and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or

treatment of Medicare beneficiaries. Under this alternative pathway for QIDPs and LPADs, a medical product that has received FDA marketing authorization and is designated by FDA as a QIDP or approved under the LPAD pathway will need to meet the requirements of § 412.87(d).

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for further discussion on this policy. We note, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739), we clarified that a new medical product seeking approval for the new technology add-on payment under the alternative pathway for QIDPs must receive marketing authorization for the indication covered by the QIDP designation. We also finalized our policy to expand our alternative new technology add-on payment pathway for certain antimicrobial products to include products approved under the LPAD pathway and used for the indication approved under the LPAD pathway.

c. Additional Payment for New Medical Service or Technology

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. As noted previously, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (72 FR 47307 through 47308).

For discharges occurring before October 1, 2019, under § 412.88, if the costs of the discharge (determined by applying operating cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), CMS made an add-on payment equal to the lesser of: (1) 50 percent of the costs of the new medical service or technology; or (2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

Beginning with discharges on or after October 1, 2019, for the reasons discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300), we finalized an increase in the new technology add-on payment percentage, as reflected at § 412.88(a)(2)(ii). Specifically, for a new technology other than a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product approved under FDA's LPAD pathway, beginning with discharges on or after October 1, 2020, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. As set forth in § 412.88(b)(2), unless the discharge qualifies for an outlier payment, the additional Medicare payment will be limited to the full MS–DRG payment plus 65 percent (or 75 percent for certain antimicrobial products (QIDPs and LPADs)) of the estimated costs of the new technology or medical service. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300) for further discussion on the increase in the new technology add-on payment beginning with discharges on or after October 1, 2019.

Section 503(d)(2) of Public Law 108–173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108–173, add-on payments for new medical services or technologies for FY 2005 and subsequent years have not been subjected to budget neutrality.

d. Evaluation of Eligibility Criteria for New Medical Service or Technology Applications

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulation at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We specified that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. In the FY 2021 IPPS/LTCH PPS final rule, to more precisely describe the various types of FDA approvals, clearances and classifications that we consider under our new technology add-on payment policy, we finalized a technical clarification to the regulation to indicate that new technologies must receive FDA marketing authorization (such as pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request, or approval of a New Drug Application (NDA)) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Consistent with our longstanding policy, we consider FDA marketing authorization as representing that a product has received FDA approval or clearance when considering eligibility for the new technology add-on payment under § 412.87(e)(2) (85 FR 58742).

Additionally, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58739 through 58742), we finalized our proposal to provide conditional approval for new technology add-on payment for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology otherwise meets the applicable add-on payment criteria. Under this policy, cases involving

eligible antimicrobial products would begin receiving the new technology add-on payment sooner, effective for discharges the quarter after the date of FDA marketing authorization provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments.

e. New Technology Liaisons

Many stakeholders (including device/biologic/drug developers or manufacturers, industry consultants, others) engage CMS for coverage, coding, and payment questions or concerns. In order to streamline stakeholder engagement by centralizing the different innovation pathways within CMS including new technology add-on payments, CMS has established a team of new technology liaisons that can serve as an initial resource for stakeholders. This team is available to assist with all of the following:

- Help to point stakeholders to or provide information and resources where possible regarding process, requirements, and timelines.
- Coordinate and facilitate opportunities for stakeholders to engage with various CMS components.
- Serve as a primary point of contact for stakeholders and provide updates on developments where possible or appropriate.

We received many questions from stakeholders interested in pursuing new technology add-on payments who may not be entirely familiar with working with CMS. While we encourage stakeholders to first review our resources available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech,* we know that there may be additional questions about the application process. Stakeholders with further questions about Medicare's coverage, coding, and payment processes, and about how they can navigate these processes, whether for new technology add-on payments or otherwise, can contact the new technology liaison team at *Medicare Innovation@cms.hhs.gov.*

f. Application Information for New Medical Services or Technologies

Applicants for add-on payments for new medical services or technologies for FY 2024 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement (unless the application is under one of the alternative pathways as previously described), along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. CMS will review the application based on the information provided by the applicant under the pathway specified by the applicant at the time of application submission. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.* To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2024, the CMS website also will post the tracking forms completed by each applicant. We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the formal request for add-on payments for new medical services and technologies to CMS. The aforementioned burden is subject to the Paper Reduction Act (PRA) and approved under OMB control number 0938–1347, and has an expiration date of 11/30/2023.

As discussed previously, in the FY 2020 IPPS/LTCH PPS final rule, we adopted an alternative inpatient new technology add-on payment pathway for certain transformative new devices and for Qualified Infectious Disease Products, as set forth in the regulations at § 412.87(c) and (d). The change in burden associated with these changes to the new technology add-on payment application process were discussed in a revision of the information collection requirement (ICR) request currently approved under OMB control number 0938–1347, with an expiration date of November 30, 2023. In accordance with the implementing regulations of the PRA, we detailed the revisions of the ICR and published the required 60-day notice on August 15, 2019 (84 FR 41723), and 30-day notice on December 17, 2019 (84 FR 68936), to solicit public comments.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Public Law 108–173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement. The process for evaluating new medical service and technology applications requires the Secretary to do all of the following:

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries.
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending.
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement.
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2023 prior to publication of the FY 2023 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on September 24, 2021 (86 FR 53056), and held a virtual town hall meeting on December 14, 2021. In the announcement notice for the meeting, we stated that the opinions and presentations provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for the FY 2023 new medical service and technology add-on payment applications before the publication of the FY 2023 IPPS/LTCH IPPS proposed rule.

Approximately 378 individuals registered to attend the virtual town hall meeting. We posted the recordings of the virtual town hall on the CMS web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.*

We considered each applicant's presentation made at the town hall meeting, as well as written comments received by the December 27, 2021, deadline, in our evaluation of the new technology add-on payment applications for FY 2023 in the development of this FY 2023 IPPS/

LTCH PPS proposed rule. In response to the published notice and the December 14, 2021, New Technology Town Hall meeting, we received written comments regarding the applications for FY 2023 new technology add on payments. As explained earlier and in the **Federal Register** notice announcing the New Technology Town Hall meeting (86 FR 53056 through 53059), the purpose of the meeting was specifically to discuss the substantial clinical improvement criterion with regard to pending new technology add-on payment applications for FY 2023. Therefore, we are not summarizing those written comments in this proposed rule that are unrelated to the substantial clinical improvement criterion. In section II.F.6. of the preamble of this proposed rule, we are summarizing comments regarding individual applications, or, if applicable, indicating that there were no comments received in response to the New Technology Town Hall meeting notice or New Technology Town Hall meeting, at the end of each discussion of the individual applications.

3. ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49434), the ICD–10–PCS includes a new section containing the new Section ''X'' codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD–10–PCS Section ''X'' codes will be handled in the same manner as the decisions for all of the other ICD–10–PCS code changes. That is, proposals to create, delete, or revise Section ''X'' codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section ''X'' code within the structure of the ICD–10–PCS. We posted ICD–10–PCS Guidelines on the CMS website at *https://www.cms.gov/medicare/icd-10/2021-icd-10-pcs,* including guidelines for ICD–10–PCS Section ''X'' codes. We encourage providers to view the material provided on ICD–10–PCS Section ''X'' codes.

As discussed in more detail in section II.F.8. of the preamble of this proposed rule, we are proposing to use NDCs instead of ICD–10–PCS Section ''X'' codes to identify cases involving the use of therapeutic agents approved for new technology add-on payments beginning with a transitional period in FY 2023. We refer the reader to section II.F.8. of the preamble of this proposed rule for a full discussion of this proposal.

4. New COVID–19 Treatments Add-On Payment (NCTAP)

In response to the COVID–19 public health emergency (PHE), we established the New COVID–19 Treatments Add-on Payment (NCTAP) under the IPPS for COVID–19 cases that meet certain criteria (85 FR 71157 through 71158). We believe that as drugs and biological products become available and are authorized for emergency use or approved by FDA for the treatment of COVID–19 in the inpatient setting, it is appropriate to increase the current IPPS payment amounts to mitigate any potential financial disincentives for hospitals to provide new COVID–19 treatments during the PHE. Therefore, effective for discharges occurring on or after November 2, 2020 and until the end of the PHE for COVID–19, we established the NCTAP to pay hospitals the lesser of (1) 65 percent of the operating outlier threshold for the claim or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment, including the adjustment to the relative weight under section 3710 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, for certain cases that include the use of a drug or biological product currently authorized for emergency use or approved for treating COVID–19.

In the FY 2022 IPPS/LTCH PPS final rule, we finalized a change to our policy to extend NCTAP through the end of the FY in which the PHE ends for all eligible products in order to continue to mitigate potential financial disincentives for hospitals to provide these new treatments, and to minimize any potential payment disruption immediately following the end of the PHE. We also finalized that, for a drug or biological product eligible for NCTAP that is also approved for new technology add-on payments, we will reduce the NCTAP for an eligible case by the amount of any new technology add-on payments so that we do not create a financial disincentive between technologies eligible for both the new technology add-on payment and NCTAP compared to technologies eligible for NCTAP only (85 FR 45162).

Further information about NCTAP, including updates and a list of currently eligible drugs and biologicals, is available on the CMS website at *https://www.cms.gov/medicare/covid-19/new-covid-19-treatments-add-payment-nctap.*

5. Proposed FY 2023 Status of Technologies Receiving New Technology Add-On Payments for FY 2022

In this section of the proposed rule, we discuss the proposed FY 2023 status of 37 technologies approved for FY 2022 new technology add-on payments, including 2 technologies approved for 2 separate add-on payments for different indications (RECARBRIO™ and FETROJA®), as set forth in the tables that follow. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. We note that, as discussed later in this section, we provided a 1-year extension of new technology add-on payments for FY 2022 for 13 technologies for which the new technology add-on payment would otherwise be discontinued beginning in FY 2022 using our authority under section 1886(d)(5)(I) of the Act.

Additionally, we note that we conditionally approved CONTEPO for FY 2022 new technology add-on payments under the alternative pathway for certain antimicrobial products (86 FR 45155), subject to the technology receiving FDA marketing authorization by July 1, 2022. As of the time of the development of this proposed rule, CONTEPO has not yet received FDA approval. If CONTEPO receives FDA marketing authorization before July 1, 2022, the new technology add-on payment for cases involving the use of this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. If FDA marketing authorization is received on or after July 1, 2022, no new technology add-on payments would be made for cases involving the use of CONTEPO for FY 2022. If CONTEPO receives FDA marketing authorization prior to July 1, 2022, we are proposing to continue making new technology add-on payments for CONTEPO for FY 2023. If CONTEPO does not receive FDA marketing authorization by July 1, 2022, then it would not be eligible for new technology add-on payments for FY 2022, and therefore would not be eligible for the continuation of new technology add-on payments for FY 2023. We further note that the applicant for CONTEPO did not submit an application for FY 2023 new technology add on payments and, therefore, the technology also would not be eligible for approval or conditional approval for

new technology add-on payments for FY 2023.

a. Proposed FY 2023 Status of Technologies Approved for FY 2022 New Technology Add-On Payments

As noted previously, we used our authority under section 1886(d)(5)(I) of the Act to allow a 1-year extension of new technology add-on payments for FY 2022 for 13 technologies for which the add-on payments would otherwise be discontinued beginning in FY 2022 because the technologies would no longer be considered ''new'' for FY 2022. In this section, we discuss the proposed FY 2023 status for the remaining 24 technologies approved for FY 2022 new technology add-on payments. Specifically, we present our proposals to continue the new technology add-on payment for FY 2023 for those technologies that were approved for the new technology add-on payment for FY 2022 and which would still be considered ''new'' for purposes of new technology add-on payments for FY 2023. We also present our proposals to discontinue new technology add-on payment for FY 2023 for those technologies that were approved for the new technology add-on payment for FY 2022 and which would no longer be considered ''new'' for purposes of new technology add-on payments for FY 2023.

Our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).

The following table lists the technologies for which we are proposing to discontinue making new technology add-on payments for FY 2023 because they are no longer ''new'' for purposes of new technology add-on payments. This table also presents the newness start date, new technology add-on payment start date, the 3-year anniversary date of the product's entry onto the U.S. market, relevant final rule citations from prior fiscal years, and coding assignments for each technology. We refer readers to the cited final rules in the following table for a complete discussion of the new technology add-on payment application, coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

We are inviting public comments on our proposals to discontinue new technology add-on payments for FY 2023 for the technologies listed in the Table BBBB–A1.

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Table II.F.–02 lists the technologies for which we are proposing to continue making new technology add-on payments for FY 2023 because they are still considered ''new'' for purposes of new technology add-on payments. This table also presents the newness start date, new technology add-on payment start date, 3-year anniversary date of the product's entry onto the U.S. market, relevant final rule citations from prior

TABLE II.F.-01: PROPOSED DISCONTINUATION OF TECHNOLOGIES APPROVED FOR FY 2022 NEW TECHNOLOGY ADD-ON PAYMENTS NO LONGER CONSIDERED NEW FOR FY 2023 BECAUSE 3-YEAR ANNIVERSARY DATE WILL OCCUR PRIOR TO APRIL 1, 2023

	Technology	FDA/Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto US Market	Previous Final Rule Citations	Coding Used to Identify Cases Eligible for NTAP
1	*Balversa™*	*04/12/2019*	*10/19/2019*	*4/12/2022*	84 FR 42237 through 42242 85 FR 58616 86 FR 44973 through 44974	XW0DXL5
2	*Jakafi®*	*05/24/2019*	*10/1/2019*	*5/24/2022*	84 FR 42265 through 42273 85 FR 58617 through 58618 86 FR 44973 through 44974	XW0DXT5
3	*BAROSTIM NEO™ System*	*08/16/2019*	*10/1/2020*	*08/16/2022*	85 FR 58716 through 58717 86 FR 44973 through 44974 86 FR 67874 through 67876	0JH60MZ in combination with 03HK3MZ or 03HL3MZ
4	*Optimizer® System*	*10/23/2019*	*10/1/2020*	*10/23/2022*	85 FR 58720 through 58721 86 FR 44973 through 44974	0JH60AZ, 0JH63AZ, 0JH80AZ or 0JH83AZ
5	*RECARBRIO™ (cUTI/ cIAI)*	*07/16/2019 commercially available in US 1/6/20*	*10/1/2020*	*1/6/2023*	85 FR 58727 through 58729 86 FR 44973 through 44974 86 FR 67874 through 67876	XW033U5 or XW043U5
6	*Soliris®*	*06/27/2019*	*10/1/2020*	*6/27/2022*	85 FR 58684 through 58689 86 FR 44973 through 44975	XW033C6 and XW043C6
7	*XENLETA™*	*08/19/2019 commercially available in US 9/10/19*	*10/1/2020*	*9/10/2022*	85 FR 58729 through 58732 86 FR 44973 through 44975	XW03366, XW04366 or XW0DX66
8	*ZERBAXA®*	*06/03/2019*	*10/1/2020*	*6/03/2022*	85 FR 58732 through 58733 86 FR 44973 through 44975	XW03396 or XW04396
9	*Azedra®*	*05/21/2019*	*10/1/2019*	*5/21/2022*	84 FR 42194 through 42201 85 FR 58615 86 FR 44973 through 44975	XW033S5 and XW043S5
10	*EXALT™ Model D*	*12/13/2019*	*10/1/2021*	*12/13/2022*	86 FR 45138 through 45140	XFJB8A7 or XFJD8A7
11	*Fetroja® (Cefiderocol)* (cUTI)	*11/19/2019 Commercially available in US 2/24/2020*	*10/1/2020*	*2/24/2023*	85 FR 58721 through 58723 86 FR 44973 through 44974 86 FR 67876	XW033A6 or XW043A6

fiscal years, proposed maximum add-on payment amount, and coding assignments for each technology. We refer readers to the cited final rules in the following table for a complete discussion of the new technology add-on payment application, coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

We note, as discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45104 through 45107), on May 1, 2020, VEKLURY® (remdesivir) received an Emergency Use Authorization (EUA) from FDA for the treatment of suspected or laboratory confirmed COVID–19 in adults and children hospitalized with severe disease. The applicant asserted that between July 1, 2020 and September 30, 2020, it entered into an agreement with the U.S. Government to allocate and distribute commercially-available VEKLURY® across the country. The applicant stated that under this agreement, the first sale of VEKLURY® was completed on July 10, 2020. The applicant stated that they transitioned to a more traditional, unallocated model of distribution as of October 1, 2020. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45107), we determined that VEKLURY® meets the newness criterion with an indication for use in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID–19 requiring hospitalization. We stated that consistent with our longstanding policy, we considered the newness period for VEKLURY® to begin on October 22, 2020, when the NDA for VEKLURY® was approved by FDA for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID–19 requiring hospitalization. We also discussed comments solicited regarding the newness period for products available through an EUA for COVID–19 in section II.F.7. of the FY 2022 IPPS/LTCH PPS final rule (86 FR 45159 through 45160), including comments we received regarding the potential variability in cost estimates for technologies available under an EUA due to government price subsidies or variable treatment practices in the context of the global pandemic and comments suggesting that CMS monitor pricing changes for products available under an EUA once a product receives full marketing authorization, instead of basing the newness period on data that may have become available under an EUA, and indicated that we would consider these comments for future rulemaking.

After further review of the information provided by the applicant, we believe that additional information related to VEKLURY®'s commercial availability is relevant to assessing the start of the newness period for VEKLURY®. The applicant stated that once VEKLURY® was issued an EUA, from May through June 2020, the entire existing supply of VEKLURY® was donated worldwide and distributed to hospitals free of charge.[26] The applicant further stated that the commercial list price of the technology was announced when it entered into the agreement with the U.S. Government previously described, in anticipation of the post-donation phase. Under this agreement, the U.S. Government allocated VEKLURY® to each hospital, and the hospitals would then choose to purchase quantities of VEKLURY® directly from the applicant's subsidiary who was the sole distributor.[27] [28]

We continue to believe this issue is complex, particularly as it relates to VEKLURY® as a technology that has been available under both an EUA and an NDA. As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45159 through 45160), while an EUA is not marketing authorization within the meaning of § 412.87(e)(2) for purposes of eligibility for new technology add-on payments, data reflecting the costs of products that have received an EUA could become available as soon as the date of the EUA issuance and prior to receiving FDA approval or clearance. In the case of VEKLURY®, we believe that there may be unique considerations in determining the start of the newness period in light of the donation period, during which the technology was distributed at no cost. Accordingly, while we continue to believe that data reflecting the costs of a product that has received an EUA could become available as soon as the date of EUA issuance for that product, we believe that with respect to VEKLURY®, such data may not have become available until after the end of the donation period, when the technology became commercially available, on July 1, 2020. For these reasons, after further consideration, we believe the newness period for VEKLURY® may more appropriately begin on July 1, 2020, the date on which the technology became available for sale under the allocation agreement. We note that VEKLURY® would still be considered new for FY 2023 regardless of whether the newness period began on May 1 (the date of the EUA), July 1 (the date the donation phase ended), October 22 (the date of the NDA), or some other date in between, as in all cases the three-year anniversary date would occur after April 1, 2023, and therefore the product would remain eligible for FY 2023 new technology add-on payments.

Therefore, as reflected in the table that follows, we are proposing to continue new technology add-on payments for VEKLURY® for FY 2023. We invite public comments on this proposal, including the newness start date for VEKLURY®. As discussed, while we continue to believe that data reflecting the costs of a product that has received an EUA could become available as soon as the date of EUA issuance for that product, we also recognize that there may be unique considerations in determining the start of the newness period for a product available under an EUA. We are continuing to consider the comments as discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45159) regarding the newness period for products available through an EUA for COVID–19, and we welcome additional comments in this proposed rule.

We further note that we are proposing to continue new technology add-on payments for Caption Guidance for FY 2023, a technology sold on a subscription basis. We continue to welcome comments from the public as to the appropriate method to determine a cost per case for technologies sold on a subscription basis, including comments on whether the cost per case should be estimated based on subscriber hospital data as described previously, and if so, whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment.

We are inviting public comments on our proposals to continue new technology add-on payments for FY 2023 for the technologies listed in the following table.

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[26] *https://stories.gilead.com/articles/an-update-on-covid-19-from-our-chairman-and-ceo.*

[27] Remdesivir for the Commercial Marketplace. *https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/factsheet.aspx.*

[28] Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response (ASPR). ASPR's Portfolio of COVID–19 Medical Countermeasures Made Available as a Licensed Product. *https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/Veklury.aspx.*

TABLE II.F.-02: PROPOSED CONTINUATION OF TECHNOLOGIES APPROVED FOR FY 2022 NEW TECHNOLOGY ADD-ON PAYMENTS STILL CONSIDERED NEW FOR FY 2023 BECAUSE 3-YEAR ANNIVERSARY DATE WILL OCCUR ON OR AFTER APRIL 1, 2023

	Technology	FDA/Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto US Market	Previous Final Rule Citations	Proposed Maximum NTAP Amount for FY 2023	Coding Used to Identify Cases Eligible for NTAP
1	*Rybrevant™*	*05/21/2021*	*10/1/2021*	*5/21/2024*	86 FR 44988 through 44996	$6,405.89	XW033B7 or XW043B7
2	*Cosela™*	*02/12/2021*	*10/1/2021*	*2/12/2024*	86 FR 45008 through 45017	$5,526.30	XW03377 or XW04377
3	*ABECMA®*	*03/26/2021*	*10/1/2021*	*3/26/2024*	86 FR 45028 through 45035	$272,675.00	XW033K7 or XW043K7
4	*StrataGraft®*	*06/15/2021*	*10/1/2021*	*6/15/2024*	86 FR 45079 through 45090	$44,200.00	XHRPXF7
5	*TECARTUS®*	*07/4/2020*	*10/1/2021*	*7/4/2023*	86 FR 45090 through 45104	$259,350.00	XW033M7 or XW043M7
6	*VEKLURY®*	*07/1/2020**	*10/1/2021*	*7/1/2023**	86 FR 45104 through 45116	$2,028.00	XW033E5 or XW043E5
7	*Zepzelca™*	*06/15/2020*	*10/1/2021*	*6/15/2023*	86 FR 45116 through 45126	$8,622.90	XW03387 or XW04387
8	*aprevo® Intervertebral Body Fusion Device*	*12/03/2020 (ALIF and LLIF) 6/30/2021 (TLIF)*	*10/1/2021*	*12/03/2023 (ALIF and LLIF) 6/30/2024 (TLIF)*	86 FR 45127 through 45133 86 FR 67874 through 67876	$40,950.00	XRGA0R7 or XRGA3R7 or XRGA4R7 or XRGB0R7 or XRGB3R7 or XRGB4R7 or XRGC0R7 or XRGC3R7 or XRGC4R7 or XRGD0R7 or XRGD3R7 or XRGD4R7
9	*aScope® Duodeno*	*07/17/2020*	*10/1/2021*	*7/17/2023*	86 FR 45133 through 45135	$1,715.59	XFJB8A7 or XFJD8A7
10	*Caption Guidance™*	*09/15/2020*	*10/1/2021*	*9/15/2023*	86 FR 45135 through 45138	$1,868.10	X2JAX47
11	*Harmony™ Transcatheter Pulmonary Valve (TPV) System*	*03/26/2021*	*10/1/2021*	*3/26/2024*	86 FR 45146 through 45149	$26,975.00	02RH38M
12	*Intercept® (PRCFC)*	*05/05/2021*	*10/1/2021*	*5/05/2024*	86 FR 45149 through 45150 86 FR 67875	$2,535.00	30233D1 or 30243D1 in combination with one of the following D62, D65, D68.2, D68.4 or D68.9
13	*ShockWave C2 Intravascular Lithotripsy (IVL) System*	*02/12/2021*	*10/1/2021*	*2/12/2024*	86 FR 45151 through 45153	$3,666.00	02F03ZZ or 02F13ZZ or 02F23ZZ or 02F33ZZ
14	*Fetroja® (HABP/VABP)*	*09/25/2020*	*10/1/2021*	*9/25/2023*	86 FR 45156 through 45157 86 FR 67876	$8,579.84	XW033A6 or XW043A6 in combination with ICD-10-CM code Y95 and one of the following: J14, J15.0, J15.1, J15.5, J15.6, J15.8, or J95.851 and one of the following: B96.1, B96.20, B96.21, B96.22, B96.23, B96.29, B96.3, B96.5, or B96.89

15	*Recarbrio™ (HABP/VABP)*	*06/04/2020*	*10/1/2021*	*6/04/2023*	86 FR 45157 through 45158 86 FR 67874	$9,576.51	XW033U5 or XW043U5 in combination with ICD-10-CM code Y95 and one of the following: J14, J15.0, J15.1, J15.5, J15.6, J15.8, or J95.851 and one of the following: B96.1, B96.20, B96.21, B96.22, B96.23, B96.29, B96.3, B96.5, or B96.89

*See discussion above, regarding our proposal that the newness period for VEKLURY® should begin on July 1, 2020, when the technology became commercially available.

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b. Status of Technologies Provided a One-Year Extension of New Technology Add-On Payments in FY 2022

As stated in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44789), our goal is always to use the best available data overall for ratesetting. The best available MedPAR data would typically be the most recent MedPAR file that contains claims from discharges for the fiscal year that is 2 years prior to the fiscal year that is the subject of the rulemaking.

In the FY 2022 IPPS/LTCH PPS final rule, for the reasons discussed, we finalized that we would use FY 2019 MedPAR data instead of FY 2020 MedPAR data to develop the FY 2022 MS–DRG relative weights (86 FR 44789 through 44793). Because we finalized that we would use FY 2019 MedPAR data instead of FY 2020 MedPAR data for the development of the FY 2022 MS–DRG relative weights, we stated that the costs for a new technology for which the 3-year anniversary date of the product's entry onto the U.S. market occurs prior to the latter half of FY 2022 may not be fully reflected in the MedPAR data used to recalibrate the MS–DRG relative weights for FY 2022. Therefore, in light of this final policy, we finalized our proposal to use our authority under section 1886(d)(5)(I) of the Act to allow for a 1-year extension of new technology add-on payments for FY 2022 for 13 technologies (see table below) for which the new technology add-on payment would have otherwise been discontinued beginning with FY 2022. We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44975 through 44979) for a complete discussion regarding this 1-year extension for FY 2022.

For FY 2023 ratesetting, as we discuss in section I.F. of this proposed rule, we believe the best available data would be the FY 2021 MedPAR file. As discussed in section I.F. of this proposed rule, for FY 2023, we are proposing to use the FY 2021 MedPAR (the best available data at the time of this proposed rule) for FY 2023 ratesetting, including for purposes of developing the FY 2023 relative weights. We refer the reader to section I.F. of this proposed rule for a complete discussion regarding our proposal to use the FY 2021 MedPAR for the FY 2023 ratesetting and recalibration of the FY 2023 MS–DRG relative weights.

As noted previously, our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. For FY 2023, because we are proposing to use FY 2021 MedPAR data to recalibrate the FY 2023 MS–DRG relative weights, we believe the costs of the 13 technologies in the following table, for which the 3-year anniversary date of the product's entry onto the U.S. market occurs prior to FY 2023 (and therefore are no longer ''new''), may now be fully reflected in the MedPAR data used to recalibrate the MS–DRG relative weights for FY 2023. As a result, we are proposing to discontinue new technology add on payments for these 13 technologies in FY 2023.

We are inviting public comments on our proposals to discontinue new technology add-on payments for FY 2023 for these 13 technologies listed in Table BBBB–A3.

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TABLE II.F.-03: PROPOSED DISCONTINUATION OF TECHNOLOGIES WHICH RECEIVED A ONE YEAR EXTENSION FOR NEW TECHNOLOGY ADD-ON PAYMENT IN FY 2022 BECAUSE 3-YEAR ANNIVERSARY DATE OCCURRED BEFORE THE SECOND HALF OF FY 2022

Technology		FDA/Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto US Market	Previous Final Rule Citations	Coding Used to Identify Cases Eligible for NTAP
1	*Cablivi®*	*02/06/2019*	*10/01/2019*	*02/06/2022*	84 FR 42201 through 42208 85 FR 58615 86 FR 44977 through 44979	XW013W5, XW033W5 and XW043W5
2	*Elzonris™*	*12/21/2018*	*10/01/2019*	*12/21/2021*	84 FR 42231 through 42237 85 FR 58615 through 58616 86 FR 44977 through 44979	XW033Q5 and XW043Q5
3	*AndexXa™*	*05/03/2018*	*10/01/2018*	*05/03/2021*	83 FR 41355 through 41362 84 FR 42193 through 42194 85 FR 58614 through 58615 86 FR 44977 through 44979	XW03372 or XW04372
4	*Spravato®*	*3/5/2019*	*10/01/2019*	*3/5/2022*	84 FR 42247 through 42256 85 FR 58616 through 58617 86 FR 44977 through 44979	XW097M5
5	*Zemdri®*	*6/25/2018*	*10/01/2018*	*6/25/2021*	83 FR 41326 through 41334 84 FR 42190 through 42191 85 FR 58613 86 FR 44977 through 44979	XW033G4 and XW04G4
6	*T2 Bacteria® Panel*	*05/24/2018*	*10/01/2019*	*05/24/2021*	84 FR 42278 through 42288 85 FR 58618 86 FR 44977 through 44979	XXE5XM5
7	*ContaCT*	*02/13/2018 (commercially available 10/01/2018)*	*10/01/2020*	*10/01/2021*	85 FR 58625 through 58636 86 FR 44977 through 44979	4A03X5D
8	*Eluvia™ Drug-Eluting Vascular Stent System*	*09/18/2018 commercially available in US 10/04/2018*	*10/01/2020*	*10/04/2021*	85 FR 58645 through 58658 86 FR 44977 through 44979	X27H385, X27H395, X27H3B5, X27H3C5, X27J385, X27J395, X27J3B5, X27J3C5, X27K385, X27K395, X27K3B5, X27K3C5, X27L385, X27L395, X27L3B5, X27L3C5
9	*Hemospray®*	*05/07/2018 (commercially available 07/01/2018)*	*10/01/2020*	*07/01/2021*	85 FR 58665 through 58672 86 FR 44977 through 44979	XW0G886 and XW0H886

Technology		FDA/Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto US Market	Previous Final Rule Citations	Coding Used to Identify Cases Eligible for NTAP
10	*IMFINZI®/ TECENTRIQ®*	*Imfinzi: 03/27/2020; Tecentriq: 03/18/2019 Newness date is 3/18/2019 for both*	*10/01/2020*	*03/18/2022*	85 FR 58672 through 58684 86 FR 44977 through 44979	Imfinzi XW03336 or XW04336 Tecentriq XW033D6 or XW043D6
11	*NUZYRA®*	*10/02/2018 (commercially available 02/01/2019)*	*10/01/2020*	*2/01/2022*	85 FR 58725 through 58727 86 FR 44977 through 44979	XW033B6 or XW043B6
12	*SpineJack® System*	*08/30/2018 (commercially available 10/11/2018)*	*10/01/2020*	*10/11/2021*	85 FR 58689 through 58701 86 FR 44977 through 44979	XNU0356 and XNU4356
13	Xospata®	11/28/2018	10/01/2019	11/28/2021	84 FR 42256 through 42260 85 FR 58617 86 FR 44977 through 44979	XW0DXV5

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6. FY 2023 Applications for New Technology Add-On Payments (Traditional Pathway)

We received 18 applications for new technology add-on payments for FY 2023 under the traditional new technology add-on payment pathway. In accordance with the regulations under § 412.87(e), applicants for new technology add-on payments must have received FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Five applicants withdrew their applications prior to the issuance of this proposed rule. We are addressing the remaining 13 applications.

a. CARVYKTI™ (ciltacabtagene autoleucel)

Janssen Biotech, Inc., submitted an application for new technology add-on payments for CARVYKTI™ (ciltacabtagene autoleucel) for FY 2023. CARVYKTI™ is an autologous chimeric-antigen receptor (CAR) T-cell therapy directed against B cell maturation antigen (BCMA) for the treatment of patients with multiple myeloma. We note that Janssen Biotech, Inc. previously submitted an application for new technology add-on payments for CARVYKTI™ for FY 2022 under the name ciltacabtagene autoleucel, as summarized in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25233 through 25239), but withdrew that application prior to the issuance of the FY 2022 IPPS/LTCH PPS final rule (86 FR 44979).

The applicant stated that ciltacabtagene autoleucel refers to both JNJ–4528, an investigational BCMA-directed CAR T-cell therapy for previously treated patients with multiple myeloma, and LCAR–B38M, the investigational product (ciltacabtagene autoleucel) being studied in China. Both JNJ–4528 and LCAR–B38M are representative of the same CAR T-cell therapy, ciltacabtagene autoleucel.

Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells.[29] Plasma cells, found in bone marrow, make the antibodies that help the body attack and kill various pathogens. According to the applicant, when damaged, malignant plasma cells rapidly spread and replace the normal cells in the bone marrow.[30] The applicant asserted the median age of onset is 69 years old and only 3% of patients are less than 45 at the age of diagnosis; it was estimated that in 2021 nearly 35,000 people would be diagnosed and more than 12,000 will die from multiple myeloma in the US.[31] According to the applicant, multiple myeloma is associated with substantial morbidity and mortality [32] and median 5 year survival is 56%.[33]

According to the applicant, introduction of new treatment options in the last 2 decades has extended the median survival of multiple myeloma patients. The applicant asserted that the introduction of proteasome inhibitors (PI) (for example, bortezomib, carfilzomib, and ixazomib), histone deacetylase inhibitors (for example, panobinostat, vorinostat), immunomodulatory agents (IMiD) (for example, thalidomide, lenalidomide, and pomalidomide), monoclonal antibodies (daratumumab and elotuzumab), and stem cell transplantation, have allowed numerous therapeutic options for patients with multiple myeloma (Rajkumar 2020). According to the applicant, the National Comprehensive Cancer Network (NCCN) recommended treatment regimen for first-line therapy of multiple myeloma is bortezomib (a PI), lenalidomide (an IMiD) and dexamethasone.[34] According to the applicant, the strategy of triplet therapies for patients with newly diagnosed multiple myeloma, followed by high-dose chemotherapy and autologous stem-cell transplantation for eligible patients, and subsequently consolidation and maintenance therapy, is the current treatment roadmap for patients.[35] However, despite these treatments, according to the applicant, most patients will relapse after first-line treatment and require further treatment [36] with only 50% survival of relapsed patients after 5 years.[37] [38] The applicant stated that as multiple myeloma progresses, each subsequent line of treatment is associated with shorter progression free survival (PFS) and decreased rate, depth, and durability of response and worsening of quality of life.[39] In addition, cumulative and long-term toxicities are often associated with long-term therapy (Ludwig, 2018). Thus, according to the applicant, there remains an ongoing need for additional therapeutic approaches when the disease is resistant to available therapy.

The applicant asserted that relapsed and refractory (r/r) multiple myeloma (RRMM) constitutes a specific unmet medical need. According to the applicant, patients with r/r disease are defined as those who, having achieved a minor response or better, relapse and then progress while on therapy, or experience progression within 60 days of their last therapy.[40] [41] The applicant stated the introduction of a new class of agents, CD38-targeting monoclonal antibodies (CD38 MoAbs), daratumumab and isatuximab, have improved options in r/r patients.[42] The applicant asserted that given these advances, guideline recommendations following first-line therapy are varied, with treatment options including combinations of novel agents with existing standard of care regimens, and include triplet and quadruplet regimens, creating a complex treatment landscape.[43] According to the applicant, while triplet regimens should be used as the standard therapy for patients with

[29] Ho, M., Chen, T., Liu, J. et al. Targeting histone deacetylase 3 (HDAC3) in the bone marrow microenvironment inhibits multiple myeloma proliferation by modulating exosomes and IL–6 trans-signaling. Leukemia 34, 196–209 (2020). *https://doi.org/10.1038/s41375-019-0493-x.*

[30] Utley A, Lipchick B, Lee KP, Nikiforov MA. Targeting Multiple Myeloma through the Biology of Long-Lived Plasma Cells. Cancers (Basel). 2020 Jul 30;12(8):2117.

[31] Surveillance, Epidemiology, and End Results (SEER) Program. SEER database 2020; *https://seer.cancer.gov/statfacts/html/mulmy.html.*

[32] Cowan AJ, Allen C, Barac A, Basaleem H, Bensenor I, Curado MP, Foreman K, Gupta R, Harvey J, Hosgood HD, Jakovljevic M, Khader Y, Linn S, Lad D, Mantovani L, Nong VM, Mokdad A, Naghavi M, Postma M, Roshandel G, Shackelford K, Sisay M, Nguyen CT, Tran TT, Xuan BT, Ukwaja KN, Vollset SE, Weiderpass E, Libby EN, Fitzmaurice C. Global Burden of Multiple Myeloma: A Systematic Analysis for the Global Burden of Disease Study 2016. JAMA Oncol. 2018 Sep 1;4(9):1221–1227.

[33] SEER database 2020; *https://seer.cancer.gov/statfacts/html/mulmy.html.*

[34] National Comprehensive Cancer Network (NCCN) NCCN clinical practice guidelines in oncology. Multiple Myeloma. Version 2. 2021—September 9, 2020.

[35] Branagan A, Lei M, Lou U, Raje N. Current Treatment Strategies for Multiple Myeloma. JCO Oncol Pract. 2020 Jan;16(1):5–14.

[36] Sonneveld P, Broij lA. Treatment of relapsed and refractory multiple myeloma. Haematologica. 2016;101(4):396–406.

[37] SEER database 2020; *https://seer.cancer.gov/statfacts/html/mulmy.html.*

[38] Global Cancer Observatory. GLOBOCAN database 2018; *https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf.*

[39] Yong K, Delforge M, Driessen C, Fink L, Flinois A, Gonzalez-McQuire S, Safaei R, Karlin L, Mateos MV, Raab MS, Schoen P, Cavo M. Multiple myeloma: patient outcomes in real-world practice. Br J Haematol. 2016 Oct;175(2):252–264.

[40] Castelli R, Orofino N, Losurdo A, Gualtierotti R, Cugno M. Choosing treatment options for patients with relapsed/refractory multiple myeloma. Expert Rev Anticancer Ther. 2014 Feb;14(2):199–215.

[41] Nooka AK, Kastritis E, Dimopoulos MA, Lonial S. Treatment options for relapsed and refractory multiple myeloma. Blood. 2015 May 14;125(20):3085–99.

[42] Van de Donk NWCJ, Richardson PG, Malavasi F. CD38 antibodies in multiple myeloma: back to the future. Blood. 2018 Jan 4;131(1):13–29.

[43] National Comprehensive Cancer Network (NCCN) NCCN clinical practice guidelines in oncology. Multiple Myeloma. Version 2. 2021—September 9, 2020.

multiple myeloma, elderly or frail patients may be treated with double regimens.[44] The applicant further states that for patients with RRMM who have received at least three prior lines of therapy, including a PI, an IMiD and an anti-CD38, there does not exist a standard or consensus for treatment at this time, and often, supportive care/palliative care is the only option.[45]

According to the applicant, multiple myeloma remains incurable and most patients eventually relapse, even with the advent of new treatments.[46] The applicant further stated that novel, innovative therapies are needed to improve long-term survival and outcomes. The applicant asserted that CAR T-cell-based therapies offer potential advantages over current therapeutic strategies. According to the applicant, while other therapies require long-term repetitive administration generally until progression of disease, CAR T-cell therapy is a single infusion treatment due to live T-cell expansion in the patient and long-term disease response. The applicant asserted that CARVYKTI™ is an autologous CAR T-cell therapy directed against B cell maturation antigen (BCMA) for the treatment of patients with multiple myeloma. The applicant stated that BCMA, a protein that is highly expressed on myeloma cells [47] and is a member of the tumor necrosis factor (TNF) receptor family, plays a central role in regulating B-cell maturation and differentiation into plasma cells.[48] [49] The applicant stated BCMA is selectively expressed on a subset of B cells (plasma cell neoplasms including myeloma cells) and is more stably expressed specifically on the B cell lineage, compared with key plasma cell marker CD138, which is also expressed on normal fibroblasts and epithelial cells.[50] [51] [52] According to the applicant, these expression characteristics make BCMA an ideal therapeutic target for the treatment of multiple myeloma.[53] [54] CARVYKTI™, according to the applicant, is a unique, structurally differentiated BCMA-targeting chimeric antigen receptor with two distinct BCMA-binding domains that can identify and eliminate myeloma cells.

The applicant asserted that CAR T-cell technology is a form of immunotherapy and is a ''living drug'' that utilizes specially altered T cells, part of the immune system, to fight cancer. According to the applicant, a sample of the patient's T cells are collected from the blood, then modified in a laboratory setting to express a CAR.[55] The applicant stated chimeric antigen receptors are specifically designed receptor proteins that are made up of three distinct features: (1) A target recognition domain (typically derived from a single domain of an antibody) that sits on the cell's exterior; (2) a co-stimulatory domain on the cell's interior that boosts activation, enhances survival and expansion of the modified cells; and (3) an interior stimulatory domain that supports activation and target killing.[56] According to the applicant, the binding domain expressed on the surface of T cells gives them the new ability to target a specific protein. The applicant stated, when the target is recognized, the intracellular portions of the receptor send signals within the T cells to destroy the target cells. The applicant asserted these engineered CAR T-cells are reinfused back into the same patient, which enables these specialized T cells to latch onto the target antigen and abolish the tumor cells.

According to the applicant, CARVYKTI™ is a CAR T-cell immunotherapy designed to recognize myeloma cells and target their destruction. According to the applicant, CARVYKTI™'s CAR T-cell technology consists of harvesting the patient's own T cells, programming them to express a chimeric antigen receptor that identifies BCMA, a protein highly expressed on the surface of malignant multiple myeloma B-lineage cells, and reinfusing these modified cells back into the patient where they bind to and eliminate myeloma tumor cells. The applicant asserted that, unlike the chimeric antigen receptor design of currently approved CAR T-cell immunotherapies, which are composed of a single-domain antibody (sdAbs), CARVYKTI™ is composed of two antibody binding domains that allow for high recognition of human BCMA (CD269) and elimination of BCMA expressing myeloma cells. According to the applicant, the two distinct BCMA-binding domains confer avidity and distinguish CARVYKTI™ from other BCMA-targeting products. The applicant stated the BCMA binding domains are linked to the receptor's interior costimulatory (4–1BB) and signaling (CD3ζ) domains through a transmembrane linker (CD8a). The applicant asserted these intracellular domains are critical components for T cell growth and anti-tumor activity [57] in the body once CAR T-cells are bound to a BCMA target on multiple myeloma cells.

With respect to the newness criterion, according to the applicant, CARVYKTI™ was granted Breakthrough Therapy designation in December 2019 for the treatment of adult patients with relapsed or refractory multiple myeloma, who previously received a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody. Per the applicant, FDA approved the Biologics License Application (BLA) for CARVYKTI™ on February 28, 2022 for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. The applicant stated that procedures involving the administration of CARVYKTI™ can be uniquely identified using the following ICD–10–PCS procedure codes: XW033A7 (Introduction of ciltacabtagene autoleucel into peripheral vein, percutaneous approach, new technology group 7) and XW043A7 (Introduction of ciltacabtagene autoleucel into central vein, percutaneous approach, new technology group 7). The applicant also noted that they will submit a request for a Healthcare Common Procedure Coding

[44] Ibid.

[45] Maples KT, Joseph NS, Harvey RD. Current developments in the combination therapy of relapsed/refractory multiple myeloma. Expert Rev Anticancer Ther. 2020 Sep 24.

[46] Rajkumar SV, Kumar S. Multiple myeloma current treatment algorithms. Blood Cancer J. 2020 Sep 28;10(9):94.

[47] Cho SF, Anderson KC, Tai YT. Targeting B Cell Maturation Antigen (BCMA) in Multiple Myeloma: Potential Uses of BCMA-Based Immunotherapy. Front Immunol. 2018 Aug 10;9:1821.

[48] Cho SF, Anderson KC, Tai YT. Targeting B Cell Maturation Antigen (BCMA) in Multiple Myeloma: Potential Uses of BCMA-Based Immunotherapy. Front Immunol. 2018 Aug 10;9:1821.

[49] Tai YT, Anderson KC. Targeting B-cell maturation antigen in multiple myeloma. Immunotherapy. 2015;7(11):1187–99.

[50] Cho SF, Anderson KC, Tai YT. Targeting B Cell Maturation Antigen (BCMA) in Multiple Myeloma: Potential Uses of BCMA-Based Immunotherapy. Front Immunol. 2018 Aug 10;9:1821.

[51] Tai YT, Anderson KC. Targeting B-cell maturation antigen in multiple myeloma. Immunotherapy. 2015;7(11):1187–99.

[52] Palaiologou M, Delladetsima I, Tiniakos D. CD138 (syndecan-1) expression in health and disease. Histol Histopathol. 2014 Feb;29(2):177–89.

[53] Ibid

[54] Frigyesi I, Adolfsson J, Ali M, Christophersen MK, Johnsson E, Turesson I, Gullberg U, Hansson M, Nilsson B. Robust isolation of malignant plasma cells in multiple myeloma. Blood. 2014 Feb 27;123(9):1336–40.

[55] June CH, Sadelain M. Chimeric Antigen Receptor Therapy. N Engl J Med. 2018 Jul 5;379(1):64–73.

[56] Sadelain M. Chimeric antigen receptors: driving immunology towards synthetic biology. Curr Opin Immunol. 2016 Aug;41:68–76.

[57] Maher J, Brentjens RJ, Gunset G, Rivière I, Sadelain M. Human T-lymphocyte cytotoxicity and proliferation directed by a single chimeric TCRzeta/CD28 receptor.

System (HCPCS) code specific to the administration of CARVYKTI™ once the product is eligible for such a code.

As previously stated, if a technology meets all three of the substantial similarity criteria as previously described, it would be considered substantially similar to an existing technology and therefore would not be considered ''new'' for purposes of new technology add-on payments.

With respect to whether a product uses the same or a similar mechanism of action when compared to an existing technology to achieve a therapeutic outcome, the applicant asserted that CARVYKTI™ has a unique mechanism of action because it has two distinct binding domains that confer avidity to the BCMA antigen, a 4–1BB costimulatory domain and a CD3z signaling domain, whereas other CAR T-cell products have only one target binding domain. The applicant asserted that ABECMA® also targets BCMA, but does so by binding to a single BCMA domain. In addition to detail provided in the applicant's FY 2022 application (as discussed in 86 FR 25235 through 25236), the applicant asserted that CARVYKTI™ differs significantly from ABECMA® and other BCMA-targeting agents, including Blenrep, because it targets BCMA with two distinct binding domains. According to the applicant, the distinct BCMA-binding moieties confer avidity and distinguish CARVYKTI™ from other BCMA CAR T-cell constructs providing a novel mechanism of action.[58] The applicant added, the 4–1BB and CD3z domains on the CAR optimize T cell activation and proliferation.[59] According to the applicant, non-clinical pharmacology and toxicology have been used to characterize the biological activity and mechanism of action of CARVYKTI™ and confirm the on-target specificity to BCMA through (1) in vitro binding characterization; (2) in vitro co-culture assays to assess CAR T-cell cytotoxicity and cytokine release; (3) in vivo efficacy studies in mice with human CAR T-cells; and (4) an in vivo safety study. According to the applicant, because CARVYKTI™ has a novel mechanism of action with two distinct BCMA-binding domains that confer binding avidity and unprecedented clinical activity compared with other novel anti-myeloma treatments in comparable study populations, it is unlike any existing technology utilized to treat relapsed/refractory multiple myeloma.

With regard to whether a product is assigned to the same DRG when compared to an existing technology, the applicant asserted that because CMS has suggested that all inpatient hospitalizations involving a CAR T-cell treatment will be assigned to DRG 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies), CARVYKTI™ is expected to be assigned to the same DRG as other multiple myeloma cases treated with a CAR T-cell therapy. We note that the DRG assignment was finalized to Pre-MDC MS–DRG 018, effective October 1, 2022 and is reflected in the V39.1 ICD–10 MS–DRG Grouper effective April 1, 2022 (86 FR 58021).[60]

With regard to whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant asserted in its application that CARVYKTI™ is indicated for a broader population than other available therapies, specifically multiple myeloma patients having received three prior therapies. The applicant asserted in its application that Blenrep and ABECMA® are indicated only for those with at least 4 prior therapies whereas CARVYKTI™ had a proposed indication for the treatment of patients with 3 or more prior therapies. According to the applicant, CARVYKTI™ could potentially be used in a broader multiple myeloma population, that includes patients after 3 prior therapies as opposed to 4 for Blenrep and ABECMA®.

According to the applicant, FDA is currently reviewing the registrational trial CARTITUDE 1. The applicant stated that in this trial, 17% (a total of 17 patients) of patients had only three prior lines of therapy; results were presented at the American Society of Hematology (ASH) 2021 meeting on fourth line patients. The applicant stated that among those with three prior lines of therapy, the response rate was 100%, the median duration of response (DoR) was 21.8 months, minimal residual disease (MRD) negativity was found in 80%, the 18-month progression free survival (PFS) was 75.6%, and the 18-month overall survival (OS) was 88.2 months. According to the applicant, because the sample size was small (17), median endpoints may not be as rigorous as in the larger population.

According to the applicant, the distinction between three and four previous lines of therapy is important. The applicant asserted with each subsequent therapy patients generally become frailer and their prognosis worsens. The applicant stated that studies comparing fourth line to fifth line are not as common as trials studying earlier lines, but in a real-world study by Yong et al. the percent of myeloma patients who were able to move from third line therapy to fourth line was 15% of all diagnosed myeloma patients, and only 1% of patients moved to a fifth line.[61] The applicant added that in the same study of those patients in first line therapy, approximately 90% of patients were able to discontinue treatment due to remission and/or planned end of treatment while only 13% of those in fifth line ended treatment due to stable disease/remission.

The applicant asserted that for these reasons, CARVYKTI™ does not meet the third criterion and is therefore a new technology with regards to the population having been studied and being targeted for use.

In summary, the applicant asserted that CARVYKTI™ meets the newness criterion because it is not substantially similar to other available therapies due to its unique mechanism of action, with two distinct binding domains that confer avidity to the BCMA antigen, and because it treats a different patient population, RRMM patients who received three prior therapies. As we stated in the FY 2022 proposed rule (86 FR 25236), we note that CARVYKTI™ may have a similar mechanism of action to that of ABECMA®. We note ABECMA® received approval for new technology add-on payments for FY 2022 for the treatment of adult patients with RRMM after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody (86 FR 45028 through 45035). Although the number of BCMA binding domains of CARVYKTI™ and ABECMA® differ, it appears that the mechanism of action for both therapies is the binding to BCMA by a CAR

[58] Xu J, Chen LJ, Yang SS, Sun Y, Wu W, Liu YF, Xu J, Zhuang Y, Zhang W, Weng XQ, Wu J, Wang Y, Wang J, Yan H, Xu WB, Jiang H, Du J, Ding XY, Li B, Li JM, Fu WJ, Zhu J, Zhu L, Chen Z, Fan XF, Hou J, Li JY, Mi JQ, Chen SJ. Exploratory trial of a biepitopic CAR T-targeting B cell maturation antigen in relapsed/refractory multiple myeloma. Proc Natl Acad Sci U S A. 2019 May 7;116(19):9543–9551.

[59] Weinkove R, George P, Dasyam N, McLellan AD. Selecting costimulatory domains for chimeric antigen receptors: functional and clinical considerations. Clin Transl Immunology. 2019 May 11;8(5):e1049.

[60] CMS Manual System, Pub 100–04 Medicare Claims Processing, Transmittal 11255. February 4, 2022; *https://www.cms.gov/files/document/r11255cp.pdf*.

[61] Yong et al. 2016. Multiple Myeloma: Patient outcomes in real-world practice. *British Journal of Haematology,* 175; 252–264. doi: 10.1111/bjh.14213.

construct, which results in T-cell activation and killing of malignant myeloma cells. We note that the applicant asserted that CARVYKTI™'s mechanism of action is unique due to its dual binding domain which affects the therapy's clinical activity, as compared to existing technologies with a single binding domain. However, we are unclear how the additional BCMA binding domain represents a change in the mechanism of action of this therapy, or if it may instead relate to an assessment of whether the technology meets the substantial clinical improvement criterion. Because of the potential similarity with the BCMA antigen and other actions, we believe that the mechanism of action for CARVYKTI™ may be the same or similar to that of ABECMA®.

We note that the applicant stated that CARVYKTI™ may serve a new patient population if approved as a fourth line treatment, as existing treatments are approved for fifth line treatment. However, we note that CARVYKTI™'s recent approval states that it is indicated for fifth line treatment and we therefore question whether CARVYKTI™ treats a new patient population.[62]

Accordingly, as it appears that CARVYKTI™ and ABECMA® are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action, are assigned to the same MS–DRG, and treat the same or similar patient population and disease, we believe that these technologies may be substantially similar to each other. We note that if this technology is substantially similar to ABECMA®, we believe the newness period for this technology would begin on March 26, 2021, the date ABECMA® received FDA approval. We are interested in information on how these two technologies may differ from each other with respect to the substantial similarity criteria and newness criterion. We are inviting public comment on whether CARVYKTI™ meets the newness criterion, including whether CARVYKTI™ is substantially similar to ABECMA® for purposes of new technology add-on payments.

With regard to the cost criterion, the applicant searched the FY 2019 MedPAR final rule to identify potential cases representing patients who may be eligible for treatment using CARVYKTI™. In its analysis, the applicant identified a primary cohort to assess whether this therapy met the cost criterion. The following ICD–10–CM diagnosis codes were used to identify claims involving multiple myeloma procedures.

ICD-10-CM	DESCRIPTION
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse

The applicant stated that it identified two cohorts for the cost analysis: Cohort A limited the analysis to MS–DRG 016 (Autologous Bone Marrow Transplant W CC/MCC or T-Cell Immunotherapy) because patients receiving autologous bone marrow transplant (BMT) are generally patients with relapsed or refractory multiple myeloma and are most similar to patients who would be eligible to receive CAR T-cell therapy; Cohort B limited the analysis to MS–DRG 018 (CAR T-Cell and Other Immunotherapies). The applicant stated that the claim search resulted in 1,215 claims in Cohort A and 268 claims in Cohort B using the FY 2019 MedPAR. The applicant stated that it used the New Technology Threshold for FY 2023 from the FY 2022 IPPS/LTCH PPS final rule for MS–DRG 018. The applicant stated that it removed all charges in the drug cost center for the prior technology because, according to the applicant, it is not possible to differentiate between different drugs on inpatient claims. Per the applicant, this is likely an overestimate of the charges that would be replaced by the use of CARVYKTI™. The applicant added that it then standardized the charges using the FY 2022 IPPS/LTCH PPS final rule impact file. Next, the applicant applied a 4-year inflation factor of 1.281834 or 28.1834%, based on the inflation factor used in the FY 2022 IPPS/LTCH PPS final rule to update the outlier threshold) (86 FR 45542). To calculate the charges for the new technology for both cohorts, the applicant stated that it first used the inverse of a simulated alternative cost-to-charge ratio (CCR) specifically for CAR T-cell therapies and second used the national average drug CCR. The applicant stated that a simulated alternative CCR was used to account for CAR T-cell therapies' higher costs compared to other drugs and the potential for hospitals' charging practices to differ for these drugs. To determine this alternative CCR for CAR T-cell therapies, the applicant referred to the FY 2021 IPPS final rule After Outliers Removed (AOR)/Before Outliers Removed (BOR) file and calculated an alternative markup percentage by dividing the AOR drug charges within MS–DRG 018 by the number of cases to determine a per case drug charge. The applicant then divided the drug charges per case by $373,000, the acquisition cost of YESCARTA® and KYMRIAH®, the CAR T-cell products used in those claims, to arrive at a CCR of 0.295. The applicant stated that it used the national average drug CCR of 0.187 from the FY 2022 IPPS/LTCH PPS final rule (86 FR 44966). For Cohort A, with the CAR T-cell CCR, the applicant calculated a final inflated average case-weighted standardized charge per case of $1,695,406, which it stated exceeded the average case-weighted threshold amount of $1,256,379. For Cohort A, with the national average drug CCR, the applicant stated that it calculated a final inflated average case-weighted standardized charge per case of $2,595,169, which it stated exceeded the average case-weighted threshold amount of $1,256,379. For Cohort B, with the CAR T-cell CCR, the applicant stated that it calculated a final inflated average case-weighted standardized charge per case of $1,713,723, which it stated exceeded the average case-weighted threshold amount of $1,256,379. The applicant stated that if CARVYKTI™ meets the cost criterion using the more conservative alternate CAR T-cell CCR to inflate the cost of the treatment to charges, then it will also meet the cost criterion using the national average drug CCR to inflate the cost to charges. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, CARVYKTI™ meets the cost criterion.

In regard to the cost criterion, we question whether the ICD–10 codes used to identify potential cases are appropriately representative of those who would receive CARVYKTI™.

[62] *https://www.fda.gov/media/156572/download.*

Specifically, we are uncertain if the applicant's identification of cases using the previously specified ICD–10 codes differentiated between those treated with one, two, three, and four prior lines of therapy. We are also seeking clarification on whether these cases are appropriately representative of the technology. We note that while the applicant provided a cost analysis for Cohort A, with a simulated alternative CCR specifically for CAR T-cell therapies, the applicant did not provide the cost analyses for Cohort B or Cohort A with the national average drug CCR. We request these cost analyses as we are unable to evaluate these analyses based on the information provided by the applicant. As we have noted in previous discussions (86 FR 25237, 86 FR 25279), the submitted costs for CAR T-cell therapies vary widely due to differences in provider billing and charging practices for this therapy, and we are continuing to consider the use of this submitted cost data for purposes of calculating a CAR T-cell CCR for use in the applicant's cost analyses given this potential for variability. Therefore, we request submission of the cost analyses with the national average drug CCR, which the applicant referenced, but did not submit, for cost criterion consideration.

We invite public comment on whether CARVYKTI™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that it believes that CARVYKTI™ represents a substantial clinical improvement over existing technologies because it: (1) Treats a new and expanded patient population, (2) offers a treatment for a patient population with limited options and continued disease progression, despite having been treated with multiple prior therapies; and (3) provides a significantly improved clinical outcome relative to other therapies, either approved or still under FDA review, used in the relapsed and refractory multiple myeloma setting.

With regard to the applicant's assertion that CARVYKTI™ treats a new and expanded patient population, the applicant stated that other multiple myeloma therapies, such as Blenrep and ABECMA®, are indicated for patients with at least four prior therapies including a PI, an IMiD, and a CD38 antibody. In its application, the applicant asserted that CARVYKTI™ may receive an indication for patients with only three prior lines of therapy. The applicant cited the CARTITUDE–1 trial where 17% of patients had three prior lines of therapy.

With regard to the applicant's assertion that CARVYKTI™ offers a treatment for a patient population with limited options and continued disease progression, despite having been treated with multiple prior therapies, the applicant cited results from the CARTITUDE–1 STUDY, a Phase 1b/2, open-label, multicenter, multi-national (including US) study (n=113) to evaluate the safety and efficacy of ciltacabtagene autoleucel in adult patients who have RRMM who have previously received a PI, an IMiD, and an anti-CD38 antibody. The applicant asserted that ciltacabtagene autoleucel was granted Breakthrough Therapy designation for patients who have RRMM who have previously received a PI, an IMiD, and an anti-CD38 antibody, based on data from the Phase 1b/2 CARTITUDE–1 study. According to the applicant, of the 113 enrolled patients, 16 discontinued the study, including 9 patients who died due to progressive disease. Ninety-seven patients received ciltacabtagene autoleucel. The Phase 1b portion of the study included 29 of the 97 patients.

Two patients died during the study: One due to cytokine release syndrome (CRS) and one due to acute myeloid leukemia (not treatment-related). According to the applicant, 24 patients were ongoing in the phase 1b dose confirmation period with an additional 59 patients ongoing in the phase 2 portion. The applicant stated the primary objective of the Phase 1b portion of the trial was to confirm the safety of the selected dose based on the data from the ongoing Phase 1 trial in China (Legend-2), as discussed later in this section. The applicant asserted the primary objective of the Phase 2 portion of the trial is to evaluate the efficacy of ciltacabtagene autoleucel.

The applicant asserted that at median follow-up of 18 months, ciltacabtagene autoleucel led to a 98% overall response rate (ORR) in all 97 study patients who received ciltacabtagene autoleucel.[63] [64] The applicant asserted that this unprecedented overall response rate of (98%), represents early, deep, and durable responses in all patients, minimal residual disease negativity (meaning minimal residual cancer cells after treatment to the -nth degree) in the majority of patients who achieved a complete response (CR) and a very manageable toxicity profile. The applicant provided a comparison of the ORR in phase 1 studies for other therapies used to treat RRMM and noted the following: Idecabtagene vicleucel ORR 60%, daratumumab ORR 31%, Selinexor ORR 26%, and Blenrep ORR 31%.[65] According to the applicant, in addition to the CARTITUDE–1 trial ORR, the Legend-2 study demonstrated an ORR of 87.8% (95% CI: 78.2, 94.3) at a 2 year follow up time period. The applicant asserted that both of these studies are ongoing and the depth and duration of response continues to improve over time.[66]

The applicant further asserted that ciltacabtagene autoleucel led to early and deep clinical responses in the phase1b/2 portion of the CARTITUDE–1 study at median follow up of 18 months. The applicant stated that results of CARTITUDE–1 showed 80% of patients attaining a stringent complete response (sCR) and 93% of patients attaining a very good partial response (VGPR) or better. According to the applicant, ORR and depth of response were independent of BCMA expression on myeloma cells at baseline. The median time to first response was one month (range, 1–9).[67] [68]

The applicant also asserted that most patients attained a status of MRD-negativity by the time they were evaluable for a CR. According to the applicant, of evaluable patients, 93.0% achieved MRD 10^{-5} negativity.[69]

[63] Usmani SZ, et al. Ciltacabtagene Autoleucel, a B B-Cell Maturation Antigen Antigen–Directed Chimeric Antigen Receptor T T-Cell Therapy, in Relapsed/Refractory Multiple Myeloma: Updated Results From CARTITUDE CARTITUDE–1. Oral presented at: ASCO Annual Meeting; June 4 4–8, 2021. *https://meetinglibrary.asco.org/*.

[64] Madduri D et al. CARTITUDE–1: Phase 1b/2 Study of Ciltacabtagene Autoleucel, a B-Cell Maturation Antigen-Directed Chimeric Antigen Receptor T-Cell Therapy, in Relapsed/Refractory Multiple Myeloma.

[65] Martin, T., et al. Comparison of outcomes with ciltacabtagene autoleucel (cilta-cel) in CARTITUDE–1 vs real-world standard of care (RW SOC) for patients (pts) with triple-class exposed relapsed/refractory multiple myeloma (RRMM). Presented at 2021 American Society of Clinical Oncology (ASCO) Annual Meeting; June 4–8, 2021; Poster #8045.

[66] Berdeja, J. Ciltacabtagene autoleucel, a B-cell maturation antigen-directed chimeric antigen receptor T-cell therapy in patients with relapsed or refractory multiple myeloma (CARTITUDE–1): A phase 1b/2 open-label study. Lancet. 2021 Jul 24;398(10297):314–324.

[67] Usmani SZ, et al. Ciltacabtagene Autoleucel, a B B-Cell Maturation Antigen Antigen-Directed Chimeric Antigen Receptor T T-Cell Therapy, in Relapsed/Refractory Multiple Myeloma: Updated Results From CARTITUDE CARTITUDE–1. Oral presented at: ASCO Annual Meeting; June 4 4–8, 2021. *https://meetinglibrary.asco.org/*.

[68] Berdeja JG, Madduri D, Usmani SZ, Singh I, Zudaire E, Yeh TM, Allred AJ, Olyslager Y, Banerjee A, Goldberg JD, Schecter S, Geng D, Wu X, Carrasco-Alfonso M, Rizvi S, Fan F, Jakubowiak AJ, Jagannath S. Update of CARTITUDE–1: A phase Ib/II study of JNJ–4528, a B-cell maturation antigen (BCMA)-directed CAR–T cell therapy, in relapsed/refractory multiple myeloma. Journal of Clinical Oncology (JCO). 2020 38:15_suppl, 8505–8505.

[69] Usmani SZ, et al. Ciltacabtagene Autoleucel, a B B-Cell Maturation Antigen Antigen-Directed

According to the applicant, 58% of patients were both MRD negative and in sCR at MRD detection level of 10^{-5}. According to the applicant, the median time to MRD 10^{-5} negativity was 1 month (0.8–7.7).[70] The applicant stated, among patients with 6 months individual follow-up, most had ciltacabtagene autoleucel CAR+ T-cells below the level of quantification (2 cells/μL) in peripheral blood.[71]

The applicant added that PFS at 12 months was 77% (95% CI; 66.0–84.37) with median PFS not having been reached.[72] According to the applicant, at median follow-up of 12.4 months, there were 14 deaths during the Phase 1b/2 study: One due to CRS and hemophagocytic lymphohistiocytosis (HLH), one due to neurotoxicity, and 12 due to other causes.[73] The applicant asserted that the CRS was manageable in most patients; CRS was the most common adverse event (AE) (94.8%) observed in the CARTITUDE–1 study. According to the applicant, the median time to onset of CRS was 7 days (range 1–12 days) post ciltacabtagene autoleucel infusion with a median duration of 4 days. The applicant asserted that 90% of patients experienced Grade 1–2 CRS and 5 patients (5%) experienced grade 3 or greater CRS.[74] According to the applicant there were 3 Grade 3 CRS, 1 Grade 4, and 1 aforementioned death due to CRS/HLH Grade 5 event.

The applicant noted that in the CARTITUDE–1 trial, neurotoxicity with immune effector cell-associated neurotoxicity syndrome (ICANS) was infrequently observed in the context of CRS and was generally low grade. Neurotoxicity with ICANS was observed in 20 patients (20.6%) including 10 patients (10.3%) with Grade 3 or above toxicity.

According to the applicant, the LEGEND–2 study[75] is an ongoing Phase 1, single-arm, open-label, multicenter, first-in-human trial to determine the safety and efficacy of ciltacabtagene autoleucel (LCAR–B38M in China) in the treatment of patients with relapsed or refractory multiple myeloma. The applicant stated enrollment in this investigator-initiated study (study proposed, initiated, and conducted by an investigator that is funded by industry) completed in November 2017; a total of 74 patients with RRMM have been treated with ciltacabtagene autoleucel CAR T-cell therapy. The applicant stated the clinical cutoff for the analysis of these 74 patients was February 6, 2018 with updated survival and efficacy data as of November 26, 2019 (which represents 2 years of follow-up from the date of the last subject's infusion). The applicant stated in the LEGEND–2 study, at a median follow up of 25 months, the median PFS for all patients was 19.9 months and 28.2 months for patients with CR. According to the applicant, 17 patients (17/57—29%) died during the study and follow up period (19 months) mostly due to progressive disease. The applicant asserted that none were related to CRS or neurotoxicity, the two most common adverse events associated with CAR T-cell therapy. At data cutoff, 57 patients had received LCAR–B38M CAR T-cells.

The applicant further asserted that outcomes from the LEGEND–2 study show that ciltacabtagene autoleucel provides a significantly improved clinical outcome relative to other therapies, either approved or still under FDA review, used in the RRMM setting. According the applicant, at a median follow up of 19 months, the overall response rate for ciltacabtagene autoleucel was 88%.[76] The applicant stated the overall survival (OS) rate at 18 months was 68% (54–79%) with a median duration of response (mDOR) of 22 months (13–29). The applicant stated that of MRD-negative patients with CR, 91% were still alive at data cut, with a 27-month (95% CI, 14.3–NE) mDOR. The applicant added that the median time to first response was 1.1 months. The applicant asserted there was no relationship between best response and baseline BCMA expression level or weight-adjusted CAR T-cells infused. We note some inconsistencies between the citation provided and what the applicant stated. Specifically, per the citation, the median time to follow-up was 25 months, with a median overall survival among all patients of 36.1 months (95% CI, 26.4–NE), and a MDOR of 29.1 months (95% CI, 19.9–NE).[77]

The applicant asserted that of patients in the LEGEND–2 study with CR, 39 of 42 were minimal residual disease negative (MRD-neg) and remained RRMM progression-free.[78] According to the applicant, the median PFS rate for all treated patients was 20 months (10–28); median PFS for MRD-neg patients with CR was 28 months (20–31).[79] The applicant stated that at 18 months, the PFS rate was 50 (36–63%) for all patients and 71% (52–84%) for MRD-neg patients with CR.[80] The applicant stated that 17 patients died during the study and the follow-up period. The causes of death included progressive disease (PD; n=11), disease relapse, PD with lung infection, suicide after PD, esophageal carcinoma, infection, pulmonary embolism and acute coronary syndrome (n=1 each). Of these, 4 did not achieve partial response (PR) or better; and 1 was not evaluable.

According to the applicant, from the LEGEND–2 study, the median time to onset of CRS was 9 days (range, 1–19) with a median duration of 9 days (range, 3–57); all but 1 CRS events resolved.[81] Tocilizumab (46%), oxygen (35%), vasopressor (11%), and intubation (1 patient) were used to treat CRS.[82] Neurotoxicity with Grade 1 aphasia, agitation and seizure-like activity was

Chimeric Antigen Receptor T T-Cell Therapy, in Relapsed/Refractory Multiple Myeloma: Updated Results From CARTITUDE CARTITUDE–1. Oral presented at: ASCO Annual Meeting; June 4 4–8, 2021. *https://meetinglibrary.asco.org/.*

[70] Usmani SZ, et al. Ciltacabtagene Autoleucel, a B B-Cell Maturation Antigen Antigen-Directed Chimeric Antigen Receptor T T-Cell Therapy, in Relapsed/Refractory Multiple Myeloma: Updated Results From CARTITUDE CARTITUDE–1. Oral presented at: ASCO Annual Meeting; June 4 4–8, 2021. *https://meetinglibrary.asco.org/.*

[71] Usmani SZ, et al. Ciltacabtagene Autoleucel, a B B-Cell Maturation Antigen Antigen-Directed Chimeric Antigen Receptor T T-Cell Therapy, in Relapsed/Refractory Multiple Myeloma: Updated Results From CARTITUDE CARTITUDE–1. Oral presented at: ASCO Annual Meeting; June 4 4–8, 2021. *https://meetinglibrary.asco.org/.*

[72] Berdeja JG, Madduri D, Usmani SZ, Singh I, Zudaire E, Yeh TM, Allred AJ, Olyslager Y, Banerjee A, Goldberg JD, Schecter S, Geng D, Wu X, Carrasco-Alfonso M, Rizvi S, Fan F, Jakubowiak AJ, Jagannath S. Update of CARTITUDE–1: A phase Ib/II study of JNJ–4528, a B-cell maturation antigen (BCMA)-directed CAR–T cell therapy, in relapsed/refractory multiple myeloma. Journal of Clinical Oncology. 2020 38:15_suppl, 8505–8505.

[73] Berdeja JG, Madduri D, Usmani SZ, Singh I, Zudaire E, Yeh TM, Allred AJ, Olyslager Y, Banerjee A, Goldberg JD, Schecter S, Geng D, Wu X, Carrasco-Alfonso M, Rizvi S, Fan F, Jakubowiak AJ, Jagannath S. Update of CARTITUDE–1: A phase Ib/II study of JNJ–4528, a B-cell maturation antigen (BCMA)-directed CAR–T cell therapy, in relapsed/refractory multiple myeloma. Journal of Clinical Oncology. 2020 38:15_suppl, 8505–8505.

[74] Berdeja JG, Madduri D, Usmani SZ, Singh I, Zudaire E, Yeh TM, Allred AJ, Olyslager Y, Banerjee A, Goldberg JD, Schecter S, Geng D, Wu X, Carrasco-Alfonso M, Rizvi S, Fan F, Jakubowiak AJ, Jagannath S. Update of CARTITUDE–1: A phase Ib/II study of JNJ–4528, a B-cell maturation antigen (BCMA)-directed CAR–T cell therapy, in relapsed/refractory multiple myeloma. Journal of Clinical Oncology. 2020 38:15_suppl, 8505–8505.

[75] Zhao, WH., Liu, J., Wang, BY. et al. A phase 1, open-label study of LCAR–B38M, a chimeric antigen receptor T cell therapy directed against B cell maturation antigen, in patients with relapsed or refractory multiple myeloma. J Hematol Oncol 11, 141 (2018). *https://jhoonline.biomedcentral.com/articles/10.1186/s13045-018-0681-6.*

[76] Wang. Bai-Yan. 2019. Long-term follow-up of a phase 1, first-in-human open-label study of LCAR–B38M, a structurally differentiated chimeric antigen receptor T (CAR–T) cell therapy targeting B-cell maturation antigen (BCMA), in patients (pts) with relapsed/refractory multiple myeloma (RRMM). Abstract #579, Presented at ASH Annual Meeting.

[77] Ibid.

[78] Ibid.

[79] Ibid.

[80] Ibid.

[81] Ibid.

[82] Ibid.

observed in 1 patient in the LEGEND–2 study.[83] The applicant believes that since ciltacabtagene autoleucel displayed a manageable CRS safety profile that it represents a substantial clinical improvement over existing therapies.

The applicant lastly discussed multiple unpublished studies which used matching-adjusted indirect treatment comparison (MAIC) and other matching techniques to compare ciltacabtagene autoleucel to other existing therapies. The applicant stated that while there are no randomized head-to-head trials comparing ciltacabtagene autoleucel to ABECMA®, there is a peer-reviewed, published MAIC where individual patient data from CARTITUDE–1 (ciltacabtagene autoleucel) and published summary-level data for ABECMA® from the KarMMA trial are compared.[84] According to the applicant, the authors concluded that ciltacabtagene autoleucel demonstrated clinically superior results for all outcomes studied (ORR, CR rate, DoR, PFS, and OS), and these were robust across all sensitivity analyses. The applicant provided, as an example, results from one study by Martin et al. (2021) which, when comparing ciltacabtagene autoleucel to ABECMA®, found that the former had a 34% higher chance of response, a 220% higher chance of a CR, a hazard ratio of 0.5 for the DoR, 0.37 for PFS, and 0.55 for OS.[85] The applicant asserted that based on these findings, ciltacabtagene autoleucel offers substantial clinical benefits for patients with triple-class exposed RRMM compared to ABECMA®.

According to the applicant, there are several unpublished studies employing MAIC and other matching techniques comparing clinical outcomes for patients receiving ciltacabtagene autoleucel and the standard of care, or other conventional therapies, such as belantamab mafadotin or selinexor and dexamethasone.[86] [87] [88] The applicant stated that in a comparison to patients receiving various conventional therapies, the authors conclude that treatment with ciltacabtagene autoleucel is associated with higher response rate and superior PFS and OS.[89] The applicant stated that in a comparison with treatment with selinexor and dexamethasone, the study authors conclude that the analysis shows that ciltacabtagene autoleucel ''offers substantially more clinical benefit'' for patients with triple-class exposed RRMM.[90] The applicant also asserted that in a study that assessed the comparative effectiveness of ciltacabtagene autoleucel to physician's choice of treatment (PCT) using an external real-world control arm from the Flatiron Health multiple myeloma cohort registry, authors found that ciltacabtagene autoleucel offers substantial clinical benefits for PFS, time to next treatment (TTNT), and OS over PCT for patients with triple class exposed RRMM.[91] According to the applicant, patients receiving ciltacabtagene autoleucel were 3.2 times more likely to achieve overall response than patients receiving belantamab mafodotin after adjusting for refractory status, cytogenetic profile, International Staging System (ISS) stage, and extramedullary disease.

Lastly, the applicant summarized data from 22 months follow-up for CARTITUDE–1, which was presented at ASH 2021.[92] The applicant asserted that compared to the previous 12-month and 18-month data, 2-year data showed responses deepening over time. The applicant stated the ORR continued at 98% (up from 96% at 12 months) and the sCR at 22 months was 82.5%, compared to 67% at 12 months and 80.4% at 18 months. According to the applicant, at 22 months, 92% of the patients with MRD status noted were MRD negative, which is consistent with 18-month data (92%) and 12-month data (93%), illustrating persistent ability for the treatment to maintain MRD negativity over time. According to the applicant, the two-year PFS was 60.5% and 71% when a sCR was achieved and the two-year OS for all patients was 74%. The applicant stated that at the 2-year median follow up, no new treatment-related deaths had occurred since the median approximately 1-year follow-up, and there were no new safety signals reported. The applicant added that adverse events were generally low grade, well tolerated and managed with standard treatment algorithms employing drugs such as tocilizumab, corticosteroids, and anakinra.

After reviewing the information submitted by the applicant as part of its FY 2023 application for new technology add-on payments for CARVYKTI™, we have the following concerns regarding the substantial clinical improvement criterion. We note that in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25238 through 25239), we expressed concern regarding a lack of comparisons between CARVYKTI™ and other existing therapies. We note that the applicant provided new references in its FY 2023 application to compare CARVYKTI™ to other therapies.[93] [94] However, we further note that many of the references provided are in abstract or presentation format with limited data on the overall study design and methodology used to achieve the presented results. With respect to the LEGEND–2 study, the authors stated that for the initial patient sample (n=57), the median number of prior lines of therapy was 3, with a range of 1 to 9.[95] Furthermore, we note that in the LEGEND–2 study only 11 (19%) of the respondents were 65 and older in the sample. As only 60% of this patient sample had received both a proteasome inhibitor and an immunomodulatory agent, and no patients had received a CD38 antibody, we question the true refractoriness of the test population in the LEGEND–2 study and whether the results are generalizable to the Medicare population for which this treatment is intended.

In addition, we request clarification on any potential inconsistencies between the statements in the

[83] Ibid.

[84] Martin et al, 2021. Matching-adjusted indirect comparison of efficacy outcomes for ciltacabtagene autoleucel in CARTITUDE–1 versus idecabtagene vicleucel in KarMMa for the treatment of patients with relapsed or refractory multiple myeloma.

[85] Ibid.

[86] Costa L, et al. Ciltacabtagene Autoleucel Versus Conventional Treatment in Patients With Relapsed/Refractory Multiple Myeloma. ASCO 2021. Poster #8030.

[87] Weisel et al. Matching-Adjusted Indirect Comparison of Ciltacabtagene Autoleucel Versus Belantamab Mafodotin in Patients With TripleClass Exposed Relapsed/Refractor y Multiple Myeloma. EHA 2021. Poster #EP978.

[88] Martin 2021, eJHaem accepted manuscript.

[89] Costa L, et al. Ciltacabtagene Autoleucel Versus Conventional Treatment in Patients With Relapsed/Refractory Multiple Myeloma. ASCO 2021. Poster #8030.

[90] Weisel et al. Matching-Adjusted Indirect Comparison of Ciltacabtagene Autoleucel Versus Belantamab Mafodotin in Patients With TripleClass Exposed Relapsed/Refractor y Multiple Myeloma. EHA 2021. Poster #EP978.

[91] Martin 2021, eJHaem accepted manuscript.

[92] Martin et al. 2021. Updated Results From CARTITUDE–1: Phase 1b/2 Study of Ciltacabtagene Autoleucel, a B-cell Maturation Antigen–Directed Chimeric Antigen Receptor T Cell Therapy, in Patients With Relapsed/Refractory Multiple Myeloma. Presented at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition; December 11–14, 2021; Oral Presentation #549.

[93] Martin et al,. Matching-adjusted indirect comparison of efficacy outcomes for ciltacabtagene autoleucel in CARTITUDE–1 versus idecabtagene vicleucel in KarMMa for the treatment of patients with relapsed or refractory multiple myeloma.

[94] Martin T, et al. Ciltacabtagene Autoleucel Versus Selinexor+ Dexamethasone in Triple-Class Exposed Patients With Relapsed/Refractory Multiple Myeloma: A Matching Adjusted Indirect Comparison.

[95] Zhao, WH., Liu, J., Wang, BY. et al. A phase 1, open-label study of LCAR–B38M, a chimeric antigen receptor T cell therapy directed against B cell maturation antigen, in patients with relapsed or refractory multiple myeloma. J Hematol Oncol 11, 141 (2018). *https://doi.org/10.1186/s13045-018-0681-6.*

applicant's new technology add-on payment application and the citation which explains the LEGEND–2 study, including inconsistencies in median time to follow-up, median OS, and mDOR, as previously noted.[96]

Finally, while the applicant has asserted that CARVYKTI™ treats a new and expanded patient population since existing treatments are indicated for patients with at least four prior therapies, we note that CARVYKTI™ was recently approved with an indication for patients with at least four prior lines of therapy as well. Therefore, we would appreciate additional clarification on any differences between CARVYKTI™ and existing therapies with respect to the patient populations indicated for treatment.

We are inviting public comment on whether CARVYKTI™ meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for CARVYKTI™.

b. DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)

Janssen Biotech, Inc., submitted an application for new technology add-on payments for DARZALEX FASPRO® for FY 2023. DARZALEX FASPRO® is a combination of daratumumab (a monoclonal CD38-directed cytolytic antibody), and hyaluronidase (an endoglycosidase) indicated for the treatment of light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone (CyBorD) in newly diagnosed patients and is administered through a subcutaneous injection.

According to the applicant, AL amyloidosis is a life-threatening blood disorder caused by increased production of misfolded immunoglobulin light chains by an abnormal proliferation of malignant CD38+ plasma cells. Per the applicant, these deficient immunoglobulin light chains aggregate into highly ordered amyloid fibrils that deposit in tissues, eventually resulting in progressive organ dysfunction and damage due to the toxic effect of the misfolded proteins (proteotoxicity) and the distortion of the normal tissue architecture by the amyloid deposits.[97] The applicant stated that the most frequently affected organs are the heart, kidney, liver, spleen, gastrointestinal tract and nervous system. Per the applicant, patients often have a poor prognosis, and as many as 30% of patients with AL amyloidosis die within the first year after diagnosis. The applicant stated that approximately 4,500 people in the US develop AL amyloidosis each year.[98] The applicant stated that while there were no FDA approved therapies prior to daratumumab, a number of therapies were used clinically to treat AL amyloidosis including combination therapies like cyclophosphamide-bortezomib-dexamethasone (CyBorD), bortezomib-lenalidomide-dexamethasone (VRd), bortezomib-melphalan-dexamethasone (VMd), melphalan-dexamethasone (Md), and bortezomib-dexamethasone (Vd). The applicant further noted that none of these combination regimens are approved for use by FDA in this specific indication.

According to the applicant, DARZALEX FASPRO® is the first and only FDA-approved treatment for patients with AL amyloidosis and is also approved for multiple indications for treatment of patients with multiple myeloma. The applicant stated that the indication for the technology for which it is submitting a new technology add-on payment application is for the treatment of adult patients with AL amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients. The applicant noted that DARZALEX FASPRO® is not indicated nor recommended to be used in patients with AL amyloidosis who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB, except in the context of controlled clinical trials.

According to the applicant, DARZALEX FASPRO® is the subcutaneous formulation of daratumumab, which is a human IgG-kappa monoclonal antibody that targets CD38, an enzymatic protein that is uniformly expressed on human plasma cells. Per the applicant, in DARZALEX FASPRO®, daratumumab is co-formulated with recombinant human hyaluronidase (rHuP20), which critically allows daratumumab to be administered in a volume of 15 mL by a 3–5 minute injection under the skin, compared to the 500–1000 mL volume and 3–7 hour administration time required for IV daratumumab. The applicant further noted that given the cardiac and renal dysfunction which afflicts many AL amyloidosis patients and makes them poor candidates for large volume IV administration, rHuP20 is a critical component of DARZALEX FASPRO®. Per the applicant, daratumamab binds to the CD38 protein on the surface of the malignant plasma cells which are responsible for abnormal amyloid protein production in AL amyloidosis, directly killing the malignant CD38+ plasma cells and/or directing the immune system to destroy them. The immunomodulatory response consists of CD8+ clonal expansion, CD38 enzymatic inhibition, complement activation and cell recruitment to enable antibody dependent cellular phagocytosis (ADPC) and antibody dependent cellular cytotoxicity (ADCC). Per the applicant, the mechanism of actions of daratumumab in AL amyloidosis are the same as the mechanisms of action of daratumumab in multiple myeloma, since both disease entities are disorders of malignant CD38+ plasma cells.[99] [100] [101]

The applicant stated that without hyaluronidase, it is not possible to inject more than 2–3 mL of drug directly into the subcutaneous tissue under the skin. Per the applicant rHuPH20 naturally mimics natural hyaluronidase and increases the permeability of subcutaneous tissue by degrading hyaluronan. By co-formulating daratumumab with rHuPH20, it becomes possible for 15 mL containing 1,800 mg of daratumamab to be administered subcutaneously in approximately 3 to 5 minutes. The applicant stated that the ability to administer daratumumab subcutaneously reduces the reaction rate to daratumumab, may improve convenience and patient satisfaction, and greatly reduces the volume of administration, which is critical in light of the cardiac dysfunction and kidney dysfunction which afflict many patients with AL amyloidosis.

[96] Wang. Bai-Yan. 2019. Long-term follow-up of a phase 1, first-in-human open-label study of LCAR–B38M, a structurally differentiated chimeric antigen receptor T (CAR–T) cell therapy targeting B-cell maturation antigen (BCMA), in patients (pts) with relapsed/refractory multiple myeloma (RRMM). Abstract #579, Presented at ASH Annual Meeting.

[97] Merlini et al. Systemic immunoglobin light chain amyloidosis. Nat Rev Dis Primers. 2018; 4:38–19.

[98] Amyloidosis Foundation. AL amyloidosis facts. *http://www.amyloidosis.org/facts/al/*. Accessed September 2021

[99] de Weers et al. Daratumumab, a Novel Therapeutic Human CD38 Monoclonal Antibody, Induces Killing of Multiple Myeloma and Other Hematogical Tumors. J Immunol 2011;186:1840–1848).

[100] Overdijk et al. Antibody-mediated phagocytosis contributes to the anti-tumor activity of the therapeutic antibody daratumumab in lymphoma and multiple myeloma. MAbs.2015;7:311–321).

[101] Krejcik J, Casneuf T, Nijhof IS, et al. Daratumumab depletes CD38+ immune regulatory cells, promotes T-cell expansion, and skews T-cell repertoire in multiple myeloma. Blood 2016; 128: 384–94.

With respect to the newness criterion, the applicant stated that DARZALEX FASPRO® was granted accelerated approval from FDA on January 15, 2021, indicated for the treatment of adult patients with light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients. Per the applicant, DARZALEX FASPRO® is not indicated and recommended for the treatment of patients with AL amyloidosis who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB outside of controlled clinical trials.[102] The applicant also stated that DARZALEX FASPRO® received FDA approval on September 26, 2019, for the treatment of adult patients with multiple myeloma as part of a combination therapy in newly diagnosed patients eligible for autologous stem cell transplant, and on May 1, 2020, for the treatment of patients with multiple myeloma. As stated previously, the indication for which the applicant submitted an application for new technology add-on payments is for the treatment of adult patients with AL amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients. The applicant stated that DARZALEX FASPRO® for newly diagnosed AL amyloidosis was commercially available immediately following the accelerated approval granted by FDA. The recommended dosage for DARZALEX FASPRO® for newly diagnosed AL amyloidosis is 1,800 mg of daratumumab and 30,000 units of hyaluronidase administered subcutaneously over approximately 3 to 5 minutes in combination with bortezomib, cyclophosphamide and dexamethasone. According to the applicant, patients receiving DARZALEX FASPRO® for this indication receive a weekly dose for the first 8 weeks (week 1 to week 8), one dose every 2 weeks from week 9 to week 24, followed by one dose monthly from week 25 onward until disease progression for a maximum of 2 years.

The applicant stated that ICD–10–PCS code 3E013GC (Introduction of other therapeutic substance into subcutaneous tissue, percutaneous approach) may currently be used to identify DARZALEX FASPRO® under the ICD–10–PCS coding system but that there are currently no ICD–10–PCS procedure codes that uniquely identify the use of DARZALEX FASPRO®. The applicant submitted a request for a unique ICD–10–PCS code to identify procedures involving the administration of DARZALEX FASPRO®. The applicant stated that E85.81 (Light chain (AL) amyloidosis) may be used to currently identify the indication for DARZALEX FASPRO® under the ICD–10–CM coding system but that there is no ICD–10–CM diagnosis code that is specific to DARZALEX FASPRO® for newly diagnosed AL amyloidosis.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments.

With respect to the first criterion, whether a technology uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant stated that it does not use the same or similar mechanism of action as existing technologies. The applicant stated that DARZALEX FASPRO® was the first drug approved by FDA for treatment of AL amyloidosis and its mechanism of action is different from that of any other drug previously used to treat AL amyloidosis. According to the applicant, the other therapies currently used to treat amyloidosis off-label (for example, bortezomib, cyclophosphamide, melphalan, lenlidomide) all have different mechanisms of action; none of them are monoclonal antibodies that specifically bind to CD38 on malignant plasma cells. The applicant stated that bortezomib induces cell death of the malignant plasma cell by inhibition of the 26S proteasome which plays a key role in cell survival by regulating protein breakdown in a controlled fashion. The applicant further stated that when bortezomib inhibits proteasome function, the normal balance within a cell is disrupted, resulting in a buildup of cell cycle and regulatory proteins which eventually leads to cell death.[103] [104] Per the applicant, lenalidomide is an immunomodulator which modulates the E3 ubiquitin ligase complex. Modulation of this E3 ubiquitin ligase complex by lenalidomide eventually leads to enhanced function of specific immune cells and induction of cell death and the exact mechanism of action of lenalidomide is still not fully understood.[105] [106] The applicant stated that both melphalan and cyclophosphamide are alkylating chemotherapy drugs that add an alkyl group to the guanine base of the DNA molecule, preventing the strands of the double helix from linking, which causes breakage of the DNA strands, affecting the ability of the cancer cell to multiply. Per the applicant, like bortezomib and lenalidomide, melphalan and cyclophosphamide are not approved by FDA for the use in patients with AL amyloidosis. The applicant also noted that while the National Comprehensive Cancer Network® (NCCN®) Guidelines for Systemic Light Chain Amyloidosis state that both IV and SQ daratumumab can be used to treat previously treated amyloidosis,[107] IV daratumumab is not approved by FDA for the treatment of patients with amyloidosis (newly diagnosed and previously treated). The applicant also stated that DARZALEX FASPRO® is the more appropriate option in the AL amyloidosis patient population due to the fact that subcutaneous dosing has a negligible volume administration (15 ml for SC vs up to 1000ml for IV), which is particularly important in patients with AL amyloidosis who often have compromised cardiac and renal function due to the amyloid deposition in cardiac and kidney tissue.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that this product is not expected to change the DRG assignment of a case when used for the treatment of AL amyloidosis.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated that DARZALEX FASPRO® does not meet this criterion because it was the first approved drug to treat patients with AL amyloidosis. The applicant also stated that the NCCN® Guidelines for Systemic Light Chain Amyloidosis reflect the limited treatment options for this specific disease. The applicant further stated that DARZALEX FASPRO® in combination with CyBorD is the only

[102] According to the applicant, continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

[103] Adams et al. Proteasome Inhibitors: A Novel Class of Potent and Effective Antitumor Agents. Cancer Res 1999;55; 2615–2622.

[104] Adams et al. The proteasome: A suitable antineoplastic target. Nat Rev Cancer 2004; 4:349–360.

[105] Kastritis et al. Primary treatment of light chain amyloidosis with Bortezomib, lenalidomide and dexamethasone. Blood Adv 2019;3:3002–3009.

[106] Revlimid Prescribing Info.

[107] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Systemic Light Chain amyloidosis (Version 1.2022). National Comprehensive Cancer Network. *www.nccn.org.* Published August 29 June 2021. Accessed July 21, 2021.

treatment with a Category 1 recommendation [108] in the NCCN® Guidelines for patients with newly diagnosed AL amyloidosis.[109]

In summary, the applicant believes that DARZALEX FASPRO® is not substantially similar to other currently available therapies and/or technologies because it has a unique mechanism of action and because it is the first FDA approved treatment for AL amyloidosis.

We are inviting public comments on whether DARZALEX FASPRO® is substantially similar to existing technologies and whether DARZALEX FASPRO® meets the newness criterion.

With respect to the cost criterion, the applicant presented the following analysis to demonstrate that DARZALEX FASPRO® meets the cost criterion. To identify cases representing patients who may be eligible for treatment with DARZALEX FASPRO®, the applicant searched the FY 2019 MedPAR database released with the FY 2022 IPPS final rule and stated that it used fee-for-service IPPS discharges, plus Maryland hospital discharges. The applicant searched for claims reporting ICD–10–CM diagnosis code E85.81 (Light chain amyloidosis) in conjunction with at least one of the following additional ICD–10–CM diagnosis codes:

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ICD-10-CM	DESCRIPTION
C90.00	Multiple myeloma not having achieved remission
D63.1	Anemia in chronic kidney disease
E85.4	Organ-limited amyloidosis
G62.9	Polyneuropathy, unspecified
I11.0	Hypertensive heart disease with heart failure
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease
I12.9	Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I43	Cardiomyopathy in diseases classified elsewhere
I48.0	Paroxysmal atrial fibrillation
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I95.1	Orthostatic hypotension
I95.9	Hypotension, unspecified
N17.9	Acute kidney failure, unspecified
N18.3	Chronic kidney disease, stage 3 (moderate)
N18.4	Chronic kidney disease, stage 4 (severe)
N18.6	End stage renal disease
Z99.2	Dependence on renal dialysis

The applicant excluded cases with a length of stay greater than 7 days from the analysis. According to the applicant, administration of DARZALEX FASPRO® would likely be delayed if a patient becomes seriously ill during the course of treatment, so it is unlikely a patient would receive DARZALEX FASPRO® during an inpatient stay lasting longer than 7 days. The applicant indicated that based on the advice of clinical experts, it also excluded cases mapped to the following MS–DRGs, as DARZALEX FASPRO® would not be an appropriate treatment for patients receiving treatment for such conditions:

[108] Per the NCCN®, a Category 1 recommendation is ''Based upon high-level evidence, there is uniform NCCN® consensus that the intervention is appropriate.''

[109] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Systemic Light Chain amyloidosis (Version 1.2022). National Comprehensive Cancer Network. *www.nccn.org.* Published August 29 June 2021. Accessed July 21, 2021.

MS-DRG	DESCRIPTION
003	ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis except Face, Mouth and Neck with Major O.R. Procedures
016	Autologous Bone Marrow Transplant with CC/MCC
024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC
026	Craniotomy and Endovascular Intracranial Procedures with CC
064	Intracranial Hemorrhage or Cerebral Infarction with MCC
065	Intracranial Hemorrhage or Cerebral Infarction with CC OR TPA in 24 Hours
070	Nonspecific Cerebrovascular Disorders with MCC
094	Bacterial and Tuberculous Infections of Nervous System with MCC
098	Non-Bacterial Infection of Nervous System except Viral Meningitis with CC
152	Otitis Media and URI with MCC
153	Otitis Media and URI without MCC
163	Major Chest Procedures with MCC
164	Major Chest Procedures with CC
175	Pulmonary Embolism with MCC or Acute Cor Pulmonale
176	Pulmonary Embolism without MCC
177	Respiratory Infections and Inflammations with MCC
178	Respiratory Infections and Inflammations with CC
180	Respiratory Neoplasms with MCC
189	Pulmonary Edema and Respiratory Failure
193	Simple Pneumonia and Pleurisy with MCC
194	Simple Pneumonia and Pleurisy with CC
207	Respiratory System Diagnosis with Ventilator Support >96 Hours
208	Respiratory System Diagnosis with Ventilator Support <=96 Hours
266	Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC
267	Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC
270	Other Major Cardiovascular Procedures with MCC
271	Other Major Cardiovascular Procedures with CC
280	Acute Myocardial Infarction, Discharged Alive with MCC
281	Acute Myocardial Infarction, Discharged Alive with CC
283	Acute Myocardial Infarction, Expired with MCC
296	Cardiac Arrest, Unexplained with MCC
330	Major Small and Large Bowel Procedures with CC
371	Major Gastrointestinal Disorders and Peritoneal Infections with MCC
372	Major Gastrointestinal Disorders and Peritoneal Infections with CC
377	Gastrointestinal Hemorrhage with MCC
378	Gastrointestinal Hemorrhage with CC
386	Inflammatory Bowel Disease with CC
388	Gastrointestinal Obstruction with MCC
389	Gastrointestinal Obstruction with CC
417	Laparoscopic Cholecystectomy without C.D.E. with MCC

418	Laparoscopic Cholecystectomy without C.D.E. with CC
436	Malignancy of Hepatobiliary System or Pancreas with CC
454	Combined Anterior and Posterior Spinal Fusion with CC
469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement
470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC
481	Hip Femur Procedures except Major Joint with CC
483	Major Joint or Limb Reattachment Procedures of Upper Extremities
521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC
535	Fractures of Hip and Pelvis with MCC
536	Fractures of Hip and Pelvis without MCC
602	Cellulitis with MCC
603	Cellulitis without MCC
652	Kidney Transplant
666	Prostatectomy with CC
742	Uterine and Adnexa Procedures for Non-Malignancy with CC/MCC
813	Coagulation Disorders
820	Lymphoma and Leukemia with Major O.R. Procedures with MCC
823	Lymphoma and Non-Acute Leukemia with Other Procedures with MCC
824	Lymphoma and Non-Acute Leukemia with Other Procedures with CC
834	Acute Leukemia without Major O.R. Procedures with MCC
835	Acute Leukemia without Major O.R. Procedures with CC
837	Chemotherapy with Acute Leukemia as Secondary Diagnosis or with High Dose Chemotherapy Agent with MCC
840	Lymphoma and Non-Acute Leukemia with MCC
841	Lymphoma and Non-Acute Leukemia with CC
853	Infectious and Parasitic Diseases with O.R. Procedures with MCC
854	Infectious and Parasitic Diseases with O.R. Procedures with CC
856	Postoperative or Post-Traumatic Infections with O.R. Procedures with MCC
864	Fever and Inflammatory Conditions
867	Other Infectious and Parasitic Diseases Diagnoses with MCC
868	Other Infectious and Parasitic Diseases Diagnoses with CC
870	Septicemia or Severe Sepsis with MV >96 HOURS
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC
872	Septicemia or Severe Sepsis without MV >96 Hours without MCC
918	Poisoning and Toxic Effects of Drugs without MCC
919	Complications of Treatment with MCC
920	Complications of Treatment with CC
981	Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC
982	Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC

After applying the case selection and exclusion criteria, the applicant's search resulted in the identification of 114 MS–DRGs using the FY 2019 MedPAR file dataset. The applicant imputed a case count of 11 for 104 MS–DRGs with fewer than 11 cases, resulting in a total of 1,494 cases mapping to the 114 MS–DRGs.

MS-DRG	Title	% of Cases
291	Heart Failure and Shock with MCC	7.23%
545	Connective Tissue Disorders with MCC	4.22%
683	Renal Failure with CC	2.14%
546	Connective Tissue Disorders with CC	2.01%
292	Heart Failure and Shock with CC	1.81%
312	Syncope and Collapse	1.47%
286	Circulatory Disorders except AMI, with Cardiac Catheterization with MCC	1.27%
640	Miscellaneous Disorders of Nutrition, Metabolism, Fluids and Electrolytes with MCC	1.20%
682	Renal Failure with MCC	1.14%
308	Cardiac Arrhythmia and Conduction Disorders with MCC	0.94%
391	Esophagitis, Gastroenteritis and Miscellaneous Digestive Disorders with MCC	0.74%
314	Other Circulatory System Diagnoses with MCC	0.74%
674	Other Kidney and Urinary Tract Procedures with CC	0.74%
641	Miscellaneous Disorders of Nutrition, Metabolism, Fluids and Electrolytes without MCC	0.74%
190	Chronic Obstructive Pulmonary Disease with MCC	0.74%
313	Chest Pain	0.74%
392	Esophagitis, Gastroenteritis and Miscellaneous Digestive Disorders without MCC	0.74%
393	Other Digestive System Diagnoses with MCC	0.74%
699	Other Kidney and Urinary Tract Diagnoses with CC	0.74%
309	Cardiac Arrhythmia and Conduction Disorders with CC	0.74%
689	Kidney and Urinary Tract Infections with MCC	0.74%
698	Other Kidney and Urinary Tract Diagnoses with MCC	0.74%
811	Red Blood Cell Disorders with MCC	0.74%
274	Percutaneous and Other Intracardiac Procedures without MCC	0.74%
304	Hypertension with MCC	0.74%
660	Kidney and Ureter Procedures for Non-Neoplasm with CC	0.74%
673	Other Kidney and Urinary Tract Procedures with MCC	0.74%
808	Major Hematological and Immunological Diagnoses except Sickle Cell Crisis and Coagulation Disorders with MCC	0.74%
847	Chemotherapy without Acute Leukemia as Secondary Diagnosis with CC	0.74%
948	Signs and Symptoms without MCC	0.74%
187	Pleural Effusion with CC	0.74%
242	Permanent Cardiac Pacemaker Implant with MCC	0.74%
264	Other Circulatory System O.R. Procedures	0.74%
287	Circulatory Disorders except AMI, with Cardiac Catheterization without MCC	0.74%
522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC	0.74%
690	Kidney and Urinary Tract Infections without MCC	0.74%
812	Red Blood Cell Disorders without MCC	0.74%
988	Non-Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC	0.74%
071	Nonspecific Cerebrovascular Disorders with CC	0.74%
186	Pleural Effusion with MCC	0.74%
226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC	0.74%
227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC	0.74%
243	Permanent Cardiac Pacemaker Implant with CC	0.74%
246	Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries or Stents	0.74%
300	Peripheral Vascular Disorders with CC	0.74%
394	Other Digestive System Diagnoses with CC	0.74%
432	Cirrhosis and Alcoholic Hepatitis with MCC	0.74%
441	Disorders of the Liver except Malignancy, Cirrhosis or Alcoholic Hepatitis with MCC	0.74%
477	Biopsies of Musculoskeletal System and Connective Tissue with MCC	0.74%
542	Pathological Fractures and Musculoskeletal and Connective Tissue Malignancy with MCC	0.74%
552	Medical Back Problems without MCC	0.74%
596	Major Skin Disorders without MCC	0.74%
809	Major Hematological and Immunological Diagnoses except Sickle Cell Crisis and Coagulation Disorders with CC	0.74%
947	Signs and Symptoms with MCC	0.74%

052	Spinal Disorders and Injuries with CC/MCC	0.74%
057	Degenerative Nervous System Disorders without MCC	0.74%
074	Cranial and Peripheral Nerve Disorders without MCC	0.74%
091	Other Disorders of Nervous System with MCC	0.74%
124	Other Disorders of the Eye with MCC	0.74%
149	Dysequilibrium	0.74%
155	Other Ear, Nose, Mouth and Throat Diagnoses with CC	0.74%
157	Dental and Oral Diseases with MCC	0.74%
166	Other Respiratory System O.R. Procedures with MCC	0.74%
191	Chronic Obstructive Pulmonary Disease with CC	0.74%
196	Interstitial Lung Disease with MCC	0.74%
205	Other Respiratory System Diagnoses with MCC	0.74%
206	Other Respiratory System Diagnoses without MCC	0.74%
225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI, HF or Shock without MCC	0.74%
247	Percutaneous Cardiovascular Procedures with Drug-Eluting Stent without MCC	0.74%
250	Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC	0.74%
252	Other Vascular Procedures with MCC	0.74%
253	Other Vascular Procedures with CC	0.74%
260	Cardiac Pacemaker Revision except Device Replacement with MCC	0.74%
299	Peripheral Vascular Disorders with MCC	0.74%
303	Atherosclerosis without MCC	0.74%
305	Hypertension without MCC	0.74%
311	Angina Pectoris	0.74%
315	Other Circulatory System Diagnoses with CC	0.74%
326	Stomach, Esophageal and Duodenal Procedures with MCC	0.74%
350	Inguinal and Femoral Hernia Procedures with MCC	0.74%
368	Major Esophageal Disorders with MCC	0.74%
433	Cirrhosis and Alcoholic Hepatitis with CC	0.74%
445	Disorders of the Biliary Tract with CC	0.74%
464	Wound Debridement and Skin Graft except Hand or Musculoskeletal and Connective Tissue Disorders with CC	0.74%
478	Biopsies of Musculoskeletal System and Connective Tissue with CC	0.74%
480	Hip and Femur Procedures except Major Joint with MCC	0.74%
500	Soft Tissue Procedures with MCC	0.74%
513	Hand or Wrist Procedures, except Major Thumb or Joint Procedures with CC/MCC	0.74%
515	Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC	0.74%
516	Other Musculoskeletal System and Connective Tissue O.R. Procedures with CC	0.74%
518	Back and Neck Procedures except Spinal Fusion with MCC or Disc Device Or Neurostimulator	0.74%
537	Sprains, Strains, and Dislocations of Hip, Pelvis and Thigh with CC/MCC	0.74%
543	Pathological Fractures and Musculoskeletal and Connective Tissue Malignancy with CC	0.74%
547	Connective Tissue Disorders without CC/MCC	0.74%
551	Medical Back Problems with MCC	0.74%
553	Bone Diseases and Arthropathies with MCC	0.74%
554	Bone Diseases and Arthropathies without MCC	0.74%
555	Signs and Symptoms of Musculoskeletal System and Connective Tissue with MCC	0.74%
559	Aftercare, Musculoskeletal System and Connective Tissue with MCC	0.74%
604	Trauma to the Skin, Subcutaneous Tissue and Breast with MCC	0.74%
638	Diabetes with CC	0.74%
643	Endocrine Disorders with MCC	0.74%
644	Endocrine Disorders with CC	0.74%
694	Urinary Stones without MCC	0.74%
696	Kidney and Urinary Tract Signs and Symptoms without MCC	0.74%
846	Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC	0.74%
866	Viral Illness without MCC	0.74%
876	O.R. Procedures with Principal Diagnosis of Mental Illness	0.74%
880	Acute Adjustment Reaction and Psychosocial Dysfunction	0.74%

884	Organic Disturbances and Intellectual Disability	0.74%
907	Other O.R. Procedures for Injuries with MCC	0.74%
908	Other O.R. Procedures for Injuries with CC	0.74%
949	Aftercare with CC/MCC	0.74%
987	Non-Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC	0.74%

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The applicant determined an average unstandardized case weighted charge per case of $47,599.

The applicant did not remove charges for related or prior technologies because, per the applicant, DARZALEX FASPRO® would not replace other therapies a patient may receive during an inpatient stay. Next, the applicant standardized the charges using the FY 2022 IPPS/LTCH PPS final rule impact file and applied a 4-year inflation factor of 1.281834 or 28.1834% based on the inflation factor used in the FY 2022 IPPS/LTCH PPS final rule to update the outlier threshold (86 FR 45542). The applicant then added charges for the new technology by multiplying the per treatment cost of DARZALEX FASPRO® by the inverse of the national average drug CCR of 0.187 from the FY 2022 IPPS/LTCH PPS final rule (86 FR 44966).

The applicant calculated a final inflated average case-weighted standardized charge per case of $92,916, which exceeded the average case-weighted threshold amount of $61,426. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that DARZALEX FASPRO® meets the cost criterion.

We are inviting public comment on whether DARZALEX FASPRO® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that DARZALEX FASPRO® represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. The applicant also asserted that DARZALEX FASPRO® demonstrates significant improvement in a number of clinical outcomes including hematologic complete response (hemCR), prolonged survival free from major organ deterioration, increased cardiac and renal response rates, with a demonstrated safety and tolerability profile and no negative impact to health-related quality of life based on patient-reported outcomes.

With regard to the claim that DARZALEX FASPRO® offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, the applicant stated that the initial standard of therapy (CyBorD) is considered inadequate, as most patients do not respond adequately to the CyBorD regimen alone. Furthermore, according to the applicant, the ANDROMEDA data shows that >80% of patients do not achieve a hemCR, >75% of patients with cardiac disease do not have an organ response, and >75% of patients with renal disease do not have an organ response when treated with the initial standard of therapy CyBorD. Per the applicant, there is a high unmet need to improve treatment for AL amyloidosis patients. The applicant stated that rapid and deep response like hemCR are critical and are strongly associated with organ response and improved survival in AL amyloidosis.[110] Per the applicant, adding DARZALEX FASPRO® to CyBorD increases the hemCR rate by three-fold and doubles the cardiac and renal response rates, thereby addressing this high unmet medical need.

With regard to the claim that the use of DARZALEX FASPRO® significantly improves clinical outcomes for a patient population as compared to currently available treatments, as stated previously, the applicant asserted that DARZALEX FASPRO® represents a substantial clinical improvement over existing technologies because it: (1) Demonstrates a consistent safety profile; (2) significantly improves hematologic complete response (hemCR rates); (3) maintains the increased hemCR rates for pre-specified subgroups; (4) shortens the time to hemCR; (5) improves very good partial response (VGPR) or better rates; (6) substantially improves cardiac response at 6 and at 12 months; (7) improves renal response at 6 and at 12 months; (8) improves major-organ deterioration or progression-free survival (MOD–PFS); (9) improves Global Health status and fatigue as of cycle 6 of treatment, and maintains health-related quality of life (HRQoL); and (10) provides important advantages for the population with AL.

In support of these claims, the applicant submitted the ANDROMEDA phase 3 trial as well as presentations related to these trials. The applicant stated that data in the ANDROMEDA study demonstrated that DARZALEX FASPRO® led to significantly better outcomes both at the time of the primary analysis [111] as well as at the time of updated analyses which were presented at the 2021 ASCO annual meeting and 2021 EHA annual meeting.[112]

ANDROMEDA was a randomized, open-label, phase 3 study of 388 patients with newly diagnosed AL amyloidosis randomized 1:1 to receive 6 cycles of CyBorD, either alone (control group, n=193) or in combination with daratumumab SC (that is, DARZALEX FASPRO®), followed by DARZALEX FASPRO® monotherapy every 4 weeks for up to 24 additional cycles (daratumumab group, n=195). The study enrolled patients between May 3, 2018 and August 15, 2019. Median age was 64 (range 34–87). The study reported a median 11.4 month follow-up for the published trial, and 20.3 months for the follow-up data. The primary endpoint was hemCR, defined as having negative serum and urine immunofixation and a free light chain ratio (FLCr) within the reference range or abnormal free light-chain ratio if the uninvolved free light chain (uFLC) is higher than the involved free light chain (iFLC). According to the applicant, this definition of hemCR is in line with a recent clarification of the Internal Society of Amyloidosis guidelines.[113] Secondary endpoints were survival free from major organ deterioration or hematologic progression (composite end point that included end-stage cardiac or renal failure,

[110] Comenzo RL, Reece D, Palladini G, et al. Consensus guidelines for the conduct and reporting of clinical trials in systemic light chain amyloidosis. Leukemia. 2012;26: 2317–2325.

[111] Kastritis et al. Daratumumab-Based Treatment for Immunoglobulin Light-Chain Amyloidosis. New England Journal of Medicine (NEJM). 2021; 385:46–58.

[112] Kastritis E, et al., Subcutaneous Daratumumab + Cyclophosphamide, Bortezomib, and Dexamethasone (CyBorD) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results from the Phase 3 ANDROMEDA Study, Oral presentation at: American Society for Oncology (ASCO) Annual Virtual Meeting; June 4–8, 2021 & Oral presentation at: European Hematology Association (EHA) Annual Virtual Meeting; June 9–17, 2021.

[113] Palladini et al. Daratumumab plus CyBord for patients with newly diagnosed AL amyloidosis: safety run-in results of ANDROMEDA. Blood.2020;136:71–80.

hematologic progression), or death, organ response, overall survival, hematologic complete response at 6 months, VGPR or better, time to and duration of hematologic complete response, time to next treatment, and reduction in fatigue. The applicant noted that the safety population in the ANDROMEDA study consisted of 193 patients in the daratumumab arm and 188 patients in the control arm.

The applicant also cited an oral presentation, presented at the American Society of Clinical Oncology (ASCO) 2021 and European Hematology Association (EHA) 2021 annual meetings, with updated data from the ANDROMEDA study after 20.3 months of follow-up, which described sustained primary outcome of higher rates of hemCR across subgroups as well as improved secondary endpoints of cardiac and renal response rate at 12 months. In the intent to treat population, there were 11 deaths in the CyBorD group compared to 7 deaths in the control group.[114]

In support of its assertion that DARZALEX FASPRO® demonstrates a consistent safety profile, the applicant cited Kastritis et al., discussed previously, stating that the safety profiles of daratumumab and bortezomib, cyclophosphamide, and dexamethasone in the ANDROMEDA trial were consistent with their known profiles and the underlying disease from previous trials.[115] To support its assertion that DARZALEX FASPRO® significantly improves hemCR rate, the applicant stated that the trial results showed that patients treated with DARZALEX FASPRO® demonstrated a statistically significant increase in hemCR compared to control (53.3% versus 18.1%; relative risk ratio, 2.9; 95% CI, 2.1 to 4.1; odds ratio, 5.1; 95% CI, 3.2 to 8.2; p<0.001 for both comparisons) at the 11.4 month median follow-up. To support its assertion that DARZALEX FASPRO® results in a shorter time to hemCR, the applicant noted that in the trial, median time to hemCR was 60 days in the daratumumab group and 85 days in the control group. In support of its assertion that the increased hemCR rate was maintained for pre-specified subgroups, the applicant also stated that hemCR remained consistent in most prespecified subgroups (for example, sex, age, weight, race, cardiac stage, etc.) receiving daratumumab.[116] The applicant also cited results from the oral presentation, discussed previously, stating that after a median follow up of 20.3 months, the percentage of patients who achieved hemCR increased to 59% in the daratumumab group vs 19% in the control group (odds ratio: 5.9; 95% CI, 3.7 to 9.4; P<0.001), and that this advantage was seen consistently across all prespecified subgroups.[117] The applicant stated that rapid and deep hematologic responses are critical and are strongly associated with organ response and improved survival in AL amyloidosis.[118]

In support of its assertion that DARZALEX FASPRO® improved VGPR or better rates, the applicant also stated that the trial demonstrated that the secondary endpoint of VGPR or better was 78.5% in the daratumumab group and 49.2% in the control group (relative risk ratio, 1.6; 95% CI, 1.4 to 1.9; odds ratio, 3.8; 95% CI, 2.4 to 5.9).[119] Per the applicant, the substantial improvements in hematologic response rates and other endpoints like cardiac and renal response and MOD–PFS indicate the clinical meaningfulness of these efficacy results.

In support of its assertion that DARZALEX FASPRO® substantially improves cardiac response at 6 and at 12 months, according to the applicant, of the subgroup that was evaluated for cardiac response (118 in the daratumumab group and 117 in the control group), 41.5% in the daratumumab group and 22.2% in the control group (odds ratio, 2.44; 95% CI: 1.35 to 4.42) demonstrated a cardiac response at 6 months.[120] The applicant noted that at a median follow up of 20.3 months, cardiac response rates were higher with in the daratumumab group compared to CyBorD alone at 6 months (42% versus 22%, odds ratio 2.4, 95% CI 1.4 to 4.4; P=0.0029) and at 12 months (57% versus 28%, odds ratio 3.5 95% CI 2.0 to 6.2; P<0.0001).[121] In addition, in support of its assertion that DARZALEX FASPRO® improves renal response at 6 and at 12 months, the applicant noted that in the subgroup evaluated for renal response (117 in the daratumumab group and 113 in the control group), 53.0% of patients in the daratumumab group and 23.9% in the control group (odds ratio, 3.34; 95% CI:1.88 to 5.94) demonstrated a renal response at 6 months.[122] The applicant noted that at a median follow up of 20.3 months, renal response rates were higher with in the daratumumab group compared to CyBorD alone at 6 months (54% vs 27%; odds ratio 3.3 95% CI 1.9 to 5.9; P<0.0001) and at 12 months (57% vs 27%; odds ratio 4.1 95% CI 2.3 to 7.3; P<0.0001).[123] The applicant noted that the percentages of patients who had a cardiac or renal response were substantially higher in the daratumumab group than in the control group, which it stated was an important finding given that organ responses are also a predictor of improved survival.

In support of its assertion that DARZALEX FASPRO® improves MOD–PFS, the applicant noted significant findings of secondary endpoint survival free from major organ deterioration or hematologic progression in the daratumumab group compared to control (hazard ratio for major organ deterioration, hematologic progression, or death, 0.58; 95% CI, 0.36 to 0.93; P = 0.02).[124]

With regard to the claim that DARZALEX FASPRO® improves Global

[114] Kastritis E, et al., Subcutaneous Daratumumab + Cyclophosphamide, Bortezomib, and Dexamethasone (CyBorD) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results from the Phase 3 ANDROMEDA Study, Oral presentation at: American Society for Oncology (ASCO) Annual Virtual Meeting; June 4–8, 2021 & Oral presentation at: European Hematology Association (EHA) Annual Virtual Meeting; June 9–17, 2021.

[115] Kastritis E, et al., Daratumumab-Based Treatment for Immunoglobulin Light-Chain Amyloidosis, N Eng J Med. 2021; 385:46–58.

[116] Kastritis E, et al., Daratumumab-Based Treatment for Immunoglobulin Light-Chain Amyloidosis, N Eng J Med. 2021; 385:46–58.

[117] Kastritis E, et al., Subcutaneous Daratumumab + Cyclophosphamide, Bortezomib, and Dexamethasone (CyBorD) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results from the Phase 3 ANDROMEDA Study, Oral presentation at: American Society for Oncology (ASCO) Annual Virtual Meeting; June 4–8, 2021 & Oral presentation at: European Hematology Association (EHA) Annual Virtual Meeting; June 9–17, 2021.

[118] Comenzo RL, Reece D, Palladini G, et al. Consensus guidelines for the conduct and reporting of clinical trials in systemic light chain amyloidosis. Leukemia. 2012;26: 2317–2325.

[119] Kastritis et al., Daratumumab for immunoglobulin light-chain amyloidosis. N Eng J Med 2021; 385:48–58.

[120] Kastritis E, et al., Daratumumab-Based Treatment for Immunoglobulin Light-Chain Amyloidosis, N Eng J Med. 2021; 385:46–58.

[121] Kastritis E, et al., Subcutaneous Daratumumab + Cyclophosphamide, Bortezomib, and Dexamethasone (CyBorD) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results from the Phase 3 ANDROMEDA Study, Oral presentation at: American Society for Oncology (ASCO) Annual Virtual Meeting; June 4–8, 2021 & Oral presentation at: European Hematology Association (EHA) Annual Virtual Meeting; June 9–17, 2021.

[122] Kastritis E, et al., Daratumumab-Based Treatment for Immunoglobulin Light-Chain Amyloidosis, N Eng J Med. 2021; 385:46–58.

[123] Kastritis E, et al., Subcutaneous Daratumumab + Cyclophosphamide, Bortezomib, and Dexamethasone (CyBorD) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results from the Phase 3 ANDROMEDA Study, Oral presentation at: American Society for Oncology (ASCO) Annual Virtual Meeting; June 4–8, 2021 & Oral presentation at: European Hematology Association (EHA) Annual Virtual Meeting; June 9–17, 2021.

[124] Kastritis et al. Daratumumab-Based Treatment for Immunoglobulin Light-Chain Amyloidosis. NEJM. 2021;385:46–58.

Health status (GHS) and fatigue as of cycle 6 of treatment, as well as maintains HRQoL, the applicant cited a poster presentation of a subgroup analysis on patient reported outcomes (PRO) for patients participating in the ANDROMEDA study.[125] The applicant noted that the patients were provided with PRO questionnaires and assessed on day 1 of cycles −1–6 as well as every 8 weeks thereafter in the daratumumab group. The applicant stated that of the 388 patients randomized in the study, compliance rates for all PRO questionnaires were >90% at baseline and >83% through Cycle 6. The questionnaires included the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30-item (EORTC QLQ–C30), the EuroQol 5-dimensional descriptive system (EQ–5D–5L), and Short Form-36 (SF–36). Secondary endpoints centered around improvements in EORTC QLQ–C30 global health status (GHS), fatigue scale scores, and SF–36 mental component summary (MCS) score. Exploratory outcomes included physical function assessment, symptom improvement, functional improvement, and health utility as measured by the SF–36, EORTC QLQC30 with supplemental symptom items, and the EQ–5D–5L.

The applicant stated that the results from this presentation show that following Cycle 6, improvements in GHS and fatigue were reported in patients in the treatment group, and that these findings further support the value of daratumumab SQ plus CyBorD (Dara-CyBorD) in patients with AL amyloidosis. The applicant also stated that patients with AL amyloidosis treated with Dara-CyBorD experienced clinical improvements without any decrement in HRQoL over 6 cycles. The applicant noted that the findings demonstrated that the median time to improvement was shorter in the treatment group than in the control group for EORTC QLQ–C30 GHS (CyBorD: 16.79 months, 95% CI:11.79 to NE, Dara-CyBorD: 7.82 months, 95% CI: 3.94 to 17.58, HR 1.53; 95% CI: 1.10 to 2.13), fatigue scales (CyBorD: NE, 95% CI:8.44 to NE, Dara-CyBorD: 9.30 months, 95% CI: 5.55 to 13.01, HR 1.39; 95% CI: 1.00 to 1.93) and EQ–5D–5L visual analog scale (CyBorD: NE, 95% CI:16.79 to NE, Dara-CyBorD: 10.05 months, 95% CI: 8.41 to NE, HR 1.21; 95% CI: 0.86 to 1.71). The applicant also noted that the findings demonstrated that median time to worsening was longer in the treatment group than in the control group for EORTC QLQ–C30 GHS (CyBorD: 2.89 months, 95% CI:2.23 to 3.78, Dara-CyBorD: 4.70 months, 95% CI: 2.83 to 7.36, HR 0.87; 95% CI: 0.66 to 1.13) and fatigue scales (CyBorD: 3.75 months, 95% CI: 2.86 to 4.76 Dara-CyBorD: 8.84 months, 95% CI: 3.75 to NE, HR 0.78; 95% CI: 0.58 to 1.04) and EQ–5D–5L visual analog scale (CyBorD: 3.38 months, 95% CI:2.79 to 4.67, Dara-CyBorD: 4.14 months, 95% CI: 2.86 to 7.66, HR 0.89; 95% CI: 0.67 to 1.19).[126]

Finally, the applicant stated that DARZALEX FASPRO® provides important advantages to the population with AL amyloidosis because the subcutaneous administration allows for a negligible volume of administration and a reduced rate of systemic administration-related reactions.[127]

After review of the information provided by the applicant, we have the following concerns regarding whether DARZALEX FASPRO® meets the substantial clinical improvement criterion. First, with respect to the ANDROMEDA trial, we note that the study's open label and unblinded design adds a potential risk of bias which may affect the treatment effect reported by the applicant. Additionally, we note that the ANDROMEDA trial used stratified randomization which resulted in potentially substantive differences between the treatment and control group at baseline; for example, the control group was slightly older, with more males, and more people at higher cardiac stage (based on N-terminal pro-B-type natriuretic peptide and high-sensitivity cardiac troponin T). The groups also differed by Eastern Cooperative Oncology Group (ECOG) performance-status scores and uninvolved free light chain (dFLC) levels, and renal function. Additionally, compared to control, the daratumumab group appeared to have higher rates of peripheral sensory neuropathy, upper respiratory infection, and neutropenia in the longer term data.[128] We question whether these differences noted at baseline are in fact significant and would have the potential to impact the treatment effect seen in this study. In terms of study outcomes, the ANDROMEDA study relied on hematologic and organ-based laboratory-based outcomes, but we question whether a primary endpoint of overall survival would have provided stronger evidence.

Second, we have concerns about the generalizability of the ANDROMEDA population and subgroups. As clarified by the applicant during the New Technology Town Hall meeting, all subjects in the ANDROMEDA trial received DARZALEX FASPRO® in the outpatient setting. As such, we question whether the outcomes for this outpatient population are generalizable to patients who are sufficiently ill to require hospitalization. In regard to subpopulations, we note that the prespecified groups and the studies of cardiac stage and Asian cohorts exhibit the same potential limitations of the main trial with small sample size, open-label, and limited follow-up. We note that small sample size resulted in wider confidence intervals in some subgroups, which may limit the generalizability of the treatment results. For example, in the ANDROMEDA prespecified groups, the subgroups 'other' race, cardiac stage I at baseline, and renal stage III had wider confidence intervals than other subgroups. Finally, while the applicant provided a phase 2 poster presentation in support of DARZALEX FASPRO® we question the extent to which these results are generalizable to the indication for which the applicant has applied for the new technology add-on payment (that is, the treatment of adult patients with light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients) given that the indication within this source (that is monotherapy in patients with Stage 3B AL amyloidosis), does not match.[129]

We note that the applicant provided the outcomes of secondary endpoints

[125] Sanchorawala et al., Health-Related Quality of Life in Patients with AL Amyloidosis Treated with Daratumumab, Bortezomib, Cyclophosphamide, and Dexamethasone: Results from the Phase 3 ANDROMEDA Study, Poster presentation at: American Society of Hematology (ASH) Annual Virtual Meeting; December 5–8, 2020.

[126] Sanchorawala et al., Health-Related Quality of Life in Patients with AL Amyloidosis Treated with Daratumumab, Bortezomib, Cyclophosphamide, and Dexamethasone: Results from the Phase 3 ANDROMEDA Study, Poster presentation at: American Society of Hematology (ASH) Annual Virtual Meeting; December 5–8, 2020.

[127] Kastritis et al. Daratumumab-Based Treatment for Immunoglobulin Light-Chain Amyloidosis. NEJM. 2021;385:46–58.

[128] Kastritis E, et al., Subcutaneous Daratumumab + Cyclophosphamide, Bortezomib, and Dexamethasone (CyBorD) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results from the Phase 3 ANDROMEDA Study, Oral presentation at: American Society for Oncology (ASCO) Annual Virtual Meeting; June 4–8, 2021 & Oral presentation at: European Hematology Association (EHA) Annual Virtual Meeting; June 9–17, 2021.

[129] Kastritis E, et al., Subcutaneous Daratumumab + Cyclophosphamide, Bortezomib, and Dexamethasone (CyBorD) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results from the Phase 3 ANDROMEDA Study, Oral presentation at: American Society for Oncology (ASCO) Annual Virtual Meeting; June 4–8, 2021 & Oral presentation at: European Hematology Association (EHA) Annual Virtual Meeting; June 9–17, 2021.

which appear to be exploratory or novel for some of the data presented in posters in support of its claims, such as the quality of life assessments [130] and hematologic response as measured by involved and uninvolved free light chain,[131] and we note that some of the endpoints are still being studied and validated. Specifically, we question whether these surrogate endpoints may be used to appropriately evaluate the measure for which they are intended to assess. We request further information on whether these secondary endpoints have been appropriately validated in relevant clinical settings.

We are inviting public comments on whether DARZALEX FASPRO® meets the substantial clinical improvement criterion.

In this section, we summarize and respond to written public comments received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for DARZALEX FASPRO®.

Comment: The applicant provided a supplemental written response pertaining to data from the ANDROMEDA trial. The applicant clarified that the ITT population represented all patients that underwent randomization, while the safety population represented patients who received at least one dose of study treatment. Per the applicant, among the 388 patients who underwent randomization (ITT population—195 vs. 193 in the treatment vs. control group, respectively), 381 received at least one dose of trial treatment (safety population—193 vs. 188 in the treatment vs. control group, respectively).

Response: We thank the applicant for its comments and will take this information into consideration when deciding whether to approve new technology add-on payments for DARZALEX FASPRO®.

[130] Sanchorawala et al., Health-Related Quality of Life in Patients with AL Amyloidosis Treated with Daratumumab, Bortezomib, Cyclophosphamide, and Dexamethasone: Results from the Phase 3 ANDROMEDA Study, Poster presentation at: American Society of Hematology (ASH) Annual Virtual Meeting; December 5–8, 2020.

[131] Comenzo et al., Reduction in Absolute Involved Free Light Chain and Difference Between Involved and Uninvolved Free Light Chain is Associated with Prolonged Major Organ Deterioration Progression Free survival in Patient with Newly Diagnosed AL Amyloidosis Receiving Bortezomib, Cyclophosphamide and Dexamethasone with or without Daratumumab: Results from ANDROMEDA, Oral presentation at: American Society of Hematology (ASH) Annual Virtual Meeting; December 5–8, 2020.

c. Hemolung Respiratory Assist System (Hemolung RAS)

ALung Technologies, Inc. submitted an application for new technology add-on payments for the Hemolung Respiratory Assist System (Hemolung RAS) for FY 2023. The applicant stated that the Hemolung RAS is the first and only FDA authorized technology for the treatment of acute, hypercapnic respiratory failure using an extracorporeal circuit to remove CO_2 directly from the blood. Per the applicant, patients experiencing acute, hypercapnic respiratory failure are unable to remove excess CO_2 waste molecules from their blood via their lungs, resulting in accumulation of CO_2 in their blood (hypercapnia), acid/base derangement (respiratory acidosis), and life-threatening clinical sequelae.[132] The applicant stated that the Hemolung RAS does not treat a specific disease but removes CO_2 directly from the blood to treat a variety of underlying respiratory disease states, including, but not limited to, cystic fibrosis (CF), chronic obstructive pulmonary disease (COPD), and asthma, where CO_2 retention (hypercapnia) is the primary cause of continued clinical deterioration.

Per the applicant, the Hemolung RAS provides low-flow, veno-venous extracorporeal carbon dioxide removal ($ECCO_2R$) using a 15.5 French dual lumen catheter inserted percutaneously in the femoral or jugular vein, providing partial ventilatory lung support independent of the lungs as an alternative or supplement to invasive mechanical ventilation. The applicant stated that the Hemolung RAS removes up to 50% of basal metabolic carbon dioxide (CO_2) production at circuit blood flows of 350–550 mL/min. According to the applicant, the Hemolung RAS is not intended to provide therapeutic levels of oxygenation. The applicant stated that during the Hemolung RAS therapy, blood passing through the circuit is oxygenated; however, at low extracorporeal blood flows, the limited oxygen-carrying capacity of blood precludes meaningful oxygenation of mixed venous blood. Extracorporeal therapy with the Hemolung RAS requires continuous systemic anticoagulation with unfractionated heparin or a standard of care alternative to prevent clotting of blood in the circuit.

With respect to the newness criterion, the applicant stated that the Hemolung RAS received Breakthrough Device Designation from FDA in 2015 specific to COPD patients experiencing acute, refractory, hypercapnic respiratory failure. The applicant stated it is not applying under the Breakthrough Device Alternative Pathway in the current application for new technology add-on payments, as the Breakthrough Device indication is different from its FDA De Novo indication. The applicant explained that the Hemolung RAS was classified as a Class III device and received a Breakthrough Device designation for COPD only. According to the applicant, on April 22, 2020, the Hemolung RAS received an Emergency Use Authorization (EUA) to treat lung failure due to COVID–19 when used as an adjunct to noninvasive or invasive mechanical ventilation in reducing hypercapnia and hypercapnic acidosis due to COVID–19 and/or maintaining normalized levels of partial pressure of carbon dioxide (PCO_2) and pH in patients suffering from acute, reversible respiratory failure due to COVID–19 for whom ventilation of CO_2 cannot be adequately, safely, or tolerably achieved. The applicant further explained Hemolung RAS was later classified as a Class II device under the De Novo pathway. The applicant indicated its De Novo classification request (DEN210006) was granted on November 13, 2021, for the indication of respiratory support providing extracorporeal carbon dioxide (CO_2) removal from the patient's blood for up to five days in adults with acute, reversible respiratory failure for whom ventilation of CO_2 cannot be adequately or safely achieved using other available treatment options and continued clinical deterioration is expected. According to the applicant, the De Novo classified Hemolung RAS became available on the market on November 15, 2021, the first business day following the FDA authorization. The applicant indicated that it is seeking new technology add-on payments for FY 2023 for the FDA De Novo indication for the treatment of hypercapnic respiratory failure due to all causes in adults, which would include the EUA indication for the use of the Hemolung RAS in patients with respiratory failure caused by COVID–19. The applicant stated that the following ICD–10–PCS code may be used to uniquely describe procedures involving the use of the Hemolung RAS: 5A0920Z (Assistance with respiratory filtration, continuous, $ECCO_2R$).

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be

[132] Nin, N. et al. Severe hypercapnia and outcome of mechanically ventilated patients with moderate or severe acute respiratory distress syndrome. Intensive Care Med 43, 200–208 (2017).

considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments. According to the applicant, patients experiencing acute, hypercapnic respiratory failure are treated pharmacologically and with non-invasive ventilatory support as a first line treatment. The applicant stated that if these treatments are insufficient to support the failing lungs, escalation of ventilatory support via intubation and invasive mechanical ventilation (IMV) are the only available treatment options. According to the applicant, patients who are intubated and invasively mechanically ventilated are at significant risk for increased morbidity and mortality. The applicant stated that no additional treatments are available if IMV is insufficient to correct refractory hypercapnia and respiratory acidosis, which ultimately lead to cardiopulmonary collapse and death. Furthermore, the applicant stated that no treatment options are available for patients who have a Do Not Intubate (DNI) order.

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant stated that the Hemolung RAS has a different mechanism of action compared to existing technologies. According to the applicant, IMV, the only existing technology used to treat acute, refractory, hypercapnic respiratory failure, utilizes positive airway pressure to deliver oxygen and remove CO_2 from the lungs, whereas the Hemolung RAS removes CO_2 directly from the blood, independent of the lungs and allowing the lungs to rest and recover. Thus, the applicant asserted that the Hemolung RAS uses a different mechanism of action when compared to the existing therapeutic option (that is, IMV). The applicant also stated that extracorporeal membrane oxygenation (ECMO) is a rescue therapy for patients experiencing refractory hypoxemic respiratory failure, where insufficient oxygenation is the source of the respiratory failure. However, the applicant stated that ECMO is not suitable, nor FDA-approved, as a treatment for acute, hypercapnic respiratory failure. Therefore, the applicant asserted that ECMO and the Hemolung RAS are fundamentally different technologies used to treat different patient populations.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG when compared to an existing technology, the applicant stated that the Hemolung RAS is assigned to the same MS–DRGs when compared to an existing technology. Per the applicant, the Hemolung RAS is an escalation therapy to be used when current therapies are unable to support a patient's failing lungs and continued clinical deterioration is expected. The applicant noted that MS–DRGs 207 and 208 (Respiratory System Diagnosis with Ventilator Support > 96 Hours and Respiratory System Diagnosis with Ventilator Support ≤ 96 Hours, respectively) relate to the treatment of respiratory failure using mechanical ventilation, so the Hemolung RAS may be assigned to the same MS–DRGs if mechanical ventilation is unable to safely or adequately remove CO_2 from the blood.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated that the Hemolung RAS and IMV are both used to treat patients experiencing acute, refractory, hypercapnic respiratory failure due to numerous disease etiologies and pathophysiologies. However, the applicant noted that the Hemolung RAS is indicated for use as an escalation therapy when IMV is unable to safely or adequately remove CO_2 from the blood and continued clinical deterioration is expected.

In summary, the applicant maintained that the Hemolung RAS is not substantially similar to currently available therapies and/or technologies because it uses a new mechanism of action and therefore the technology meets the ''newness'' criterion.

As noted previously, the applicant received an FDA De Novo classification for the device on November 13, 2021 (with the product becoming commercially available on November 15, 2021), for the FDA De Novo indication that is the subject of this application, for the treatment of hypercapnic respiratory failure due to all causes in adults. This De Novo indication would include use of the product for the indication for which the applicant initially received an EUA from FDA, for the use of the Hemolung RAS in patients with respiratory failure caused by COVID–19. In the FY 2005 IPPS/LTCH PPS final rule, we stated that the intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first two to three years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the MS–DRG weights (69 FR 49002). While our policy is, generally, to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market as discussed in prior rulemaking (77 FR 53348), we have noted that data reflecting the costs of products that have received an EUA could become available as soon as the date of the EUA issuance and prior to receiving FDA approval or clearance (86 FR 45159). We refer readers to section II.F.7. of the FY 2022 IPPS/LTCH PPS final rule (86 FR 45159 through 45160), for discussion of our solicitation of comments regarding the newness period for products available through an EUA for COVID–19. As discussed in section II.F.4 of the preamble of this proposed rule, we are continuing to consider the comments we received regarding the newness period for products available through an EUA for COVID–19 as discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45159), and we welcome additional comments in this proposed rule.

Therefore, because data reflecting the costs of the Hemolung RAS used for the indication of COVID–19 could be available beginning with the EUA on April 22, 2020, we question whether the newness period for the use of the Hemolung RAS for patients with COVID–19 should begin with the date of EUA issuance, April 22, 2020, while the newness period for the use of Hemolung RAS for patients with other causes of hypercapnic respiratory failure unrelated to COVID–19 should begin on the date of commercial availability of the De Novo classified device, November 15, 2021. As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45159 through 45160), under the current regulations at 42 CFR 412.87(e)(2) and consistent with our longstanding policy of not considering eligibility for new technology add-on payments prior to a product receiving FDA approval or clearance, a product available only through an EUA would not be eligible for new technology add-on payments. Therefore, cases involving pediatric patients, or cases involving the use of the Hemolung RAS for greater than 5 days, would not be eligible for new technology add-on payment if the Hemolung RAS is approved for new technology add-on payment for the patient population indicated in its FDA De Novo marketing authorization.

We invite public comments on whether the newness period for the Hemolung RAS when used for patients with COVID–19 should begin on April 22, 2020 (the date of its EUA), when the product became available on the market for this indication. We are inviting

public comments on whether the Hemolung RAS is substantially similar to existing technologies and whether the Hemolung RAS meets the newness criterion.

With respect to the cost criterion, the applicant presented the following analysis. The applicant searched the FY 2019 MedPAR Limited Data Set (LDS) for cases that received ventilator support to identify patients who may have been eligible for the Hemolung RAS. The applicant reviewed multiple ICD–10–CM and ICD–10–PCS codes related to respiratory failure and hypercapnic disease and determined that two ICD–10–PCS codes were most applicable: 5A1955Z (Respiratory ventilation, greater than 96 consecutive hours) and 5A1945Z (Respiratory ventilation, 24–96 consecutive hours). We note that, in the applicant's analysis, it listed ICD–10–PCS code 5A1955Z as 5A1935Z (Respiratory ventilation, greater than 96 consecutive hours), but we believe the applicant intended to reference the correct ICD–10–PCS code 5A1955Z (Respiratory ventilation, greater than 96 consecutive hours) to correctly map to MS–DRG 207 (Respiratory System Diagnosis with Ventilator Support > 96 Hours).

The applicant identified 68,317 cases mapping to MS–DRGs 207 (Respiratory System Diagnosis with Ventilator Support > 96 Hours) and 208 (Respiratory System Diagnosis with Ventilator Support <= 96 Hours). MS–DRG 207 contained 24.6% of the cases and MS–DRG 208 contained the remaining 75.4% of cases.

Next, the applicant removed 100% of the inhalation charges and charges associated with a 1-day length of stay (LOS) in the intensive care unit (ICU). The applicant explained that it removed the 1 day of routine care plus ICU day charges based on an assumed LOS reduction associated with the use of the Hemolung RAS from relevant cases (as compared to cases without the Hemolung RAS) to estimate the potential decrease in costs as a result of the use of the Hemolung RAS.[133] The applicant then standardized the charges and applied a 4-year inflation factor of 1.281834 or 28.1834%, based on the inflation factor used in the FY 2022 IPPS/LTCH PPS final rule and correction notice to calculate outlier threshold charges (86 FR 45542). The applicant then added charges for the new technology, which it calculated by dividing the cost of the Hemolung RAS by the national average CCR for inhalation therapy, which is 0.147 (86 FR 44966).

The applicant calculated a final inflated average case-weighted standardized charge per case of $178,436, which exceeded the average case-weighted threshold amount of $102,867. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that the Hemolung RAS meets the cost criterion.

After review of the cost analysis provided by the applicant, we question whether the analysis should have included patients who would also require a tracheostomy, which could result in cases mapping to the Pre-Major Diagnostic Category (Pre-MDC) MS–DRGs 003 or 004 if used with mechanical ventilation, and whether the inclusion of those additional MS–DRGs would impact the cost analysis. We are seeking comments on whether the Hemolung RAS meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that the Hemolung RAS offers a treatment option for patients unresponsive to non-invasive mechanical ventilation (NIV), patients unresponsive to invasive mechanical ventilation (IMV), and patients ineligible for currently available treatments (that is, failure of NIV with DNI order). Further, the applicant asserted that the Hemolung RAS significantly improves clinical outcomes relative to available services or technologies.

With regard to the claim that the Hemolung RAS offers a treatment option for patients unresponsive to NIV, the applicant noted that while acute respiratory failure can often be treated with NIV, which does not require intubation and is typically safe and well tolerated, 12–50% of patients are unresponsive to NIV as a result of several factors, including elevated respiratory rates, uncorrected respiratory acidosis, and reduced level of consciousness.[134] [135] [136] Further, the applicant stated that if a patient fails NIV, the only currently indicated treatment is escalation to IMV; however, per the applicant, intubation and IMV following NIV failure is associated with a 200% increase in mortality compared to patients successfully treated with NIV; 27% vs 9% mortality rate, respectively.[137]

The applicant asserted that the Hemolung RAS can be an effective tool for patients unresponsive to NIV by rapidly correcting respiratory acidosis (pH and arterial partial pressure of carbon dioxide ($PaCO_2$)), thereby reducing respiratory drive and improving NIV efficacy. In support of this claim, the applicant submitted a consensus paper by Combes et al.[138] In this consensus paper, 14 clinical experts in critical care and respiratory support using $ECCO_2R$ convened to determine how $ECCO_2R$ therapy is applied, identify how patients are selected, and discuss how treatment decisions are made. Per the applicant, the results of the paper showed that there were two groups of patients where $ECCO_2R$ therapy was indicated—patients with acute respiratory distress syndrome (ARDS) or patients with COPD. The treatment goal for $ECCO_2R$ therapy in patients with ARDS is to provide ultra-protective lung ventilation via managing CO_2 levels. The criteria for initiating $ECCO_2R$ therapy in patients with ARDS and on NIV is when there was no decrease in $PaCO_2$ and no decrease in respiratory rate. In patients with acute COPD exacerbation, treatment targets were patient comfort, pH between 7.30–7.35, respiratory rate less than 20–25 breaths per minute, decrease of $PaCO_2$ by 10–20%, weaning from NIV, decrease in bicarbonate levels (HCO_3), and maintaining hemodynamic stability. The clinical experts came to the consensus that $ECCO_2R$ therapy may be an effective support treatment for adults with ARDS or COPD exacerbation, but noted the need for further evidence from randomized clinical trials and/or high quality prospective studies to better guide decision-making.

The applicant also submitted three peer-reviewed publications in support of this claim. First the applicant cited Bonin et al.,[139] a case study of a 50-year-

[133] Tiruvoipati, et al., ''Effects of Hypercapnia and Hypercapnic Acidosis on Hospital Mortality in Mechanically Ventilated Patients:'' *Crit Care Med.* Vol 456(7). e649–e656.

[134] Conti, V. et al. Predictors of outcome for patients with severe respiratory failure requiring noninvasive mechanical ventilation. Eur Rev Med Pharmacol Sci 19, 3855–3860 (2015).

[135] Bott, J. et al. Randomised controlled trial of nasal ventilation in acute ventilatory failure due to chronic obstructive airways disease. Lancet 341, 1555–1557 (1993).

[136] Phua, J., Kong, K., Lee, K.H., Shen, L. & Lim, T.K. Noninvasive ventilation in hypercapnic acute respiratory failure due to chronic obstructive pulmonary disease vs. other conditions: Effectiveness and predictors of failure. Intensive Care Med 31, 533–539 (2005).

[137] Chandra, D. et al. Outcomes of noninvasive ventilation for acute exacerbations of chronic obstructive pulmonary disease in the United States, 1998–2008. Am. J. Respir. Crit. Care Med. 185, 152–159 (2012).

[138] Combes, A. et al. $ECCO_2R$ therapy in the ICU: Consensus of a European round table meeting. Critical Care 24, (2020).

[139] Bonin, F., Sommerwerck, U., Lund, L. & Teschler, H. Avoidance of intubation during acute exacerbation of chronic obstructive pulmonary disease for a lung transplant candidate using

Continued

old male awaiting a bilateral lung transplant, admitted for COPD exacerbation caused by infection. The patient was initially treated with antibiotics and continuous NIV, which he tolerated for three days. After three days, the patient decompensated due to a spontaneous pneumothorax. The lung was emergently reinflated, but the patient's respiratory status continued to decline with a $PaCO_2$ between 72–85 mmHg, pH of less than 7.3, and a respiratory rate of 30–40. The patient showed signs of exhaustion but did not qualify for intubation due to the recent pneumothorax. The patient consented to the Hemolung RAS therapy and within the first hour of treatment, the patient's respiratory rate improved to around 10 breaths/minute. However, the patient was no longer able to tolerate the NIV minimum set breathing rate, so the minimum set breathing rate was turned off. The $PaCO_2$ decreased to 55–60 mmHg for the duration of therapy (6 days). The patient was able to be successfully weaned from continuous NIV. The patient was also able to take oral nutrition and participate in interventions against pressure sores. After day 6, the patient was able to wean from the Hemolung RAS support and continue with intermittent NIV support.

Second, the applicant cited a multi-national pilot study done by Burki et al.[140] in India and Germany. There were 20 COPD patients with hypercapnic respiratory failure treated with $ECCO_2R$ therapy and placed into 1 of 3 groups. Group 1 had seven patients on NIV with a high likelihood of requiring IMV; Group 2 had two patients who could not be weaned from NIV; and Group 3 had 11 patients on IMV who failed weaning attempts. The authors found that the device was well-tolerated with complications and rates similar to those seen with central venous catheterization. The patients in Group 1 successfully avoided IMV as a result of $ECCO_2R$ therapy, although three patients died within 30 days of $ECCO_2R$ therapy due to underlying disease states. The patients in Group 2 were successfully weaned from continuous NIV after receiving $ECCO_2R$ therapy and were alive 30 days after $ECCO_2R$ therapy, but remained on intermittent non-invasive, positive-pressure ventilation (NIPPV) support. Of the patients in Group 3, nine of the 11 patients had been on IMV for greater than 15 days prior to $ECCO_2R$ therapy. In Group 3, three patients were weaned from IMV, three patients had decreased IMV support, one patient expired from retroperitoneal bleed following catheterization, and one patient remained on the same level of ventilatory support despite receiving $ECCO_2R$ therapy. The authors concluded that the single catheter, low-flow $ECCO_2R$ system, provided clinically useful levels of CO_2 removal in patients with COPD and could be a potentially valuable addition to the treatment of hypercapnic respiratory failure.

Third, the applicant cited a case series by Tiruvoipati et al. (2016),[141] which retrospectively reviewed 15 patients among three Australian ICUs treated with the Hemolung RAS who had severe hypercapnic respiratory failure due to COPD, ARDS, asthma, or bronchiolitis obliterans syndrome (BOS), to show that $ECCO_2R$ was safe and effective in the removal of CO_2. For five patients (four with COPD and one with BOS), the indication for the Hemolung RAS was to avoid intubation, whereas for the other 10 patients (five with acute lung injury/ARDS, three with asthma, and two with COPD), the indication was to institute lung-protective ventilation. The median age of the patients was 61.5 years; 12 patients were men, the median Acute Physiology and Chronic Health Evaluation III (APACHE III) score was 85, and the median duration of $ECCO_2R$ was 5 days. The primary outcome measures of the study were clearance of CO_2 and change in pH with the use of $ECCO_2R$. Secondary outcome measures included complications associated with Hemolung RAS use, survival to weaning from the Hemolung RAS, and survival to ICU and hospital discharge. There was no specified protocol for managing mechanical ventilation across the three centers; however, all centers used low-pressure ventilation for ARDS. For asthma, the mechanical ventilation was characterized by low tidal volume, low respiratory rate, and short inspiratory time associated with prolonged expiratory time to avoid dynamic hyperinflation. Four of the five patients treated for this indication, as well as all 10 patients who were treated to institute lung-protective ventilation, avoided intubation; successful lung-protective ventilation was achieved by a reduction in peak inspiratory pressure, tidal volume, and minute ventilation. The clearance of CO_2 and return of $PaCO_2$ to near-normal levels was achieved within 6 hours, and there was significant reduction in minute ventilation and peak airway pressures. Complications reported during the study included hemorrhage, thrombocytopenia, and compartment syndrome, none of which required cessation of the Hemolung RAS therapy. Overall, 93.3% of the patients survived to discontinuation of $ECCO_2R$, 73.3% of patients survived to ICU discharge, and 66.66% of patients survived to hospital discharge. In conclusion, the study authors stated that the Hemolung RAS appears to be safe and effective for managing hypercapnic respiratory failure of various etiologies, but noted that more research is needed to clarify which patients may benefit most from this therapy.

In addition to the previous peer-reviewed studies, the applicant also cited the Hemolung RAS Registry Program Analysis in support of its claim.[142] Per the applicant, the voluntary Hemolung RAS Registry Program collected data from commercial use of the Hemolung RAS outside of the US as well as US EUA therapies. 176 patients from the Hemolung RAS Registry were analyzed to evaluate the benefits and safety of the Hemolung RAS therapy. The applicant stated that the Hemolung RAS Registry Program Analysis demonstrated that 86% (19/22) of patients failing NIV avoided intubation due to the Hemolung RAS therapy.

With respect to the applicant's assertion that the Hemolung RAS offers a treatment option for patients unresponsive to IMV and are retaining CO_2, the applicant stated that the Hemolung RAS de-couples CO_2 removal from the mechanical ventilator thereby allowing correction of hypercapnia and hypercapnic acidosis without a dangerous escalation of ventilator settings. The applicant provided 10 publications that document the use of the Hemolung RAS in patients unresponsive to IMV to significantly reduce ventilator settings to lung safe levels or to significantly correct and control hypercapnic acidosis, including

extracorporeal carbon dioxide removal with the Hemolung. The Journal of Thoracic and Cardiovascular Surgery 145, e43–e44 (2013).

[140] Burki, N. et al. A novel extracorporeal CO_2 removal system: Results of a pilot study of hypercapnic respiratory failure in patients with COPD. Chest 143, 678–686 (2013).

[141] Tiruvoipati, R. et al. Early experience of a new extracorporeal carbon dioxide removal device for acute hypercapnic respiratory failure. Crit Care Resusc 18, 261–269 (2016).

[142] Alung, Inc., HL–CA–1600, Hemolung RAS Registry. A Retrospective Registry Involving Voluntary Reporting of De-identified, Standard of Care Data Following the Commercial Use of the Hemolung Respiratory Assist System (RAS). *ClinicalTrials.gov*. Retrieved December 21, 2021, from Hemolung RAS Registry Program—Full Text View—*ClinicalTrials.gov*.

Tiruvoipati et al. (2016) [143] and Combes et al.,[144] discussed previously.

In the first case study, a 44-year-old male with acute asthma exacerbation went into respiratory arrest and was intubated in the emergency department (ED).[145] The patient was found to have a left tension pneumothorax, which was decompressed, and then developed a second tension pneumothorax on the right side, which was also decompressed. The patient was transferred to the ICU for further management. The patient continued to deteriorate over the subsequent 48 hours due to subcutaneous emphysema and ongoing air leaks, and after 72 hours had uncontrollable hypercapnia ($PaCO_2$ 73, pH 7.22) despite optimal medical management with corticosteroids, nebulized and intravenous bronchodilators, magnesium, ketamine, and muscle relaxants. $ECCO_2R$ was indicated for hypercapnia and to facilitate de-escalation of IMV. After initiating $ECCO_2R$, it was possible to decrease the support on the IMV while maintaining satisfactory gas exchange and allowing the withdrawal of muscle relaxants. Within 1 hour of initiation of $ECCO_2R$, the pH improved from 7.22 to 7.28, and the $PaCO_2$ went from 68.1 to 60.6. The patient remained on $ECCO_2R$ for a total of 7 days mainly due to ongoing air leaks from three chest drains and a bleeding complication that was managed with transfusion. After discontinuing $ECCO_2R$ therapy, the patient received a tracheostomy to assist in weaning from IMV. The patient was successfully weaned from IMV after 23 days in the ICU and was ultimately discharged home. The authors discussed that while this patient could have been treated with ECMO, the use of ECMO is limited to specialized centers and requires a multidisciplinary approach for a successful outcome.

In the second case study, the Hemolung RAS system was used to treat hypercapnia in a 58-year-old male patient with an out-of-hospital cardiac arrest where mechanical ventilation failed to achieve normocapnia.[146] The patient was intubated in the ED and treated with nebulized bronchodilators, corticosteroids, and therapeutic hypothermia. Initially, the $PaCO_2$ was 82 mmHg (baseline 50 mmHg) with a pH of 7.20, but as the next few hours progressed, the patient became more difficult to ventilate and the $PaCO_2$ increased to 94 mmHg. $ECCO_2R$ therapy was indicated to prevent lung injury and secondary brain injury. After initiating the Hemolung RAS, the minute ventilation and the respiratory rate could be decreased and the team was able to optimize the inspiratory and expiratory time ration to minimize the risk of barotrauma. The patient was on the Hemolung RAS therapy for 3 days and was able to de-escalate the ventilator settings, but still required mechanical ventilation. After cessation of the Hemolung RAS therapy, the patient started to show signs of significant hypoxic brain injury. Despite maximal medical treatment, the neurological prognosis was considered to be very poor, and all life-sustaining therapies were withdrawn. The authors stated that $ECCO_2R$ therapy is safe to use in a metropolitan hospital where the staff have a limited period of education, and that the extracorporeal therapy was delivered without complications. The authors also stated that ECMO is not an option in every health care center since it requires a specialized team including cardiac surgeons and perfusionists and is costly. The authors stated that $ECCO_2R$ is less invasive and able to provide partial respiratory support. Thus, the authors concluded that $ECCO_2R$ may have a role in patients with severe respiratory failure when IMV alone is inadequate and in centers that are not capable of initiating ECMO in the management of severe hypercapnic respiratory failure.

Next, the applicant cited a United Kingdom case study about a 48-year-old male presenting to the ED with 7 days of cough, fever, and shortness of breath.[147] He tested positive for COVID–19 via respiratory viral swab and had a chest x-ray demonstrating bilateral infiltrates. He initially required supplemental oxygen via facemask and oral doxycycline to treat possible bacterial co-infection. He continued to deteriorate, was trialed on NIV and failed, and was then transitioned to IMV on day four of the hospitalization and transferred to the ICU for further management. The patient continued to deteriorate and within a week and was found to be in ARDS due to COVID–19 pneumonitis. The patient was treated with several strategies for lung recruitment, and was referred to ECMO but was declined on the basis of futility. The treatment team felt that continuing to treat the patient with high airway pressure was contributing to the progression of the ARDS, so the Hemolung RAS was initiated as a rescue therapy. After initiation, the $PaCO_2$ and pH improved, which allowed the treatment team to reduce the tidal volume and respiratory rate. The patient spent 6 days on the Hemolung RAS without bleeding events or vasopressors and could continue to receive prone position ventilation without complication. The patient was successfully weaned from the Hemolung RAS and then completed a slow respiratory wean followed by a percutaneous tracheostomy. The patient was ultimately discharged from the ICU to home with mobility and cognition intact. The authors concluded that $ECCO_2R$ can be used as a rescue therapy for patients with hypercapnic respiratory failure resulting from ARDS in COVID–19 pneumonitis and to facilitate lung protective ventilation in patients on IMV. According to the authors, refractory hypercapnia is an acceptable indication for ECMO in ARDS and that $ECCO_2R$ can be considered as rescue therapy if ECMO is deemed inappropriate or cannot be delivered due to resource constraints. Per the authors, potential advantages of using $ECCO_2R$ over ECMO include lack of requirement for transfer to an ECMO center, smaller catheter size, and lower blood flow rate which may reduce the likelihood of complications.

The applicant also cited a case study of an 18-year-old male with solitary mediastinal metastasis and ARDS, in which the Hemolung RAS was used to facilitate de-escalation of mechanical ventilation.[148] Post-treatment with chemotherapy, a residual mediastinal mass was found with extension to the left lung hilum. The patient underwent lung resection and was extubated postoperatively without issue. The patient became febrile and developed a progressively extensive right lung infiltrate. On postoperative day five, the patient developed severe hypercapnia, hypoxemia, and hypotension, necessitating re-intubation and invasive mechanical ventilation. The Hemolung RAS was initiated to provide $ECCO_2R$. Arterial PCO_2 decreased from 73 to 53

[143] Tiruvoipati, R. et al. Early experience of a new extracorporeal carbon dioxide removal device for acute hypercapnic respiratory failure. Crit Care Resusc 18, 261–269 (2016).

[144] Combes, A. et al. $ECCO_2R$ therapy in the ICU: Consensus of a European round table meeting. Critical Care 24, (2020).

[145] Tiruvoipati R, et al. Low-flow veno-venous extracorporeal carbon dioxide removal in the management of severe status asthmatics: A case report. Clin Respir J. 2014;10(5):653–656.

[146] Tiruvoipati R, et al. Management of severe hypercapnia post cardiac arrest with extracorporeal carbon dioxide removal. Anaesth Intensive Care. 2014;42(2):248–252.

[147] Tully RP, et al. The successful use of extracorporeal carbon dioxide removal as a rescue therapy in a patient with severe COVID–19 pneumonitis. Anaesthesia Reports 2020; 8:113–115.

[148] Akkanti B, et al. Low-flow extracorporeal carbon dioxide removal using the Hemolung Respiratory Dialysis System® to facilitate lung-protective mechanical ventilation in acute respiratory distress syndrome. J Extra Corpor Technol. 2017;49(2):112–114.

mmHg within 4 hours (with a concomitant pH increase from 7.28 to 7.44), permitting tidal volume reduction to 3.5 mL/kg, and plateau airway pressure to 25 cm H2O, with simultaneous hemodynamic improvement. $ECCO_2R$ was titrated to maintain an arterial PCO_2 between 45 and 50 mmHg, and the patient was weaned and decannulated after 71 hours of support. The patient was removed from mechanical ventilation within 24 hours and then transferred to an intermediate care unit. No $ECCO_2R$-related complications were observed. The authors stated the Hemolung RAS has a conceptual advantage over ECMO as the Hemolung RAS uses one small dual-lumen venous catheter, without additional arterial access and its attendant risks. The authors concluded that in appropriately selected patients, a minimally invasive $ECCO_2R$ approach may be useful.

Next, the applicant cited a case study by Saavedra-Romero et al.,[149] which describes the use of $ECCO_2R$ immediately administered with lung-protective mechanical ventilation on a patient with COVID–19 ARDS in her mid-60s. The authors stated that, upon arrival to the ICU, on inpatient day 5, the patient's oxygen saturation by pulse oximeter (SpO_2) was 77%, blood pressure (BP) 90/40 on norepinephrine at 10 mcg/min, and the patient's initial arterial blood gas (ABG) results were pH = 7.14, $PaCO_2$ = 90 mmHg, PaO_2 = 52 mmHg, and HCO_3 = 30mEq/L. The patient had significant whole-body subcutaneous crepitus, and the chest x-ray (CXR) showed an inflated right lung, subcutaneous emphysema, and an appropriately positioned endotracheal tube (ETT). The patient became increasingly tachycardic and tachypneic due to further worsening of hypercapnia and respiratory acidosis. $ECCO_2R$ was initiated using the Hemolung RAS and was administered for 17 days without complications. Ventilator settings were maintained at PEEP of 14, rate of 26, and minute ventilation at 7.8 liters during the first 24 hours. Respiratory rate and tidal volumes were subsequently titrated downward, maintaining adequate oxygen levels and permissive hypercapnia. The patient's chest tubes were removed 4 days after the Hemolung RAS decannulation, and the patient was weaned from mechanical ventilation 28 days from ICU admission, and discharged 47 days after admission. The authors stated that this case report highlights the use of $ECCO_2R$ to facilitate effective treatment of a patient with severe hypercapnic respiratory failure secondary to COVID–19 ARDS and multiple risk factors for death. The authors stated that treatment with $ECCO_2R$ allowed a lung-protective ventilator management strategy with ultralow tidal volumes, minimizing the risk of ventilator-induced lung injury, attenuating severe hypercapnia and acidosis, and limiting the expansion of an existing pneumothorax. The authors concluded that $ECCO_2R$ facilitates early lung-protective ventilation and control of refractory hypercapnia and can be safely utilized to increase the likelihood of survival among patients with severe COVID–19 ARDS.

Finally, the applicant cited a case study by Bermudez et al.,[150] in which a 33-year-old male with cystic fibrosis (CF), post double lung transplantation who developed severe hypercarbic respiratory failure due to adenovirus pneumonia requiring hospitalization, tracheostomy, and prolonged IMV for greater than 30 days. The patient was transferred to a tertiary care center and was treated with the Hemolung RAS because of persistent hypoxemia and hypercarbia. The patient was not a candidate for ECMO because of frail clinical condition, volume overload, and need for a redo lung transplantation. After 4 days of the Hemolung RAS support, the patient was weaned from vasopressors, and after 9 days, the patient was accepted as a candidate for redo lung transplantation because of considerable clinical improvement.

Lastly, the applicant provided a retrospective, multicenter study of 31 patients placed on the Hemolung RAS at 8 sites across the U.S.[151] The cohort was comprised of patients with COVID–19 who were mechanically ventilated with severe hypercapnia and respiratory acidosis and treated with low-flow extracorporeal CO_2 removal treated between March 4 and September 30, 2020. Two patients underwent cannulation but were never started on therapy due to a vascular access failure in one patient and immediate circuit clotting in the other. For the 29 patients who received the Hemolung RAS treatment, analysis of covariance revealed a significant improvement trend in both pH and $PaCO_2$ ($p<0.0001$). Comparison of time intervals yielded a statistically significant improvement in pH (7.24 ± 0.12 to 7.35 ± 0.07; $p<0.0001$) and decrease in PCO_2 (79 ± 23 to 58 ± 14; $p<0.0001$) from baseline to 24 hours after start of therapy. There were numerical, but not significant, decreases from baseline to 24 hours in respiratory rate (26.6 ± 5.4 to 23.4 ± 4.9), tidal volume (407 ± 100 to 386 ± 75 mL), and minute ventilation (10.2 ± 3.2 to 8.7 ± 2.2 L/min). The authors indicated that this is the first reported use of $ECCO_2R$ in the U.S. for this patient population. The authors reported that limitations of the study are its small size and single-cohort retrospective nature. The applicant stated that the study results demonstrated the efficacy of $ECCO_2R$ using the Hemolung RAS to improve respiratory acidosis in patients with severe hypercapnic respiratory failure due to COVID–19.

In addition to the case reports and retrospective study, the applicant also cited to the Hemolung RAS Registry Program Analysis, discussed previously, in support of its claim.[152] The applicant stated that the Hemolung RAS Registry Program Analysis demonstrated clinically and statistically significant correction of pH and $PaCO_2$ within the first day of the Hemolung RAS therapy ($p<0.05$).[153] Additionally, the applicant noted that the statistical analysis showed this correction in pH and $PaCO_2$ was independent of the patient's primary diagnosis.

With respect to the applicant's assertion that the Hemolung RAS offers a treatment option for patients ineligible for currently available treatments (for example, patients with a DNI order), the applicant reiterated that intubation with IMV is the only currently available treatment option for patients failing NIV; however, the applicant indicated that these patients have no other therapeutic options if they were to fail NIV because of their preference to not be intubated. According to the applicant, the CO_2 removal by the Hemolung RAS would rapidly correct the pH and $PaCO_2$ which would reduce the respiratory drive and improve NIV

[149] Saavedra-Romero R, et al. Treatment of Severe Hypercapnic Respiratory Failure Caused by SARS–CoV–2 Lung Injury with $ECCO_2R$ Using the Hemolung Respiratory Assist System. Case Reports in Critical Care 2021; 1–5.

[150] Bermudez, et al. ''Prolonged Use of the Hemolung Respiratory Assist System as a Bridge to Redo Lung Transplantation'' Annals of Thorac Surg. 2015 Vol 100 (6). P. 2330–2333.

[151] Akkanti B, et al. Physiologic Improvement in Respiratory Acidosis Using Extracorporeal CO_2 Removal With Hemolung Respiratory Assist System in the Management of Severe Respiratory Failure From Coronavirus Disease 2019. Critical Care Explorations. 2021;3:e0372.

[152] Alung, Inc., HL–CA–1600, Hemolung RAS Registry. A Retrospective Registry Involving Voluntary Reporting of De-identified, Standard of Care Data Following the Commercial Use of the Hemolung Respiratory Assist System (RAS). *ClinicalTrials.gov*. Retrieved December 21, 2021, from Hemolung RAS Registry Program—Full Text View—*ClinicalTrials.gov*.

[153] Ibid. *ClinicalTrials.gov*. Retrieved December 21, 2021, from Hemolung RAS Registry Program—Full Text View—*ClinicalTrials.gov*.

efficacy and prevent continued clinical deterioration.[154] [155]

The applicant submitted three peer-reviewed case reports that have documented the use of the Hemolung RAS in patients failing NIV with a DNI order. In the first case study done in Germany,[156] a 72-year-old female with a past medical history of severe COPD (GOLD 4, nocturnal home ventilation therapy) with a DNI order presented to an ED in a hypercapnic coma. The patient had a Glasgow Coma Score of 3, pH of 6.97, and $PaCO_2$ greater than 150 mm Hg. The patient was hemodynamically stable on NIV with a respiratory rate of 28, oxygen saturation of 88% on supplemental oxygen with an inspired fraction (FiO_2) of 30%. After 30 minutes of NIV treatment, the patient's $PaCO_2$ improved, but the patient was nearly unconscious and was transferred to the ICU. Because of the high predictive mortality for patients with severe COPD who fail NIV and require intubation and invasive mechanical ventilation, combined with the patient's DNI order, the Hemolung RAS was initiated to supplement treatment. Within the first hour of treatment with both NIV and Hemolung RAS, the $PaCO_2$ levels continued to decrease from 109 mmHg to 89 mmHg and the patient's level of consciousness improved after about 25 minutes. Ultimately, the patient was able to start oral nutrition, communicate, and start mobilizing early because of her improved mental state within four hours of starting the Hemolung RAS and was discharged to rehabilitation.

The second case study by Mani et al. described two patients with severe COPD admitted to the ICU with an acute COPD exacerbation requiring NIV, but failed NIV treatments.[157] A 69-year-old female in India was admitted with acute COPD exacerbation, waning consciousness and a pH of 7.20 and $PaCO_2$ of 101 mmHg. After starting NIV for 2 hours, the $PaCO_2$ had risen to 105 mmHg and pH had dropped to 7.193. After 1 hour of the Hemolung RAS treatment and NIV, the $PaCO_2$ declined to 93 mmHg with a pH 7.25. After 6 hours of treatment with the Hemolung RAS and NIV, the patient was awake with a $PaCO_2$ of 68 mmHg and a pH of 7.35. Ultimately, she was discharged to home on home oxygen and nocturnal NIV. There was also a report of a 78-year-old male with COPD and other comorbidities who had a DNI order in Germany. He was admitted with an acute COPD exacerbation and treated with NIV after his initial arterial blood gas (ABG) showed $PaCO_2$ 92 mmHg and pH of 7.24. After treatment with both the Hemolung RAS and NIV for 1 hour, the patient's $PaCO_2$ dropped to 68 mmHg and pH 7.33. Ultimately, the patient was discharged to home on nocturnal NIV. Both patients were both diagnosed with thrombocytopenia as a known complication of extracorporeal therapy, but neither required transfusion.

The applicant submitted a third case study in which Cole et al. describe a 62-year-old female with past medical history of COPD (GOLD class 3) and 2 recent hospitalizations for COPD exacerbations in the past 60 days.[158] The patient had hypercapnic respiratory failure for which she did not want to be intubated, so she was started on NIV. She initially improved, but by day four of NIV treatment, she deteriorated, as evidenced by tachypnea and fatigue due to increased work of breathing. She was started on the Hemolung RAS and within two hours therapy with the Hemolung RAS alone (patient requested to stop NIV with the initiation of the Hemolung RAS), the patient's respiratory rate improved. Within 6 hours, the patient was able to converse and fully engage with her treatment. Ultimately the patient was discharged to home at her baseline activity level and did not require home oxygen therapy, and was not readmitted to hospital within 30 days of discharge.

Furthermore, the applicant claimed that the Hemolung RAS significantly improves clinical outcomes relative to services or technologies previously available by mitigating the harmful clinical sequelae from hypercapnic acidosis and facilitates de-escalation of high pressure and high volume ventilatory support or prevent intubation, both of which are known predictors for poor clinical outcomes. Thus, per the applicant, the correction of hypercapnia and hypercapnic acidosis (that is, pH and $PaCO_2$) are appropriate surrogate markers for improved clinical outcomes in critically ill, mechanically ventilated patients. Per the applicant, the use of correction of hypercapnia and hypercapnic acidosis as surrogate markers for improved clinical outcomes was accepted by FDA as evidence of the clinical benefit of the Hemolung RAS as part of FDA's clearance of its De Novo request.

The applicant asserted that the pH and $PaCO_2$ correction due to the Hemolung RAS therapy provide the following six improved outcomes: (1) Reduced mortality in intubated and IMV patients; (2) reduced length of stay in IMV patients; (3) de-escalation of mechanical ventilation settings (decreased rate of subsequent diagnostic or therapeutic interventions); (4) avoidance of intubation following NIV failure; (5) reduced mortality in NIV patients; and (6) improvement in activities of daily living/quality of life.

In support of its assertion that the Hemolung RAS reduces mortality in intubated and IMV patients, the applicant cited two background studies.[159] [160] In the study by Nin et al., the authors completed a secondary analysis of 3 prospective, non-interventional cohort studies in 1,899 patients with ARDS among 40 ICUs. The goal of the study was to determine the relationship between severe hypercapnia (PaO_2 ≥50 mmHg) in the first 48 hours following onset of ARDS and mortality. The applicant stated that the study results demonstrate that severe hypercapnia in IMV patients was independently associated with increased risk of ICU mortality (odds ratio: 1.93, 95% CI: 1.32–2.81, p=0.001). The second study by Tiruvoipati et al (2017), was a multicenter, binational, retrospective study that included 252,812 patients of 3 cohorts: Normocapnia and normal pH (n=110,104), compensated hypercapnia (n=20,463), and hypercapnic acidosis (n=122,245), that aimed to determine the relationship between these states and Acute Physiology and Chronic Health Evaluation (APACHE) III score and mortality. The study found that those with compensated hypercapnia and hypercapnic acidosis had higher APACHE III scores (49.2 vs. 53.2 vs. 68.6, p<0.01); mortality was highest in the hypercapnic acidosis patients (OR: 1.18, 95% CI: 1.1–1.25) and lowest in the normocapnia and normal pH,

[154] Burki, N. et al. A novel extracorporeal CO_2 removal system: Results of a pilot study of hypercapnic respiratory failure in patients with COPD. Chest 143, 678–686 (2013).

[155] Tiruvoipati, R. et al. Early experience of a new extracorporeal carbon dioxide removal device for acute hypercapnic respiratory failure. Crit Care Resusc 18, 261–269 (2016).

[156] Engel, M., Albrecht, H. & Volz, S. Use of Extracorporeal CO_2 Removal to Avoid Invasive Mechanical Ventilation in Hypercapnic Coma and Failure of Noninvasive Ventilation. J Pulm Respir Med 6, 1–3 (2016).

[157] Mani, R.K., Schmidt, W., Lund, L.W. & Herth, F.J.F. Respiratory dialysis for avoidance of intubation in acute exacerbation of COPD. ASAIO J 59, 675–678 (2013).

[158] Cole, S. et al. Extracorporeal carbon dioxide removal as an alternative to endotracheal intubation for noninvasive ventilation failure in acute exacerbation of COPD. J Int Care Soc 15, 344–346 (2014).

[159] Nin, et al., ''Severe hypercapnia and outcome of mechanically ventilated patients with moderate or severe acute respiratory distress syndrome'' Intensive Care Med. 2017. p. 200–208.

[160] Tiruvoipati, et al., ''Effects of Hypercapnia and Hypercapnic Acidosis on Hospital Mortality in Mechanically Ventilated Patients'' Crit Care Med. 2017. Vol 456 (7). e649–e656.

p<0.001. The applicant stated that the adjusted odds ratio for hospital mortality remained significantly higher in compensated hypercapnia and hypercapnic acidosis when compared with patients with normocapnia and normal pH irrespective of their P/F ratios.

In support of the applicant's second assertion that use of the Hemolung RAS contributes to reduced LOS in IMV patients, the applicant cited Tiruvoipati et al (2017), previously discussed.[161] The median hospital LOS was 10.5 days in the normocapnia and normal pH group, 12 days in the compensated hypercapnia group and 11 days in the hypercapnic acidosis group (p<0.001). The median ICU LOS was 1.9 days vs 2.2 days vs. 2.9 days in the normocapnia/normal pH group vs. compensated hypercapnia group vs. the hypercapnic acidosis group, respectively (p<0.001). The authors noted that that there was increased mortality in patients with hypercapnic acidosis and compensated hypercapnia with unclear cause.

In support of the applicant's assertion that use of the Hemolung RAS results in de-escalation of mechanical ventilation settings and decreased rate of subsequent diagnostic or therapeutic interventions, the applicant cited the Tully et al. case report,[162] discussed previously, in which intubated patients had a 20% decrease in peak airways pressure and 30% decrease in driving pressure during the Hemolung RAS therapy. The applicant also cited the Tiruvoipati et al. (2016) study, discussed previously, in which 10 patients showed a 19% decrease in peak respiratory pressure and a 26% decrease in minute ventilation within 1 day of the Hemolung RAS therapy.[163] The applicant also cited the Hemolung RAS Registry Program Analysis,[164] which demonstrated statistically significant correction of pH and $PaCO_2$ within the first day of the Hemolung RAS therapy (p<0.05).

In support of its assertion that use of the Hemolung RAS contributes to avoidance of intubation following NIV failure, the applicant noted that respiratory acidosis is the primary determinant of NIV failure citing risk charts using a background study from Confalonieri et al.,[165] in which data from 1,033 patients admitted to experienced hospital units was used to predict the likelihood of failure of noninvasive positive pressure ventilation (NPPV). The prediction charts were calculated using the APACHE II, GCS, pH, and respiratory rate data of 1,033 patients admitted with acute respiratory failure due to exacerbation of COPD treated with NIV. The applicant stated that the study results show that pH < 7.25 (acidosis) after 2 hours of NIV is the primary determinant of NIV failure [odds ratio: 21.02; 95% CI: 10.07–43.87], and that additionally, a pH between 7.25 and 7.29 (acidosis) after 2 hours of NIV is also significant predictor of NIV failure [odds ratio: 2.92; 95% CI: 1.62–5.28]. The applicant stated that accuracy and generalizability of the model's ability to predict NIV failure was validated on an independent group of 145 COPD patients treated with NIV.

In a prospective, single-arm feasibility study, Burki et al., previously discussed, stated that 100% (7/7) patients failing NIV and treated with the Hemolung RAS therapy avoided intubation and 100% (2/2) patients failing NIV with a DNI and treated with the Hemolung RAS therapy were successfully weaned from NIV.[166] The applicant cited a retrospective review by Tiruvoipati et al. (2016), also previously discussed, in which 80% (4/5) of patients failing NIV and treated with Hemolung RAS therapy avoided intubation.[167] Furthermore, the applicant cited an unpublished study of the Hemolung RAS Registry Program Analysis,[168] in which 86% of patients (19 of the 22 patients in the analysis) who failed NIV and were treated with the Hemolung RAS therapy avoided intubation.

In support of the assertion that the Hemolung RAS reduced mortality in NIV patients, the applicant submitted two retrospective studies as background studies, in addition to two case studies that utilized the technology. The first background study[169] was a retrospective analysis of data from the Healthcare Cost and Utilization Project's Nationwide Inpatient Sample between 1998 and 2008 to assess the pattern and NIPPV use for acute exacerbations of COPD. The patient cohort was defined as people greater than 35-years-old admitted with a primary diagnosis of COPD or a primary diagnosis of respiratory failure with a secondary diagnosis of COPD. The study demonstrated a decline over time in overall in-hospital mortality for those patients treated with NIPPV without a subsequent need for IMV. Mortality was high and increased over time in patients who transitioned from NIPPV to IMV (27%) compared to those patients who did not transition (9%). Charges for hospitalization increased from 1998 to 2008, especially for patients who transitioned from NIPPV to IMV. LOS decreased in all patients except those who transitioned from NIPPV to IMV. The authors noted a few limitations that would have allowed for a more detailed examination of predictors of NIPPV failure and death, including the lack of information on the severity of the exacerbation, response to NIPPV treatment, end-of-life decision-making, or location of the patient in the hospital (ICU vs. medical ward vs. ED, etc.).

The applicant also cited a retrospective study by Sprooten et al.[170] as background, that looked at patients admitted to the Respicare Unit located in Maastricht University Medical Center (MUMC) in the Netherlands between 2009 and 2011 who met the criteria of admitted for exacerbation of COPD requiring NIV therapy and a definitive COPD diagnosis. In-hospital mortality was 14% with a median LOS of 16.5 days. Overall, this single-center study showed that patients who are admitted to the hospital for a first hospitalization requiring NIV for acute respiratory due to COPD exacerbation have a high short-

[161] Ibid.

[162] Tully RP, et al. The successful use of extracorporeal carbon dioxide removal as a rescue therapy in a patient with severe COVID–19 pneumonitis. Anaesthesia Reports 2020; 8:113–115.

[163] Tiruvoipati, R, et al. Effects of Hypercapnia and Hypercapnic Acidosis on Hospital Mortality in Mechanically Ventilated Patients*: Critical Care Medicine. 2017;45(7):e649–e656.

[164] Alung, Inc., HL–CA–1600, Hemolung RAS Registry. A Retrospective Registry Involving Voluntary Reporting of De-identified, Standard of Care Data Following the Commercial Use of the Hemolung Respiratory Assist System (RAS). *ClinicalTrials.gov*. Retrieved December 21, 2021, from Hemolung RAS Registry Program—Full Text View—*ClinicalTrials.gov*.

[165] Confalonieri M, et al. A chart of failure risk for noninvasive ventilation in patients with COPD exacerbation. European Respiratory Journal. 2005;25(2):348–355.

[166] Burki N, et al. A novel extracorporeal CO_2 removal system: Results of a pilot study of hypercapnic respiratory failure in patients with COPD. Chest. 2013;143(3):678–686.

[167] Tiruvoipati R, et al. Early experience of a new extracorporeal carbon dioxide removal device for acute hypercapnic respiratory failure. Crit Care Resusc. 2016;18(4):261–269.

[168] The applicant cited an unpublished study using data collected from physicians as part of the Hemolung Registry Program. We believe information regarding the Hemolung Registry Program is available here: Alung, Inc., HL–CA–1600, Hemolung RAS Registry. A Retrospective Registry Involving Voluntary Reporting of De-identified, Standard of Care Data Following the Commercial Use of the Hemolung Respiratory Assist System (RAS). *ClinicalTrials.gov*. Retrieved December 21, 2021, from Hemolung RAS Registry Program—Full Text View—*ClinicalTrials.gov*.

[169] Chandra, et al, ''Outcomes of noninvasive ventilation for acute exacerbations of chronic obstructive pulmonary disease in the United States, 1998–2008'' Am J Respir Crit Care Med. 2012. Vol 185 (2). p. 152–159.

[170] Sprooten, et al. ''Predictors for long-term mortality in COPD patients requiring non-invasive positive pressure ventilation for the treatment of acute respiratory failure'' Clinical Resp J. 2020. Vol 14 (12). p. 1144–1152.

and long-term mortality rate. According to the article, older age, NIV use greater than eight days and lack of successful NIV response were independent prognostic factors to two-year mortality rather than response of levels of $PaCO_2$ or pH.

The applicant also cited two case studies where the Hemolung RAS was used to successfully treat patients in hypercapnic respiratory failure caused by COPD. The applicant stated that in these case reports, the Hemolung RAS therapy prevented imminent death in COPD patients with a DNI order who were failing NIV. In a case study by Engel et al., previously described,[171] a 72-year-old female with hypercapnic coma due to COPD exacerbation was administered the Hemolung RAS; after 4 hours, $PaCO_2$, pH, and clinical parameters improved, and the patient was weaned off therapy after 7 days.

In a second study by Mani et al., previously described,[172] the Hemolung RAS was used to treat two patients. The first patient, a 69-year-old female with COPD, was placed on the Hemolung RAS after failing NIV treatment. After 66 hours of treatment, the patient was weaned off the Hemolung RAS, and was discharged home 4 days later. The second patient, a 78-year-old male with COPD, was placed on the Hemolung RAS after failing NIV treatment. After 48 hours of treatment, the patient was weaned off the Hemolung RAS, and was discharged home 10 days later.

In support of the assertion that the Hemolung RAS improves activities of daily living/quality of life, the applicant submitted one randomized controlled trial (RCT) abstract and three case studies. In the RCT abstract by Barrett at al.,[173] 18 patients (median age: 67.5 years) with acute hypercapnic respiratory failure due to exacerbations of COPD were randomized to receive NIV alone or $ECCO_2R$ and NIV. The applicant stated that the study included patients who were at high risk of failing NIV (pH<7.30 after ≥1 hour of NIV). The applicant stated that the control arm continued to be treated with NIV only (n=9) and the test arm was treated with $ECCO_2R$ (n=9). The primary endpoint was the time to cessation of NIV. Secondary outcomes included device tolerance and complications, changes in arterial blood gases (ABGs) and hospital survival. The time to NIV discontinuation was shorter in the $ECCO_2R$ arm (7 hours) vs in the NIV alone arm (24.5 hours), p = 0.004. The study claimed that dyspnea rapidly improved with $ECCO_2R$, but that ICU and hospital LOS were longer with the $ECCO_2R$ group and there was no difference in mortality or functional outcomes at follow-up. The authors concluded that $ECCO_2R$ can be an alternative to NIV for patients who are at risk of failing or cannot tolerate NIV, or for patients in whom a more rapid correction of hypercapnia is desirable.

The applicant referred to three case studies using the Hemolung RAS to treat hypercapnic respiratory failure, to demonstrate improvement in activities of daily living/quality of life. In the case study by Engel et al., previously described,[174] the applicant stated that early mobilization, communication, and nutrition were facilitated with Hemolung therapy. In the Bermudez et al. case study, previously discussed,[175] the Hemolung RAS was successfully used to bridge a patient with COPD to a lung transplantation. The applicant stated that considerable clinical improvement attributed to Hemolung therapy permitted the patient to be awake and mobilized to sit on the edge of the bed. In the Bonin et al. case study, previously discussed,[176] the applicant stated that drinking and recovery from pressure sores were possible by day three of the Hemolung RAS.

After review of the information provided by the applicant, we have the following concerns regarding whether the Hemolung RAS meets the substantial clinical improvement criterion. We note that the evidence provided for several of the claims of substantial clinical improvement include small, non-randomized studies without the use of comparators or controls, including case studies, which may affect the ability to draw meaningful conclusions about treatment outcomes from the results of the studies. The benefits of avoiding intubation or de-escalating IMV settings are described in case studies, but the absence of comparative data may make it more difficult to determine whether there are clinically meaningful changes in these outcomes. We also note that in the one abstract of an RCT using the Hemolung RAS,[177] although the time to NIV discontinuation was shorter in the $ECCO_2R$ arm than in the NIV alone arm, the ICU and hospital length of stay were longer with the $ECCO_2R$ group and there were no differences in mortality or functional outcomes at follow-up. Additionally, while the applicant states that the Hemolung RAS results in improved clinical outcomes, such as reducing mortality in NIV patients compared to continuing the patient's previous treatment, given that many of the case studies provided as evidence to support improved clinical outcomes included only one or two patients, it is not clear whether or not the results of these studies are generalizable to the Medicare population. We also note that several of the case studies, for example, Bonin et al., Mani et al., Tully et al., etc., mentioned by the applicant included patients and cases from outside the U.S., and we question if there may be differences in treatment guidelines between these countries that may have affected clinical outcomes. Lastly, we note that for several of the claims of substantial clinical improvement, the applicant provided evidence from background studies that did not utilize the Hemolung RAS to support the use of the technology to improve clinical outcomes. For example, in support of its assertion that the Hemolung RAS reduces mortality in NIPPV patients, the study cited by the applicant only addressed NIPPV as a treatment option to treat exacerbations in patients with COPD, but did not directly address the use of the Hemolung RAS as an intervention.

We are inviting public comments on whether the Hemolung RAS meets the substantial clinical improvement criterion.

In this section, we summarize and respond to written public comments received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for the Hemolung RAS.

[171] Engel, et al. ''Use of Extracorporeal CO_2 Removal to Avoid Invasive Mechanical Ventilation in Hypercapnic Coma and Failure of Noninvasive Ventilation'' J. Pulm & Resp Med. 2016 Vol 6 (3) p.1–3.

[172] Mani, R.K., Schmidt, W., Lund, L.W. & Herth, F.J.F. Respiratory dialysis for avoidance of intubation in acute exacerbation of COPD. ASAIO J 59, 675–678 (2013).

[173] Barrett, N, et al. A randomized controlled trial of Non-Invasive Ventilation compared with $ECCO_2R$ for Acute Hypercapnic Exacerbations of COPD. ASAIO J. 2021; 67 (Supp 3) Presented at the 32nd Annual ELSO Conference.

[174] Engel, et al. ''Use of Extracorporeal CO_2 Removal to Avoid Invasive Mechanical Ventilation in Hypercapnic Coma and Failure of Noninvasive Ventilation'' J. Pulm & Resp Med. 2016 Vol 6 (3) p.1–3.

[175] Bermudez, et al. ''Prolonged Use of the Hemolung Respiratory Assist System as a Bridge to Redo Lung Transplantation'' Annals of Thorac Surg. 2015 Vol 100 (6). p. 2330–2333.

[176] Bonin, et al. ''Avoidance of intubation during acute exacerbation of chronic obstructive pulmonary disease for a lung transplant candidate using extracorporeal carbon dioxide removal with the Hemolung''. J Thorac Cardiovac Surg. 2013. Vol 145 (5). e43–e44.

[177] Barrett, N, et al. A randomized controlled trial of Non-Invasive Ventilation compared with $ECCO_2R$ for Acute Hypercapnic Exacerbations of COPD. ASAIO J. 2021; 67 (Supp 3) Presented at the 32nd Annual ELSO Conference.

Comment: The applicant submitted a public comment from a commenter who supported the use of the Hemolung RAS. The commenter explained that they have treated five patients with the Hemolung RAS (two in the Investigational Device Exemption (IDE) clinical trial for the Hemolung RAS in patients with COPD and three via the EUA for COVID–19 pneumonia) and found the Hemolung RAS to be reliable and safe. They noted that they found that it consistently removed roughly 80 ml of CO_2 per minute with a blood flow rate of 300–400 mL/min and it allowed the reduction of ventilator settings including tidal volume and rate while maintaining or lowering the $PaCO_2$. They further commented that the nurses and staff found it easy to use and comparable to continuous veno-venous hemofiltration (CVVHD). The commenter also offered that they anticipate using the Hemolung RAS in a number of clinical scenarios, such as to avoid intubation or facilitate extubation in patients with hypercapnic respiratory failure due to COPD or other forms of acute chronic hypercapnic respiratory failure. Lastly, the commenter explained that the randomized controlled trial (RCT) was very difficult to enroll due to a number of factors including the challenges of getting rapid consent when trying to enroll patients failing NIV, consent concerns by proxies, difficulties enrolling at night and on weekends, and many others. However, the commenter believed that when it is available outside of the context of a clinical trial, the Hemolung RAS will be used more often to reduce the need for IMV in hypercapnic patients, enhance comfort, and permit more efficient use of ICU resources.

The applicant also submitted a second public comment from a commenter who supported the Hemolung RAS for release for clinical use, especially during the COVID–19 pandemic during which the commenter had seen an increase in the admission rate for COPD patients infected with COVID–19. The commenter stated they believe that the Hemolung RAS can reduce LOS and ICU ventilation days. In support, the commenter stated that its site has been involved in the Hemolung RAS trial in the US and has a large population of COPD patients who are admitted with exacerbation of COPD, with the majority requiring mechanical ventilation. The commenter stated that the Hemolung RAS had allowed them to avoid mechanical ventilation or successfully extubate patients enrolled in the study. They further stated that they have not had any serious adverse side effects with the use of the device and that the nursing and respiratory therapy staff acquired the needed skill to use the device with minimal training.

Response: We thank the applicant for its comments and will take this information into consideration when deciding whether to approve new technology add-on payments for the Hemolung RAS.

d. Lifileucel

Iovance Biotherapeutics submitted an application for new technology add-on payments for lifileucel for FY 2023. According to the applicant, lifileucel is a proprietary, one-time autologous Tumor Infiltrating Lymphocytes (TIL) cell-based therapy for the treatment of unresectable or metastatic melanoma. TIL cell therapy with lifileucel involves the adoptive cell transfer (ACT) of autologous T-cells directly isolated from the tumor tissue and expanded ex vivo without any prior selection or genetic modification. Tumor antigen-specific T-cells are located within tumor lesions, where a dysfunctional state and low numbers prevent them from effectively eradicating the tumor. By isolating autologous TIL from the tumor microenvironment and expanding them, the lifileucel manufacturing process produces large numbers of reinvigorated T-cells. Following the infusion of lifileucel, the TIL migrate back into the tumor, including metastases, where they trigger specific tumor cell killing upon recognition of tumor antigens. We note that Iovance Biotherapeutics previously submitted an application for new technology add-on payments for lifileucel for FY 2022, as summarized in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25272 through 25282), but withdrew the application prior to the issuance of the FY 2022 IPPS/LTCH PPS final rule (86 FR 44979).

As noted in our prior review, the applicant stated relapsed and refractory metastatic melanoma presents a high unmet medical need with low survival rates and limited durable treatment options.[178] Despite the advances in available treatments, responses in patients with metastatic melanoma are at times inadequate, with many patients either not responding (40% to 65%) [179] [180] or displaying primary or acquired resistance (≤70%) and the disease progresses.[181] [182] [183] [184] [185] The applicant stated there are currently no approved agents for the treatment of patients with metastatic melanoma who fail available standard-of-care therapies, which include immune checkpoint inhibitors (ICI) and BRAF/MEK inhibitors. According to the applicant, the only commonly used available therapy for these patients post progression is chemotherapy. The applicant stated that as demonstrated in the literature referenced previously, retreatment with chemotherapy [186] [187] [188] or experimental combined ICIs [189] offers a poor Objective Response Rate (ORR) [190] of 4%–10%,[191] [192] [193] a median

[178] Sarnaik A, et al. Safety and efficacy of lifileucel (LN–144) tumor infiltrating lymphocyte therapy in metastatic melanoma patients after progression on multiple therapies—independent review committee data update. Poster presented at SITC 2019. Poster Number: P865 and abstract; Journal: J Immunotherapy Cancer 2020;8:A12.

[179] Mooradian MJ and Sullivan RJ. What to do when anti-PD–1 therapy fails in patients with melanoma. Oncology (Williston Park) 2019;33:141–8.

[180] Gide TN, et al. Primary and acquired resistance to immune checkpoint inhibitors in metastatic melanoma. Clin Cancer Res 2018;24:1260–70.

[181] Luke JJ, et al. Targeted agents and immunotherapies: Optimizing outcomes in melanoma. Nature Reviews Clinical Oncology. Doi:10.1038/ncrclinonc.2017.43. Published online April 4, 2017.

[182] Mooradian MJ and Sullivan RJ. What to do when anti-PD–1 therapy fails in patients with melanoma. Oncology (Williston Park) 2019;33:141–8.

[183] Gide TN, et al. Primary and acquired resistance to immune checkpoint inhibitors in metastatic melanoma. Clin Cancer Res 2018;24:1260–70.

[184] Schachter J, et al. Pembrolizumab versus ipilimumab for advanced melanoma: Final overall survival results of a multicenter, randomized, open-label phase 3 study (KEYNOTE–006). Lancet 2017; 390:1853–62.

[185] Ugurel S, et al. Survival of patients with advanced metastatic melanoma: The impact of novel therapies-update 2017. Eur J Cancer 2017; 83:247–257.

[186] Goldinger SM, et al. The utility of chemotherapy after immunotherapy failure in metastatic melanoma: A multicenter case series. J Clin Oncol 2018;36:e21588–e.

[187] Larkin J, et al. Overall survival in patients with advanced melanoma who received nivolumab versus investigator's Choice chemotherapy in CheckMate 037: A randomized, controlled, open-label Phase III trial. J Clin Oncol 2018;36:383–90.

[188] Ribas A, et al. Pembrolizumab versus investigator-choice chemotherapy for ipilimumab-refractory melanoma (KEYNOTE–002): A randomised, controlled, phase 2 trial. Lancet Oncol. 2015; 16(8): 908–18.

[189] Kirchberger MC, et al. Combined low-dose ipilimumab and pembrolizumab after sequential ipilimumab and pembrolizumab failure in advanced melanoma. Eur J Cancer. 2016;65:182–184. doi:10.1016/j.ejca. 2016.07.003.

[190] As used by the applicant and the studies provided, Objective Response Rate (ORR) is the combination of Complete and Partial Responses.

[191] Weichenthal M, et al. Salvage therapy after failure from anti-PD–1 single agent treatment: A study by the German ADOReg melanoma registry. J Clin Oncol 37, 2018 (suppl; abstr 9505).

[192] Larkin J, et al. Overall survival in patients with advanced melanoma who received nivolumab versus investigator's Choice chemotherapy in CheckMate 037: A randomized, controlled, open-label Phase III trial. J Clin Oncol 2018;36:383–90.

[193] Ribas A, et al. Pembrolizumab versus investigator-choice chemotherapy for ipilimumab-

PFS of 2.7–3.7 months [194] [195] [196] and a median OS of ~7–8 months.[197] [198]

According to the applicant, lifileucel is being studied for effectiveness in solid tumors. The applicant stated that in addition to the pivotal programs researching metastatic melanoma (C–144–01) and advanced cervical cancer (C–145–04) patients, TIL cell therapy is being investigated in the treatment of patients with locally advanced, recurrent, or metastatic non-small-cell lung cancer (IOV–COM–202 and IOV–LUN–202) as well as in peripheral blood lymphocyte (PBL) blood cancers. The applicant asserted lifileucel is expected to be administered primarily in the hospital inpatient setting to assure appropriate patient monitoring and to ensure the supervision of a qualified physician experienced with the use and administration of IL–2 (for example, aldesleukin). However, the applicant added, some treatment centers may make the clinical decision to infuse lifileucel as an outpatient procedure.

With respect to the newness criterion, the applicant indicated that they are pursuing a Biologics License Application (BLA) for lifileucel from FDA. The applicant added that the proposed prescribing information for lifileucel is currently in development and will be submitted upon BLA submission to FDA. The applicant stated the proposed indication for lifileucel is as a one-time autologous TIL immunotherapy for the treatment of patients with unresectable or metastatic melanoma who have been previously treated with at least one systemic therapy, including a PD–1 blocking antibody and, if BRAF V600 mutation positive, a BRAF inhibitor or BRAF inhibitor with MEK inhibitor. The applicant stated lifileucel has received Regenerative Medicine Advanced Therapy (RMAT), Orphan Drug, and Fast Track designations from FDA for the treatment of advanced melanoma. The applicant stated that currently, the following ICD–10–PCS procedure codes, effective October 1, 2021, uniquely identify procedures involving the administration of lifileucel in the inpatient setting: XW033L7 (Introduction of lifileucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7) and XW043L7 (Introduction of lifileucel immunotherapy into central vein, percutaneous approach, new technology group 7). Based on their clinical trial protocol and proposed label, the applicant stated a single dose of lifileucel contains between 1×109 and 150×109 autologous TIL suspended in up to four patient-specific infusion bags for intravenous infusion. The applicant stated patients receive pre-treatment in the form of a nonmyeloablative lymphodepleting chemotherapy regimen of cyclophosphamide 60 mg/kg intravenously daily for 2 days followed by fludarabine 25 mg/m^2 intravenously daily for 5 days before infusion of lifileucel administration within 24 hours of the last dose. The applicant stated that 3 to 24 hours following the administration of lifileucel, patients should receive a post-treatment of a short course of high dose IL–2 (600,000 IU/kg every 8–12 hours for up to a maximum of six doses).

If a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that lifileucel does not use the same or similar mechanism of action as compared to currently available products used in the treatment of advanced melanoma. The applicant stated that clinical studies suggest that TIL therapy lyses tumor cells via the following mechanism: [199]

- Reinfused TIL circulate in the blood until they recognize tumor-specific antigens (TSAs) on the surface of the tumor cells via chemokines produced by the tumor. The TIL depart the capillaries, migrate to the tumor, and recognize tumor antigen peptides presented by MHC molecules on the surface of the tumor cells via their T cell receptors.
- Upon tumor antigen recognition, the TIL are activated and release perforin, a pore-forming protein.
- TIL then release granzyme, a pro-apoptotic protease, which enters the tumor via the pores, causing lysis of the tumor cells.
- TIL also release IFN-γ, which promotes macrophage activation to phagocytize (that is, engulf and internalize) the lysed tumor cell debris and present tumor antigens.
- TIL therapy mediates regression of tumors both by direct cell lysis and by inducing cytokine- (IFN-γ) mediated tumor cell killing.

According to the applicant, the currently available first and second line treatments for advanced melanoma include kinase inhibitors (BRAF and MEK inhibitors) and immune checkpoint inhibitors (anti-CTLA–4 antibody and anti-PD–1 antibody).[200] [201] The applicant explained that kinase inhibitors selectively inhibit the mutated BRAF V600E- or V600K kinase and MEK inhibitors are used in combination with BRAF inhibitors to interfere with the signaling of the MEK–1 and MEK–2 protein within the cancer cell.[202] [203] [204] [205] The applicant next explained that immune checkpoint inhibitors include CTLA–4 blocking antibodies and PD–1 blocking antibodies that are humanized monoclonal or recombinant IgG4 kappa immunoglobulin produced in recombinant Chinese hamster ovary cell lines.[206] [207] [208] The applicant asserted that there are no approved treatment options for patients with metastatic melanoma that have progressed after two lines of therapy but stated that some patients may receive high-dose IL–2 or

refractory melanoma (KEYNOTE–002): A randomised, controlled, phase 2 trial. Lancet Oncol. 2015; 16(8): 908–18.

[194] Goldinger SM, et al. The utility of chemotherapy after immunotherapy failure in metastatic melanoma: A multicenter case series. J Clin Oncol 2018;36:e21588–e.

[195] Larkin J, et al. Overall survival in patients with advanced melanoma who received nivolumab versus investigator's Choice chemotherapy in CheckMate 037: A randomized, controlled, open-label Phase III trial. J Clin Oncol 2018;36:383–90.

[196] Ribas A, et al. Pembrolizumab versus investigator-choice chemotherapy for ipilimumab-refractory melanoma (KEYNOTE–002): A randomised, controlled, phase 2 trial. Lancet Oncol. 2015; 16(8): 908–18.

[197] Kirchberger MC, et al. Combined low-dose ipilimumab and pembrolizumab after sequential ipilimumab and pembrolizumab failure in advanced melanoma. Eur J Cancer. 2016;65:182–184. doi:10.1016/j.ejca. 2016.07.003.

[198] Goldinger SM, et al. The utility of chemotherapy after immunotherapy failure in metastatic melanoma: A multicenter case series. J Clin Oncol 2018;36:e21588–e.

[199] Chávez-Galán L, et al. Cell death mechanisms induced by cytotoxic lymphocytes. Cell Mol Immunol. 2009; 6(1): 15–25.

[200] Luke JJ, et al. Targeted agents and immunotherapies: Optimizing outcomes in melanoma. Nature Reviews Clinical Oncology. Doi:10.1038/ncrclinonc.2017.43. Published online April 4, 2017.

[201] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines. Melanoma: Cutaneous. V2.2021—February 19, 2021. *https://www.nccn.org.*

[202] Zelboraf (vemurafenib) prescribing information. Genentech, 2011.

[203] Tafinlar (dabrafenib) prescribing information. Novartis, 2013.

[204] Mekinst (trametinib) prescribing information. Novartis, 2013.

[205] Cotellic (cobinmetnib) prescribing information. Novartis, 2015.

[206] Keytruda (pembrolizumab) presecribing information. Merck & Co., Inc.; 2019.

[207] Yervoy (ipilmumab) prescribing information. Bristol Myers Squibb, 2011.

[208] Opdivo (nivolumab) prescribing information. Bristol Myers Squibb, 2014.

cytotoxic agents per NCCN clinical practice guidelines.[209]

According to the applicant, TIL cell therapy with lifileucel uses a novel and distinct mechanism of action which delivers a highly customized, personalized, and targeted treatment for unresectable or metastatic melanoma. According to the applicant, lifileucel TIL cell therapy involves the Adoptive Cell Therapy (ACT) of autologous T-cells directly isolated from the patient's tumor tissue and expanded ex vivo. The applicant added that following the infusion of lifileucel, the TIL migrates back into the patient's tumor deposits, including metastases, where they trigger specific tumor cell killing upon recognition of tumor antigens. According to the applicant, after approval, lifileucel will be the only personalized, cellular therapy indicated for the treatment of unresectable or metastatic melanoma.

The applicant stated that as well as having tumor recognition, discussed previously, TIL therapy is personalized, polyclonal, and neoantigen-specific. According to the applicant, TIL is inherently personalized because it is derived from the patient's tumor tissue. According to the applicant, theoretically, tumor tissue TIL recognize a multitude of an individual's tumor specific antigens (TSAs) as opposed to CAR T-cell therapies which recognize only one TSA.[210] The applicant asserted that TIL therapy is polyclonal because it can recognize an array of different tumor antigens which best addresses the high mutational diversity of solid tumors.[211] [212] According to the applicant, TIL is neoantigen-specific because the TIL therapy process ensures the inclusion of neoantigen-specific T cell clones without prior knowledge of the number or identity of those neoantigens.[213]

The applicant asserted TIL cell therapy with lifileucel is also highly differentiated from currently approved CAR T-cell therapies which treat liquid tumors: YESCARTA® (axicabtagene ciloleucel) and KYMRIAH® (tisagenlecleucel), both approved for the treatment of large B-cell lymphoma in adults, and recently approved TECARTUS™ (brexucabtagene autoleucel) indicated for the treatment of relapsed/refractory mantle cell lymphoma (MCL) and ABECMA® (idecabtagene vicleucel) indicated for the treatment of relapsed/refractory multiple myeloma. The applicant stated that while other ACT, including CAR T-cell therapies, utilize circulating T-cells from the blood, TIL therapy harvests neoantigen-directed T-cells that are isolated from a tumor biopsy. The applicant stated that whereas T-cells are genetically altered to have special receptors called chimeric antigen receptors in CAR T-cell therapy, TIL from tumor tissue fragments are cultured with IL–2 to allow outgrowth of TIL cell population during pre-rapid expansion (pre-REP). The applicant asserted that TIL cells obtained at the end of the pre-REP are subsequently cultured with IL–2, anti-CD–2 and feeder cells to start REP which is lastly cryopreserved.

According to the applicant, CAR T-cell therapies mainly target only single/surface tumor antigens, versus TIL cell therapy which targets multiple tumor antigens. The applicant added that CAR T-cells return to the bloodstream and lymphatic system and have more contact with blood tumor cells which may reduce their ability to penetrate tumor tissue through the vascular endothelium. The applicant stated another obstacle with the use of CAR T-cell therapy in the treatment of solid tumors is a phenomenon known as ''tumor antigen escape'' where a tumor expresses alternative forms of the target antigen that lack the extracellular epitopes recognized by CAR T-cells.[214] The applicant stated that there are no examples of successful utility of CAR T-cell therapy in solid tumors. The applicant further stated that the TIL mechanism of action does not rely on genetically engineered receptors, but maintains some physiologic control and therefore avoids hyperactivation that may be responsible for complications from CAR T-cell therapy such as cytokine release syndrome (CRS) or neurotoxicity.[215] Per the applicant, there have been no off-tissue effects found to date following treatment with TIL cell therapy, and TIL therefore offers a differentiated safety profile compared to CAR T-cell products or ICIs and confirms the mechanism of action differentiation discussed previously.

With respect to the second criterion, whether a product is assigned to the same or different MS–DRG, the applicant stated that in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44798 through 44806), CMS finalized its proposal to assign existing procedure codes describing CAR T-cell, non-CAR T-cell and other immunotherapies to Pre-MDC 018 and to modify the title to ''Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies'' to better reflect the cases reporting the administration of non-CAR T-cell therapies and other immunotherapies. The applicant stated their appreciation and support for CMS' final decision to assign lifileucel ICD–10–PCS codes to Pre-MDC MS–DRG 018. The applicant agreed that while the clinical and resource intensity of lifileucel is comparable to that of CAR T-cell therapy inpatient episodes of care, the TIL cell therapy mechanism of action and patient population differ from autologous CAR T-cell therapy.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that if FDA grants approval, lifileucel will be the only FDA-approved cellular treatment for patients with unresectable or metastatic melanoma who have been previously treated with at least one systemic therapy, including a PD–1 blocking antibody and, if BRAF V600 mutation positive, a BRAF inhibitor or BRAF inhibitor with MEK inhibitor. The applicant asserted lifileucel will be the first and only FDA-approved cellular treatment for this challenging to treat patient population.

After review of the information provided by the applicant, we note that in regard to the MS–DRG assignment, while the applicant stated that lifileucel is assigned to the same MS–DRG as CAR T-cell therapies, it seems that lifileucel maps to a different MS–DRG than existing treatments for metastatic melanoma. We also note that there are currently other therapies for the treatment of metastatic melanoma and we are not certain that the distinction of being the first cellular treatment is relevant to the third criterion. We are seeking public comment on whether lifileucel would indeed be the only FDA approved treatment for the patient population identified here.

We are inviting public comments on whether lifileucel is substantially

[209] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines. Melanoma: Cutaneous. V2.2021—February 19, 2021. *https://www.nccn.org.*

[210] Raskov H, et al. British Journal of Cancer (2021) 124:359–367; *https://doi.org/10.1038/s41416-020-01048-4.*

[211] Fardis M, et al. Current and future directions for tumor infiltrating lymphocyte therapy for the treatment of solid tumors. Cell and Gene Therapy Insights, 2020; 6(6), 855–863.

[212] Schumacher TN and Schreiber RD. Neoantigens in cancer immunotherapy. Science 2015; (6230): 69–74.

[213] Fardis M, et al. Current and future directions for tumor infiltrating lymphocyte therapy for the treatment of solid tumors. Cell and Gene Therapy Insights, 2020; 6(6), 855–863.

[214] Qu J, et al.: Chimeric antigen receptor (CAR)-T-cell therapy in non-small-cell lung cancer (NSCLC): Current status and future perspectives. Cancer Immunol Immunother 70:619–631, 2021.

[215] Fardis M, et al. Current and future directions for tumor infiltrating lymphocyte therapy for the treatment of solid tumors. Cell and Gene Therapy Insights, 2020; 6(6), 855–863.

similar to other currently available therapies and/or technologies and whether this technology meets the newness criterion.

With regard to the cost criterion, the applicant provided the following analyses to demonstrate the technology meets the cost criterion: (1) A primary cohort, (2) a cohort with a principle or admitting diagnosis of melanoma and metastasis, and (3) a cohort with any diagnosis of melanoma and metastasis. The ICD–10 codes used to identify melanoma and metastasis and MS–DRGs identified by the applicant (for the primary cohort) are listed in the following tables.

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MS-DRG Assignments for Primary Cohort	
MS-DRG	**Description**
838	Chemo w Acute Leukemia as Sdx w CC or High Dose Chemo Agent
847	Chemotherapy w/o Acute Leukemia as Secondary Diagnosis w CC
837	Chemo w Acute Leukemia as Sdx or w High Dose Chemo Agent w MCC
846	Chemotherapy w/o Acute Leukemia as Secondary Diagnosis w MCC
981	Extensive O.R. Procedure Unrelated To Principal Diagnosis w MCC
330	Major Small & Large Bowel Procedures w CC
829	Myeloproliferative Disorders or Poorly Differentiated Neoplasms w Other Procedure w CC/MCC
939	O.R. Proc w Diagnoses of Other Contact w Health Services w MCC
029	Spinal Procedures w CC or Spinal Neurostimulators
641	Misc Disorders of Nutrition, Metabolism, Fluids/Electrolytes w/o MCC
596	Major Skin Disorders w/o MCC
542	Pathological Fractures & Musculoskelet & Conn Tiss Malig w MCC
181	Respiratory Neoplasms w CC
374	Digestive Malignancy w MCC
308	Cardiac Arrhythmia & Conduction Disorders w MCC
841	Lymphoma & Non-Acute Leukemia w CC
595	Major Skin Disorders w MCC
481	Hip & Femur Procedures Except Major Joint w CC
054	Nervous System Neoplasms w MCC
393	Other Digestive System Diagnoses w MCC

Melanoma ICD-10-CM Codes	
ICD-10-CM	**Description**
C43	Malignant melanoma of skin
C43.0	Malignant melanoma of lip
C43.1	Malignant melanoma of eyelid, including canthus
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.11	Malignant melanoma of right eyelid, including canthus
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.12	Malignant melanoma of left eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.2	Malignant melanoma of ear and external auricular canal
C43.20	Malignant melanoma of unsp ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.3	Malignant melanoma of other and unspecified parts of face
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.5	Malignant melanoma of trunk
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.6	Malignant melanoma of upper limb, including shoulder
C43.60	Malignant melanoma of unsp upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.7	Malignant melanoma of lower limb, including hip
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip

Melanoma ICD-10-CM Codes	
ICD-10-CM	**Description**
C43.72	Malignant melanoma of left lower limb, including hip
C438	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
D03.0	Melanoma in situ of lip
D03.10	Melanoma in situ of unspecified eyelid, including canthus
D03.11	Melanoma in situ of right eyelid, including canthus
D03.12	Melanoma in situ of left eyelid, including canthus
D03.20	Melanoma in situ of unspecified ear and external auricular canal
D03.21	Melanoma in situ of right ear and external auricular canal
D03.22	Melanoma in situ of left ear and external auricular canal
D03.30	Melanoma in situ of unspecified part of face
D03.39	Melanoma in situ of other parts of face
D03.4	Melanoma in situ of scalp and neck
D03.51	Melanoma in situ of anal skin
D03.52	Melanoma in situ of breast (skin) (soft tissue)
D03.59	Melanoma in situ of other part of trunk
D03.60	Melanoma in situ of unspecified upper limb, including shoulder
D03.61	Melanoma in situ of right upper limb, including shoulder
D03.62	Melanoma in situ of left upper limb, including shoulder
D03.70	Melanoma in situ of unspecified lower limb, including hip
D03.71	Melanoma in situ of right lower limb, including hip
D03.72	Melanoma in situ of left lower limb, including hip
D03.8	Melanoma in situ of other sites
D03.9	Melanoma in situ, unspecified

Metastasis ICD-10-CM Codes	
ICD-10-CM	**Description**
C77	Secondary and unspecified malignant neoplasm of lymph nodes
C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck
C77.1	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes
C77.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
C77.3	Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes
C77.4	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes
C77.5	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions
C77.9	Secondary and unspecified malignant neoplasm of lymph node, unspecified
C78	Secondary malignant neoplasm of respiratory and digestive organs
C78.0	Secondary malignant neoplasm of lung
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.1	Secondary malignant neoplasm of mediastinum
C78.2	Secondary malignant neoplasm of pleura
C78.3	Secondary malignant neoplasm of other and unspecified respiratory organs
C78.30	Secondary malignant neoplasm of unspecified respiratory organ
C78.39	Secondary malignant neoplasm of other respiratory organs
C78.4	Secondary malignant neoplasm of small intestine
C78.5	Secondary malignant neoplasm of large intestine and rectum
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C78.8	Secondary malignant neoplasm of other and unspecified digestive organs
C78.80	Secondary malignant neoplasm of unspecified digestive organ
C78.89	Secondary malignant neoplasm of other digestive organs

Metastasis ICD-10-CM Codes	
ICD-10-CM	**Description**
C79	Secondary malignant neoplasm of other and unspecified sites
C79.0	Secondary malignant neoplasm of kidney and renal pelvis
C79.00	Secondary malignant neoplasm of unspecified kidney and renal pelvis
C79.01	Secondary malignant neoplasm of right kidney and renal pelvis
C79.02	Secondary malignant neoplasm of left kidney and renal pelvis
C79.1	Secondary malignant neoplasm of bladder and other and unspecified urinary organs
C79.10	Secondary malignant neoplasm of unspecified urinary organs
C79.11	Secondary malignant neoplasm of bladder
C79.19	Secondary malignant neoplasm of other urinary organs
C79.2	Secondary malignant neoplasm of skin
C79.3	Secondary malignant neoplasm of brain and cerebral meninges
C79.31	Secondary malignant neoplasm of brain
C79.32	Secondary malignant neoplasm of cerebral meninges
C79.4	Secondary malignant neoplasm of other and unspecified parts of nervous system
C79.40	Secondary malignant neoplasm of unspecified part of nervous system
C79.49	Secondary malignant neoplasm of other parts of nervous system
C79.5	Secondary malignant neoplasm of bone and bone marrow
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C79.6	Secondary malignant neoplasm of ovary
C79.60	Secondary malignant neoplasm of unspecified ovary
C79.61	Secondary malignant neoplasm of right ovary
C79.62	Secondary malignant neoplasm of left ovary
C79.7	Secondary malignant neoplasm of adrenal gland
C79.70	Secondary malignant neoplasm of unspecified adrenal gland
C79.71	Secondary malignant neoplasm of right adrenal gland
C79.72	Secondary malignant neoplasm of left adrenal gland
C79.8	Secondary malignant neoplasm of other specified sites
C79.81	Secondary malignant neoplasm of breast
C79.82	Secondary malignant neoplasm of genital organs
C79.89	Secondary malignant neoplasm of other specified sites
C79.9	Secondary malignant neoplasm of unspecified site

Interleukin-2 or Other Central or Peripheral Vein Chemotherapy ICD-10-PCS Codes	
ICD-10-PCS	**Description**
3E03002	Introduction of high-dose interleukin-2 into peripheral vein, open approach
3E03003	Introduction of low-dose interleukin-2 into peripheral vein, open approach
3E03005	Introduction of other antineoplastic into peripheral vein, open approach
3E03302	Introduction of high-dose interleukin-2 into peripheral vein, percutaneous approach
3E03303	Introduction of low-dose interleukin-2 into peripheral vein, percutaneous approach
3E03305	Introduction of other antineoplastic into peripheral vein, percutaneous approach
3E04002	Introduction of high-dose interleukin-2 into central vein, open approach
3E04003	Introduction of low-dose interleukin-2 into central vein, open approach
3E04005	Introduction of other antineoplastic into central vein, open approach
3E04302	Introduction of high-dose interleukin-2 into central vein, percutaneous approach
3E04303	Introduction of low-dose interleukin-2 into central vein, percutaneous approach
3E04305	Introduction of other antineoplastic into central vein, percutaneous approach

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To conduct the primary analysis, the applicant identified a cohort of patients that would be eligible for lifileucel that met the criteria of having any ICD–10 diagnosis of melanoma from ICD–10–CM codes C43.XXX and D03.XXX (where XXX represents all codes in the broader category) also noted in the prior tables, and any ICD–10 diagnosis of metastasis from ICD–10–CM codes C77.X, C78.XX, and C79.XX (where the X and XX represent all codes in the

broader categories respectively) and in the prior tables, and any ICD–10 procedure code indicating administration of IL–2 or other chemotherapy via central or peripheral vein from the previous tables.

The applicant used the FY 2019 MedPAR file dataset with the FY 2019 final rule with Correction Notice IPPS Impact File and the FY 2023 New Technology Thresholds to perform their cost analyses. Using the FY 2019 MedPAR file dataset, the applicant's search resulted in the identification of 20 MS–DRGs to which cases in the primary cohort mapped, as previously listed. The applicant provided two sensitivity cohorts: (1) A principal or admitting ICD–10 diagnosis of melanoma and metastasis; and (2) any ICD–10 diagnosis of melanoma and metastasis. The applicant stated that the analysis was limited to Medicare discharges from facilities paid under the IPPS by only including hospitals listed in the FY 2019 IPPS/LTCH PPS final rule IPPS Impact File. The previously discussed criteria resulted in 39 claims from 20 MS–DRGs in the primary cohort, 387 claims from 80 MS–DRGs in the sensitivity cohort 1, and 4,985 claims from 372 MS–DRGs in sensitivity cohort 2. The applicant imputed a case count of 11 for those MS–DRGs with fewer than 11 cases. For each cohort, the applicant provided two analyses, first using the national pharmacy CCR of 0.187 from the FY 2022 IPPS/LTCH PPS final rule (86 FR 44966) to calculate charges, and second using the applicant-calculated CAR T-cell CCR (0.2936) to calculate charges. The applicant first calculated a case weighted threshold of $1,256,379 for the primary, sensitivity one, and sensitivity two cohorts where the MS–DRG 018 threshold was applied for all MS–DRGs identified. We note, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44806) we finalized our proposal to assign other immunotherapies to MS–DRG 018 (for example, Introduction of lifileucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7), in addition to CAR T-cell therapies. Therefore, it seems the appropriate threshold for comparison is that of MS–DRG 018, with an average case-weighted threshold amount of $1,256,379.

For these analyses, to calculate the average charge per case, the applicant used the cases identified based on the claims data search and mapped them to the MS–DRG 018 threshold. To determine the charges for lifileucel, the applicant converted cost to charges by dividing by the national average pharmacy CCR of 0.187 from the FY 2022 IPPS/LTCH PPS final rule (86 FR 44966), and in secondary analyses, by a CAR T-cell CCR of 0.2936 calculated by the applicant. To estimate the CAR T-cell CCR, the applicant obtained the total drug charges for cases in MS–DRG 018 from the FY 2022 IPPS final rule AOR/BOR file. Next the applicant divided the total drug charges ($184,237,653.25) by the number of cases (145) to get an average drug charge per case of $1,270,605. Using the acquisition cost of YESCARTA® and KYMRIAH® ($373,000) as the cost per case, the applicant divided by the charge per case ($1,270,605) to get a CCR of 0.2936.

The applicant stated no charges were removed for the prior technology because previous treatments will continue to be reflected in cases where lifileucel is administered. Next the applicant calculated the average standardized charge per case using the FY 2019 IPPS/LTCH PPS final rule impact file. A 3-year inflation factor of 20.4686% was obtained from the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542) and applied to the average standardized charge per case.

The applicant calculated the final inflated average case-weighted standardized charge per case by adding the estimated charges for the technology to the inflated average standardized charge per case. The applicant determined a final inflated average case-weighted standardized charge per case of $2,196,319 and $1,448,803 from the primary cohort, pharmacy and CAR T-cell CCR analyses with CAR T-cell thresholds respectively, which both exceed the average case-weighted threshold amount of $1,256,379.

The applicant determined a final inflated average case-weighted standardized charge per case of $2,139,220 and $1,391,704 from the sensitivity cohort one using the pharmacy and CAR T-cell CCR analyses with CAR T-cell thresholds respectively, which both exceed the average case-weighted threshold amount of $1,256,379.

The applicant determined a final inflated average case-weighted standardized charge per case of $2,136,701 and $1,389,185 from the sensitivity cohort two using the pharmacy and CAR T-cell CCR analyses with CAR T-cell thresholds respectively, which both exceed the average case-weighted threshold amount of $1,256,379.

Because the final inflated average case-weighted standardized charge per case for all the analyses exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

As we have noted in previous discussions (86 FR 25237, 86 FR 25279), the submitted costs for CAR T-cell therapies vary widely due to differences in provider billing and charging practices for this therapy, and we are continuing to consider the use of this submitted cost data for purposes of calculating a CAR T-cell CCR for use in the applicant's cost analyses given this potential for variability. We invite public comments on whether lifileucel meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that lifileucel represents a substantial clinical improvement over existing technologies. The applicant asserted that the one-time administration of lifileucel, an autologous TIL immunotherapy, has demonstrated substantial clinical improvement compared to current therapies used to treat patients with unresectable or metastatic melanoma who have been previously treated with at least one systemic therapy; that patients with unresectable or metastatic melanoma who have failed at least one prior systemic therapy will have substantially improved ORRs compared with patients treated with currently available therapies; that responses continue to deepen over time after a single infusion of lifileucel; and that efficacy and safety data have shown lifileucel is an effective therapy for advanced melanoma patients.

The applicant asserted that when approved by FDA, lifileucel will provide a treatment option for patients with advanced melanoma who relapse on or do not tolerate treatment with immune checkpoint inhibitors and BRAF-targeted therapies and who respond poorly to a subsequent round of therapy with these agents or chemotherapy. The applicant stated metastatic melanoma is capable of rapidly metastasizing to distant organs and accounts for the majority of skin cancer-related deaths.[216] [217] According to the applicant, despite the advances in available treatments, there are currently no treatment options based on data from patients with advanced melanoma who have progressive disease after one line of immune checkpoint inhibitor therapy (for BRAF wild-type tumors), or two

[216] Luke JJ, et al. Targeted agents and immunotherapies: Optimizing outcomes in melanoma. Nature Reviews Clinical Oncology. Doi:10.1038/ncrclinonc.2017.43. Published online April 4, 2017.

[217] American Cancer Society. Cancer Facts and Figures 2020. *https://www.cancer.org/content/dam/cancerorg/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2020/cancer-facts-and-figures-2020.pdf.* Accessed April 6, 2020.

lines of therapy (for BRAF V600 mutation-positive tumors).[218] The applicant added, patients recurring with advanced melanoma after adjuvant anti-PD–1 therapy for high-risk disease represent an emerging unmet need.[219] As the applicant stated previously, patient outcomes are consistently poor for this population. Based on the C–144–01 study, the applicant concluded that treatment with lifileucel represents substantial clinical improvement over published, poor outcomes for retreatment with chemotherapy.

The applicant next stated that lifileucel significantly improves clinical outcomes compared to current therapies. In support of this assertion, the applicant provided data from two of four cohorts of the C–144–01 study, an ongoing phase 2 multicenter study (NCT02360579) to assess the efficacy and safety of autologous TIL in patients with stage IIIc-IV metastatic melanoma. Those 4 cohorts are:

- Cohort 1 (n=30 generation 1 non-cryopreserved TIL product), not included for review as part of the applicant's application for new technology add-on payments.
- Cohort 2 (n=66 generation 2 cryopreserved TIL product), included for review as part of the applicant's application for new technology add-on payments.
- Cohort 3 (a sub-sample of n=10 from cohorts 1, 2, and 4), not included for review as part of the applicant's application for new technology add-on payments.
- Cohort 4 (n=75 generation 2 cryopreserved TIL product), will be provided to FDA as part of the applicant's BLA and will be provided to CMS upon FDA approval.

The applicant stated that patients were enrolled between April 2017 and January 2019 at 26 sites.

According to the applicant, the primary objective of this study was to evaluate the efficacy of lifileucel in patients with unresectable or metastatic melanoma using the ORR, as assessed by the independent review committee (IRC) per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1.[220] The applicant added that secondary objectives were to: (1) Evaluate the efficacy endpoints of duration of response (DOR), disease control rate (DCR), and progression free survival (PFS); (2) further evaluate the efficacy of lifileucel in patients with unresectable or metastatic melanoma by assessing DOR, DCR, and PFS; (3) to evaluate overall survival (OS); and (4) to characterize the safety profile of lifileucel. For cohort 2, 60 patients were determined to allow estimation of the ORR using the maximum half width of the two-sided 95% confidence limit of less than 13.2% when ORR is expected to range from 20–50%. For cohort 4, approximately 75 patients were planned to be infused based on the null hypothesis of 10% ORR (based on historical control) which resulted in over 90% power to demonstrate superiority to this control. Patients included in this study were 18 years or older, had an ECOG (Eastern Cooperative Oncology Group) performance status of 0 or 1 upon entry, an estimated life expectancy of greater than or equal to 3 months, and had unresectable or metastatic melanoma (stage IIIC or IV) treated with at least one prior systemic therapy including an anti-PD–1 antibody and a BRAF/MEK inhibitor. Patients had at least one measurable target lesion, as defined by RECIST v1.1 (which was not used for tumor resection), and at least one resectable lesion (or aggregate of lesions resected). Patients were required to have a washout period of at least 28 days from prior anticancer therapy(ies) to the start of the planned nonmyeloablative lymphodeletion (NMA–LD) preconditioning regimen. According to the applicant, all patients were to receive the pre-treatment, pre-medication, and post-treatment as described in the discussion of the newness criterion, in combination with the infusion of lifileucel. The applicant explained that prior to the infusion of lifileucel, the patients received NMA–LD with cyclophosphamide (60 mg/kg) intravenously daily for 2 days followed by fludarabine (25 mg/m2) intravenously for 5 days to eliminate potentially suppressive immune cells which support the tumor and to maximize engraftment and potency of the lifileucel therapy through homeostatic proliferation.[221]

The applicant stated that the patients in this study had a high tumor burden at baseline and had received a mean of 3.3 lines (range, 1–9) of prior therapies. Twenty-eight patients (42%) had liver and/or brain lesions at baseline. Each prior line of therapy was defined as any concomitant therapy given to the patient even if more than one target for each treatment was involved.[222] The applicant added that 77% of patients had progressed on prior anti-CTLA–4 blockade therapy, 99% had progressed on prior anti-PD–1/PD–L1 therapy, and 88% had received BRAF/MEK inhibitors. All patients had received PD on their prior therapy before study entry.

Next, the applicant discussed the efficacy results from the C–144–01 study. The applicant stated that regardless of location of tumor resected and BRAF mutational status, and across ages (20–79 years), patients responded to lifileucel therapy. According to the applicant, at the data cutoff of April 2020 patients in cohort 2 (n=66) had an ORR of 36% (95% CI 25, 49) and a DCR of 80% (95% CI 69, 89). When considering best overall response, two patients (3%) achieved complete response (CR), 22 patients (33%) achieved partial response (PR), 29 patients (44%) achieved stable disease (SD), 9 patients (14%) had progressive disease (PD), and 4 patients (6%) were non-evaluable. The applicant highlighted that the ORR (36.5% for those less than 65 years and 35.7% for those 65 and older) and DCR (71.2% for those less than 65 years and 78.6% for those 65 and older) were consistent across age groups. The applicant contends that these results following the one-time, single infusion of lifileucel represent a substantial improvement over chemotherapy which offers poor ORR of 4%–10%.[223] [224] The applicant added that the primary-refractory subset (n=42), defined as patients who had a best overall response of progressive disease to first immune checkpoint inhibitor, had an ORR of 41% (95% CI, 26, 57) with 2 CRs (5%), 15 PRs (36%), 17 (41%) SD, and 5 (12%) having PD. The applicant asserted that this subset is important because 40%–65% of all patients with metastatic melanoma and >70% of those treated with anti–CTLA–4 therapy have disease that is primary

[218] Sarnaik A, et al. Lifileucel, a tumor-infiltrating lymphocyte therapy, in metastatic melanoma. JCO, DOI: 10.1200/JCO.21.00612, Published online May 12, 2021.

[219] Sarnaik A, et al. Lifileucel, a tumor-infiltrating lymphocyte therapy, in metastatic melanoma. JCO, DOI: 10.1200/JCO.21.00612, Published online May 12, 2021.

[220] Eisenhauer EA, et al. New response evaluation criteria in solid tumours: Revised RECIST guideline (version 1.1). European Journal of Cancer. 45 (2009) 228–247.

[221] Rosenberg, SA and Restifo, N. Adoptive cell transfer as personalized immunotherapy for human cancer, Science. 2015;348 (6230):62–68.

[222] Ghate S, et al. Patterns of treatment and BRAF testing with immune checkpoint inhibitors and targeted therapy in patients with metastatic melanoma presumed to be BRAF positive. Melanoma Res 2019;29:301–10.

[223] Larkin J, et al. Overall survival in patients with advanced melanoma who received nivolumab versus investigator's Choice chemotherapy in CheckMate 037: A randomized, controlled, open-label Phase III trial. J Clin Oncol 2018;36:383–90.

[224] Ribas A, et al. Pembrolizumab versus investigator-choice chemotherapy for ipilimumab-refractory melanoma (KEYNOTE–002): A randomised, controlled, phase 2 trial. Lancet Oncol. 2015; 16(8): 908–18.

refractory to initial immune checkpoint inhibitor therapy.[225] [226] [227] [228] [229]

Next, the applicant asserted that, because the median duration of response (DOR) had not been reached at a median follow-up of 33 months, the treatment effect will be durable and provide long-term benefit to those treated with lifileucel. The applicant added that the median time from infusion to best response was 1.4 months (1.3–8.7 months). At 18.7 months the median OS was 17.4 months (95% CI, 11.0 to not reached), with 1-year OS of 58% (95% CI, 45 to 69).[230] The applicant stated that a univariable Cox proportional hazards regression model was used to estimate hazard ratios with 95% confidence intervals between subgroups on DOR which found that for every 6-month decrease in cumulative duration of prior anti-PD–1/anti-PD–L1 therapy, the median DOR to lifileucel was nearly doubled.[231] The applicant concluded from these results that shorter duration of prior anti–PD–1 therapy maximizes DOR to lifileucel treatment and that all newly diagnosed patients should be closely monitored for progression on anti–PD–1 therapy.[232]

Lastly, the applicant stated that the safety profile of lifileucel was consistent with the underlying advanced disease and the known toxicities associated with the single course of lymphodepleting preconditioning regimen and IL–2. The applicant stated that all patients experienced at least one treatment-emergent adverse event (TEAE) during the course of the study with the most common adverse event of any grade being hematologic along with chills, pyrexia, fatigue, tachycardia, and hypotension.[233] The applicant added that the most common grade ¾ TEAEs included thrombocytopenia (89%), chills (80%), anemia (68%), pyrexia (59%), neutropenia (56%), febrile neutropenia (55%), hypophosphatemia (46%), leukopenia (42%), lymphopenia (35%), and tachycardia (35%) [234] which were consistent with the lymphodepletion regimen and known profile of IL–2.[235] [236] [237] One patient died due to intra-abdominal hemorrhage reported as possibly related to TIL and one due to acute respiratory failure assessed as not related to TIL.[238] The applicant stated that there was no difference in the incidence of TEAEs (for example any grade, among grades 3 to 4, and among grade 5) in patients 65 or older as compared to those younger than 65. The applicant asserted that this profile of the incidence of TEAEs over time, including grade ¾ TEAEs that decreased rapidly over time reaching background rate by approximately day 10 post lifileucel administration, is reflective of the potential benefit of the one-time treatment with lifileucel.

In addition to the evidence summarized previously and in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25281), the applicant submitted one article [239] and two presentations with abstracts [240] [241] in support of its claims regarding substantial clinical improvement. The published article discussed the C–144–01 trial previously summarized and provided greater detail on Cohort 2; [242] the authors described the study design, patient sample, and study endpoints for Cohort 2. In addition to previously discussed information, the authors stated that 78 patients underwent tumor resection in preparation for participation in this trial, however only 66 patients received lifileucel. The article stated that three of the patients either received a low dosage or did not receive TIL and nine patients could not be treated because of other causes; while it is not directly stated in the article it is likely that these patients were not included in the analysis. The authors added that only 25% of patients had progressed after achieving a response from lifileucel. The authors stated that the median DOR had not been reached with a 1-year DOR of 69% (95% CI, 46–84). The authors stated that 34 (52%) of patients received anti-PD–1 plus anti-CTLA–4 combination therapy, either as frontline (n=5, 23%) or after failing frontline therapy (n=9, 29%); the ORRs for these subsets were 33% and 32%, respectively. According to the authors, the ORRs for patients with primary resistance (n=17) or acquired resistance (n=11) to anti-PD–1 plus anti-CTLA–4 combination therapy were 35% and 27%, respectively. The article lastly discussed similar safety outcomes as previously discussed by the applicant.

[225] Mooradian MJ and Sullivan RJ. What to do when anti-PD–1 therapy fails in patients with melanoma. Oncology (Williston Park) 2019;33:141–8.

[226] Gide TN, et al. Primary and acquired resistance to immune checkpoint inhibitors in metastatic melanoma. Clin Cancer Res 2018;24:1260–70.

[227] Larkin J, et al. Combined nivolumab and ipilimumab or monotherapy in untreated melanoma. N Engl J Med 2015;373:23–34.

[228] Wolchok JD, et al. Overall survival with combined nivolumab and ipilimumab in advanced melanoma. N Engl J Med 377:1345–1356, 2017.

[229] Gide TN, et al. Primary and acquired resistance to immune checkpoint inhibitors in metastatic melanoma. Clin Cancer Res 2018;24:1260–70.

[230] Sarnaik A, et al. Lifileucel, a tumor-infiltrating lymphocyte therapy, in metastatic melanoma. JCO, DOI: 10. 1200/JCO.21.00612, Published online May 12, 2021.

[231] Larkin JMG, et al. Lifileucel (LN–144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced melanoma: Evaluation of impact of prior anti–PD–1 therapy. Abstract 9505, oral session; 2021 American Society of Clinical Oncology's (ASCO) Annual Meeting. Abstract 9505, oral session. JCO, DOI: 10.1200/JCO/2021.39.15_suppl.9505, JCO 39, no. 15_suppl (May 20, 2021) 9505–9505. Published online May 28, 2021.

[232] Larkin JMG, et al. Lifileucel (LN–144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced melanoma: Evaluation of impact of prior anti–PD–1 therapy. Abstract 9505, oral session; 2021 American Society of Clinical Oncology's (ASCO) Annual Meeting. Abstract 9505, oral session. JCO, DOI: 10.1200/JCO/2021.39.15_suppl.9505, JCO 39, no. 15_suppl (May 20, 2021) 9505–9505. Published online May 28, 2021.

[233] Sarnaik A, et al. Long-term follow up of lifileucel (LN–144) cryopreserved autologous tumor infiltrating lymphocyte therapy in patients with advance melanoma progressed on multiple prior therapies. Oral presentation at ASCO2020. Abstract Number: 10006; Journal: J Clin Oncol 38:2020.

[234] Sarnaik A, et al. Long-term follow up of lifileucel (LN–144) cryopreserved autologous tumor infiltrating lymphocyte therapy in patients with advance melanoma progressed on multiple prior therapies. Oral presentation at ASCO2020. Abstract Number: 10006; Journal: J Clin Oncol 38:2020.

[235] Rosenberg SA, et al. Durable complete responses in heavily pretreated patients with metastatic melanoma using Tcell transfer Immunotherapy. Clinical Cancer Research. 2011;17(13):4550–4557. doi:10.1158/1078–0432.CCR–11- 0116. 2,75,101

[236] Goff SL, et al. Randomized, prospective evaluation comparing intensity of lymphodepletion before adoptive transfer of tumor-infiltrating lymphocytes for patients with metastatic melanoma. J Clin Oncol. 2016 Jul 10;34(20):2389–97. PubMed PMID: 27217459. Pubmed Central PMCID:PMC4981979.

[237] Dudley ME, et al. Adoptive cell therapy for patients with metastatic melanoma: Evaluation of intensive myeloablative chemoradiation preparative regimens. J Clin Oncol. 2008; 26(32): 5233–5239.

[238] Sarnaik A, et al. Long-term follow up of lifileucel (LN–144) cryopreserved autologous tumor infiltrating lymphocyte therapy in patients with advance melanoma progressed on multiple prior therapies. Oral presentation at ASCO2020. Abstract Number: 10006; Journal: J Clin Oncol 38:2020.

[239] Sarnaik A, et al. Lifileucel, a tumor-infiltrating lymphocyte therapy, in metastatic melanoma. JCO, DOI: 10. 1200/JCO.21.00612, Published online May 12, 2021.

[240] Larkin JMG, et al. Lifileucel (LN–144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced melanoma: Evaluation of impact of prior anti–PD–1 therapy. Abstract 9505, oral session; 2021 American Society of Clinical Oncology's (ASCO) Annual Meeting. Abstract 9505, oral session. JCO, DOI: 10.1200/JCO/2021.39.15_suppl.9505, JCO 39, no. 15_suppl (May 20, 2021) 9505–9505. Published online May 28, 2021.

[241] Chesney JA, et al. Lifileucel (LN–144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced (unresectable or metastatic melanoma: Sustained duration of response at 28 month follow up. Oral presentation CT008; American Association for Cancer Research (AACR) Annual Meeting 2021. Oral presentation. Cancer Research, DOI: 10.1158/1538–7445.AM2021–CT008 Published July 2021.

[242] Sarnaik A, et al. Lifileucel, a tumor-infiltrating lymphocyte therapy, in metastatic melanoma. JCO, DOI: 10. 1200/JCO.21.00612, Published online May 12, 2021.

Finally, the applicant discussed presentations from the American Association for Cancer Research (AACR) 2021 annual meeting (28-month follow-up data) [243] and the 2021 American Society of Clinical Oncology (ASCO) annual meeting (33-month follow-up data).[244] The first presentation provided 28-month follow up data from the C–144–01 study of the efficacy and safety of lifileucel cohort 2.[245] Data presented is similar to the preceding presentation and article discussed previously. According to the second presentation, 81% (50/62) of patients had a reduction in tumor burden while 11 patients (17.7%) had further sum of diameters (SOD) reduction since April 2020.[246] The presentation stated that 79% of responders to lifileucel received prior ipilimumab. The presentation provides a brief case study of a patient who achieved PR at day 42 and CR at day 84. The presentation concluded that: Lifileucel resulted in a 36.4% ORR with a median DOR not reached at 33.1 months; patient responses deepened over time with continued decrease in tumor size for 11 patients (17.7%); and that early intervention with lifileucel at the time of initial progression on anti-PD–1 agents may maximize the benefit seen.

In response to concerns expressed by CMS in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25281 and 25282) about the appropriateness of the ORR as the primary outcome, the applicant stated the ORR was determined to be the appropriate primary endpoint for C–144–01 following a review of studies in patients with advanced cancers where FDA approval has been granted and in consultation with key opinion leaders in oncology. The applicant next summarized their June 17, 2021, public comment letter to CMS.[247] In their comment the applicant stated that FDA has described the significance of ORR as assessed by its magnitude and duration of effect. The comment added that ORR can represent direct clinical benefit based on the specific disease, context of use, magnitude of the effect, the number of CRs, the durability of response, the disease setting, the location of the tumors, available therapy, and the risk-benefit relationship. According to the comment, the surrogate endpoint of ORR has allowed for earlier measurement of lifileucel results and has demonstrated direct, ongoing clinical benefit for patients with metastatic melanoma with limited treatment options. Furthermore, the comment stated further evidence of ORR as an accepted and important efficacy measure for metastatic or unresectable melanoma is that it has been recognized by the National Comprehensive Cancer Network (NCCN) in the NCCN Clinical Practice Guidelines in Oncology, Melanoma: Cutaneous, Version 2.2021.[248] The comment concluded that given the limited treatment options and poor response rates for patients, lifileucel has demonstrated a favorable risk-benefit profile and represents a substantial clinical improvement for patients with metastatic melanoma who otherwise have limited treatment options.

The applicant next addressed the second concern raised by CMS in the FY 2022 PPS/LTCH PPS proposed rule in response to the FY 2022 application for new technology add-on payments, that CMS was unable to verify the appropriateness of a historical control because the evidence describing it was not provided. According to the applicant, only dacarbazine (DTIC) is an appropriate comparator for Cohort 4 as it is the only chemotherapy agent approved for the treatment of metastatic melanoma. The applicant added that other published studies provide evidence on other treatment options without prior anti-PD–1 and are not pertinent comparators for the C–144–01 study population (weighted average ORR of DTIC alone was 15.3% across 24 studies).[249] The applicant stated that a more recent study in the post-immune checkpoint inhibitor era reported ORR of 4% from the investigator's choice arm.[250] While not appropriate for direct comparison to Cohort 4, the applicant asserted that these studies do provide historical ORR information in metastatic melanoma in general and demonstrate that the ORR in these historical studies approximates the 10% ORR from the DTIC arm of the Goldinger 2018 study.[251] According to the applicant, at the End-of-Phase 2 (EOP2) meeting held in September 2018, FDA concluded that a controlled trial likely could not be concluded in the patient population of interest. The applicant stated the precedence for a 10% historical control rate in the metastatic melanoma population was established in FDA's approval of BLA 125514 for KEYTRUDA, a PD–1 indicated for the treatment of patients with unresectable or metastatic melanoma, among other oncologic indications. According to the applicant, FDA's Medical Review Summary dated August 2, 2014 stated, ''There are no historical data of the response rate of chemotherapies in patients who are refractory to ipilimumab; however, response rate of chemotherapies ranged from 5% to 10% in three recently completed Phase 3 studies (ipilimumab in 1st line melanoma patients, and trametinib and vemurafenib in patients with BRAF V600E mutation). Therefore, the applicant stated that it is reasonable to use 10% as the null hypothesis for testing the anti-tumor activity of MK–3475 against putative chemotherapies in this population.'' [252] The applicant concluded that the chemotherapy control arms of the original registration study of pembrolizumab (KEYTRUDA) and nivolumab (OPDIVO) provide further support for the 10% historical control rate for Study C–144–01. According to the applicant, these two studies provide a substantial and

[243] Chesney JA, et al. Lifileucel (LN–144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced (unresectable or metastatic melanoma: Sustained duration of response at 28 month follow up. Oral presentation CT008; American Association for Cancer Research (AACR) Annual Meeting 2021. Oral presentation. Cancer Research, DOI: 10.1158/1538–7445.AM2021–CT008 Published July 2021.

[244] Larkin JMG, et al. Lifileucel (LN–144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced melanoma: Evaluation of impact of prior anti–PD–1 therapy. Abstract 9505, oral session; 2021 American Society of Clinical Oncology's (ASCO) Annual Meeting. Abstract 9505, oral session. JCO, DOI: 10.1200/JCO/2021.39.15_suppl.9505, JCO 39, no. 15_suppl (May 20, 2021) 9505–9505. Published online May 28, 2021.

[245] Chesney JA, et al. Lifileucel (LN–144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced (unresectable or metastatic melanoma: Sustained duration of response at 28 month follow up. Oral presentation CT008; American Association for Cancer Research (AACR) Annual Meeting 2021. Oral presentation. Cancer Research, DOI: 10.1158/1538–7445.AM2021–CT008 Published July 2021.

[246] Larkin JMG, et al. Lifileucel (LN–144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced melanoma: Evaluation of impact of prior anti–PD–1 therapy. Abstract 9505, oral session; 2021 American Society of Clinical Oncology's (ASCO) Annual Meeting. Abstract 9505, oral session. JCO, DOI: 10.1200/JCO/2021.39.15_suppl.9505, JCO 39, no. 15_suppl (May 20, 2021) 9505–9505. Published online May 28, 2021.

[247] Sarnaik A. Public comment letter, CMS 1752–P. June 20, 2020. *www.regulations.gov.*

[248] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines. Melanoma: Cutaneous. V2.2021—February 19, 2021. *https://www.nccn.org.*

[249] Lui P, et al. Treatments for metastatic melanoma: Synthesis of evidence from randomized trials. Cancer treatment reviews. 2007;33(8):665–680.

[250] Ribas A, et al. Pembrolizumab versus investigator-choice chemotherapy for ipilimumab-refractory melanoma (KEYNOTE–002): A randomised, controlled, phase 2 trial. Lancet Oncol 16:908–918, 2015.

[251] Goldinger SM, et al. The utility of chemotherapy after immunotherapy failure in metastatic melanoma: A multicenter case series. J Clin Oncol 36, 2018 (suppl; abstr e21588).

[252] Center for Drug Evaluation and Research (CDER), Application #125514Orig1s000 Medical Review. (Keytruda) *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125514Orig1s000MedR.pdf.*

coherent data set for response to chemotherapy following treatment with ipilimumab, an immune checkpoint inhibitor, as well as a BRAF inhibitor, where indicated. The applicant reported that these studies had ORRs of 4% (95% CI 2,9) (n=179) [253] and 10.6% (95% CI 3.5, 23.1) (n=47).[254]

After review of the information provided by the applicant, we have the following concerns regarding the substantial clinical improvement criterion. We note that while multiple references were provided in support of substantial clinical improvement, those that evaluate lifileucel are based solely on the C–144–01 trial. We question whether there are methods by which lifileucel might be compared to existing treatments which were used to construct the historical controls in the studies provided. Similar to the discussion in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25279 through 25282) we also note that a historical control is used for all of the studies provided and that the analyses using this historical control do not account for baseline differences between the groups being compared. This makes it difficult to determine if the results seen are due to the treatment, random occurrences, or bias. We also question whether the patient sample or samples used to construct the historical control are representative of the C–144–01 cohort.

We note a low sample size in the primary reference which is used to explain the findings of C–144–01.[255] First, we note that the study enrolled 66 of 78 patients who underwent tumor resection. Given the small sample size, the 12 patients who withdrew represent a substantial proportion of the total patients evaluated and may make it even more difficult to determine whether the results of the patients remaining in the study are generalizable, especially to the Medicare patient population. We are concerned that those patients who were not included in the study may have had poorer clinical outcomes as compared to those evaluated in the study which would potentially bias the results seen in the study. Second, in regard to the sample studied, we note a median age of 55 with males represented at 59%; data on race, ethnicity, and other demographics are not presented. We question whether the sample evaluated is appropriately representative of the Medicare population and whether this sample has a disease burden similar to that seen in Medicare beneficiaries.

Next, we note that according to the applicant, high-dose IL–2 has been used to treat MM in the past and is given as a post-treatment to lifileucel. The applicant asserted that the occurrence of grade 3 and 4 TEAEs was early and consistent with the lymphodepletion regimen (NMA–LD) and known profile of IL–2. If lifileucel is always given in conjunction with the pre- and post-treatments, we question how it is possible to determine the cause of the TEAEs which are categorized as severe based on the Common Terminology Criteria for Adverse Events v4.03. We further note that we have not received any analyses which controlled for the amount of IL–2 used per patient. There did not appear to be a discussion of how the number of doses of IL–2 administered to a patient interacted with lifileucel and impacted the treatment effects (for example, CR, PR, SD), and TEAEs. We believe it is important to understand the effect of IL–2 on the response rate and these values as it may be possible for higher doses of IL–2 leading to better patient outcomes or worse TEAEs as compared to those with fewer doses of IL–2. Specifically, we question whether the effect seen in C–144–01 is due to lifileucel itself or due to other factors such as the use of IL–2, general changes in medical practice over time, and the specific sample identified for the trial at hand.

Separate from our concern about the use of a historical comparator, we note that according to the applicant, based on data from 1985 through 1993 analyzing 270 patients across 8 clinical trials, high dose IL–2 resulted in an ORR of 16% and CR of 6%, as compared to an ORR of 36% for the C–144–01 trial. However, we question whether the differences in the studies, the samples, and the time period in which the studies were conducted may account for this difference in the ORR values as opposed to the use of lifileucel itself.

We are inviting public comments on whether lifileucel meets the substantial clinical improvement criterion.

We received a comment from the applicant in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for lifileucel.

Comment: In response to CMS' question related to the level of therapeutic effect of IL–2 which is administered following the one-time, single administration of lifileucel TIL therapy, the applicant described IL–1 and discussed its approved therapeutic use. The applicant asserted that IL–2 is a naturally occurring cytokine that has been shown to drive T cell activation and effector function. The applicant added that IL–2 plays a role in the maintenance of CD4 regulatory T cells and differentiation of CD8+ T cells into mature cytotoxic cells. According to the applicant, to support T-cell activity after the lifileucel infusion, a short course of high-dose IL–2 (for example, aldesleukin) is administered in vivo at 600,000 IU/kg every 8 to 12 hours for up to 6 doses beginning 3 to 24 hours after lifileucel is infused. The applicant stated this short course of high-dose IL–2 differs substantially from the typical high-dose IL–2 antineoplastic regimens discussed previously: 79% lower dose IL–2 is instead administered to support the migration, antitumor cytotoxicity and persistence of the infused TIL, not for antineoplastic effect.

According to the applicant, the methodology of adoptive cell transfer (ACT), giving autologous ex vivo expanded TIL to nonmyeloablated lymphodepleted cancer patients followed by a short course of high-dose IL–2 was developed in 1988.[256] [257] The applicant stated that in a phase I trial which evaluated the anti-tumor effect of TIL therapy with varying IL–2 doses in 15 patients with metastatic melanoma, tumor response was not seen in patients that did not receive any IL–2 (n=6).[258] The applicant next stated that in a second study, patients who experienced an objective response received fewer doses of high-dose IL–2 as compared to non-responders.[259] According to the applicant, this might be explained by the fact that IL–2 administration

[253] Hamid O, et al. Final Analysis of a randomized trial comparing pembrolizumab versus investigator-choice chemotherapy for ipilimumab-refractory advanced melanoma. Eur J Cancer. 2017 Nov;86:37–45. Doi: 10.1016/j.ejca.2017.07.022.

[254] Weber JS, et al. Nivolumab versus chemotherapy in patients with advanced melanoma who progressed after anti-CTLA–4 treatment (Checkmate 037); a randomized, controlled, open-label, phase 3 trial. Lancet Oncol 2015: 16:375–384.

[255] Sarnaik A, et al. Lifileucel, a tumor-infiltrating lymphocyte therapy, in metastatic melanoma. JCO, DOI: 10. 1200/JCO.21.00612, Published online May 12, 2021.

[256] Rosenberg SA, Packard BS, Aebersold PM, et al. Use of Tumor-Infiltrating Lymphocytes and Interleukin-2 in the Immunotherapy of Patients with Metastatic Melanoma. A Preliminary Report. N Engl J Med. 1988; 319(25):1676–80.

[257] Topalian SL, Solomon D, Avis FP, et al. Immunotherapy of Patients with Advanced Cancer Using Tumor-Infiltrating Lymphocytes and Recombinant Interleukin-2: A Pilot Study. J Clin Oncol. 1988;6(5):839–53.

[258] Dudley ME, Wunderlich JR, Robbins PF, et al. Cancer Regression and Autoimmunity in Patients after Clonal Repopulation with Antitumor Lymphocytes. Science. 2002;298(5594):850–4.

[259] Yao, X., Ahmadzadeh, M., Lu, Y.C., Liewehr, D.J., Dudley, M.E., Liu, F., Schrump, D.S., Steinberg, S.M., Rosenberg, S.A., Robbins, P.F., 2012. Levels of peripheral CD4(þ)FoxP3(þ) regulatory T cells are negatively associated with clinical response to adoptive immunotherapy of human cancer. Blood 119, 5688e5696.

significantly increased the number of CD4+FoxP3+regulatory T-cells (Tregs) with a direct correlation between the number of IL–2 doses given and reconstitution of Treg numbers in the blood and an inverse correlation between reconstitution of the Tregs and the probability of achieving an anti-tumor response. The applicant summarized that the use of IL–2 in TIL therapy is not for antineoplastic effect, but instead for the sole purpose of creating the right cytokine environment and supporting T-cell activity after the lifileucel infusion.

Next the applicant stated that the purpose of the comment letter was to respond to CMS' question on whether a multivariate analysis had been conducted to determine the impact of independent predictors on the efficacy results of lifileucel and, specifically, if the impact of IL–2 had been analyzed in such a univariable analysis. The applicant noted that the updated analyses are proprietary until further notice. We note that we are therefore unable to discuss them in this proposed rule or consider them in support of this application.

Response: We appreciate the applicant's comments. We will take these comments into consideration when deciding whether to approve new technology add-on payments for lifileucel.

e. LIVTENCITY™ (maribavir)

Takeda Pharmaceuticals U.S.A., Inc. submitted an application for new technology add-on payments for LIVTENCITY™ (maribavir) for FY 2023. LIVTENCITY™ is a cytomegalovirus (CMV) pUL97 kinase inhibitor indicated for the treatment of adults and pediatrics (12 years of age and older and weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) to ganciclovir, valganciclovir, cidofovir, or foscarnet.

According to the applicant, LIVTENCITY™ is the only antiviral therapy indicated to treat post-transplant patients with CMV in solid organ transplant (SOT) and hematopoietic stem cell transplant (HCT). Per the applicant, LIVTENCITY™ provides multi-targeted anti-CMV activity by inhibiting protein kinase UL97 and its natural substrates, which subsequently inhibits CMV DNA replication, encapsidation, and nuclear egress of viral capsids.

The applicant stated that CMV is one of the most common viral infections experienced by transplant recipients, with an estimated incidence rate between 16%–56% in SOT recipients and 30%–70% in HCT recipients.[260] CMV is a beta herpesvirus that commonly infects humans; serologic evidence of prior infection can be found in 40%–100% of various populations.[261] CMV typically resides latent and asymptomatic in the body but may reactivate during periods of immunosuppression. The applicant estimated that there are approximately 200,000 adult transplants per year globally and an estimated 1,435 cases of CMV post-transplant in the Medicare population per year. The applicant stated that in transplant patients, reactivation of CMV can potentially lead to serious consequences including loss of the transplanted organ and, in extreme cases, death.

Per the applicant, there are four FDA-approved therapies for the treatment and/or prevention (that is, prophylaxis) of CMV disease: Valganciclovir, ganciclovir, foscarnet, and cidofovir. The applicant stated that ganciclovir and valganciclovir are approved for prevention of CMV disease in transplant recipients and for treatment of CMV retinitis in immunocompromised hosts, including those with Acquired Immune Deficiency Syndrome (AIDS); and foscarnet and cidofovir are approved for treatment of CMV retinitis in AIDS patients. Per the applicant, none of these four therapies are FDA-approved for the treatment of resistant or refractory CMV infection and disease. The applicant provided a table that included the therapy, transplant type, mechanism of action, approved indications that were CMV-related, and the formulation(s).

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[260] Azevedo L, Pierrotti L, Abdala E, et al. Cytomegalovirus infection in transplant recipients. Clinics.2015;70(7):515–523. doi:10.6061/clinics/2015(07)09; World Health Organization (WHO). International Report on Organ Donation and Transplantation Activities-Executive Summary 2018.

[261] Krech U. Complement-fixing antibodies against cytomegalovirus in different parts of the world. Bull WHO. 1973(49):103–106.

Therapies Indicated in Post-transplant Patients with CMV Infection/Disease				
Therapy	**Valganciclovir**[262]	**Ganciclovir**[263]	**Foscarnet**[264]	**Cidofovir**[265]
Transplant Type	HCT/SOT	HCT/SOT	HCT/SOT	HCT/SOT
Mechanism of Action	Inhibition of viral DNA polymerase (pUL54) activity (inhibits DNA replication)	Inhibition of viral DNA polymerase (pUL54) activity (inhibits DNA replication)	Inhibition of viral DNA polymerase (pUL54) activity (inhibits DNA replication)	Inhibition of viral DNA polymerase (pUL54) activity (inhibits DNA replication)
Approved Indications (CMV-related)	Treatment of CMV retinitis in patients with AIDS (adults) Prevention of CMV disease in kidney, heart, and kidney-pancreas post-transplant patients at high risk (adults) Prevention of CMV disease in kidney and heart transplant patients at high risk (pediatric)	Treatment of CMV retinitis in immunocompromised adult patients, including patients with AIDS Prevention of CMV disease in adult transplant recipients at risk for CMV disease	Treatment of CMV retinitis in patients with AIDS Combination treatment with ganciclovir for patients who have relapsed after monotherapy with either drug	Treatment of CMV retinitis in patients with AIDS
Formulation	Oral	Intravenous	Intravenous	Intravenous

BILLING CODE 4120–01–C

With respect to the newness criterion, the applicant stated that LIVTENCITY™ was granted Breakthrough Therapy, Priority Review, and Orphan Drug designations from FDA, and subsequently received FDA approval for its New Drug Application on November 23, 2021. LIVTENCITY™ is indicated for the treatment of adults and pediatric patients (12 years of age or older and weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir, or foscarnet. Per the applicant, LIVTENCITY™ became commercially available on December 2, 2021. The applicant did not explain the reason for the delay between market authorization and commercial availability. The recommended dosing is 400 mg (two 200 mg tablets) orally twice daily with or without food. The applicant stated that if LIVTENCITY™ is co-administered with carbamazepine, then the dosage is increased to 800 mg twice daily; if co-administered with phenytoin or phenobarbital, the dosage is increased to 1,200 mg twice daily.

According to the applicant, ICD–10–PCS code 3E0DX29 (Introduction of other anti-infective into mouth and pharynx, external approach) may be used to identify administration of LIVTENCITY™ but does not uniquely identify it. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for LIVTENCITY™ beginning in FY 2023.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments.

With respect to the first criterion, whether a technology uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant stated that LIVTENCITY™ targets a different gene locus (pUL97 vs. pUL54) than the existing therapies to treat CMV infection, including those resistant or refractory to conventional therapy. Specifically, LIVTENCITY™ inhibits CMV DNA replication, encapsidation, and nuclear egress of viral capsids

[262] VALCYTE® (valganciclovir) United States Prescribing Information (2018).

[263] CYTOVENE–IV® (ganciclovir) United States Prescribing Information (2018).

[264] FOSCAVIR® (foscarnet) United States Prescribing Information (2017).

[265] VISTIDE® (cidofovir) United States Prescribing Information (2010).

through inhibition of pUL97 and its natural substrates. The applicant provided the mechanisms of action for the other existing anti-CMV drugs, namely valganciclovir ganciclovir, foscarnet, and cidofovir in the table previously listed and concluded that the LIVTENCITY™ uses a different mechanism of action compared to existing anti-CMV drugs.

With respect to the second criterion, whether a technology is assigned to the same or a different MS–DRG when compared to an existing technology, the applicant stated that LIVTENCITY™ is expected to be assigned to the same MS–DRGs as therapies that are currently used off-label for the treatment of CMV infection or disease.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant noted that there are no other existing therapies indicated to treat the same or similar type of disease or patient population as LIVTENCITY™. The applicant noted that currently available therapies are used off-label to treat patients with refractory or resistant CMV infection or disease. Thus, the applicant maintained that LIVTENCITY™ is indicated to treat a different patient population compared to existing technologies.

In summary, the applicant asserted that LIVTENCITY™ is not substantially similar to other currently available therapies because it uses a new mechanism of action and is indicated to treat a unique patient population and/or disease and, therefore, the technology meets the newness criterion. We are inviting public comments on whether LIVTENCITY™ is substantially similar to existing technologies and whether LIVTENCITY™ meets the newness criterion. As noted previously, the applicant did not explain the reason for the delay between market authorization and commercial availability, and we therefore also request additional information regarding this point.

With respect to the cost criterion, the applicant presented the following analysis. To identify patients who may be eligible to receive LIVTENCITY™ as a treatment, the applicant searched the 2019 MedPAR dataset for cases with the following ICD–10–CM codes for CMV and post-transplant SOT and HCT infection. The applicant included inpatient discharges under Medicare fee-for-service (FFS) and excluded Medicare Advantage discharges.

BILLING CODE 4120–01–P

ICD-10-CM Code	Description
B25	Cytomegaloviral disease
B.25.0	Cytomegaloviral pneumonitis
B25.1	Cytomegaloviral hepatitis
B25.2	Cytomegaloviral pancreatitis
B25.8	Other cytomegaloviral diseases
B25.9	Cytomegaloviral diseases, unspecified
B27.10	Cytomegaloviral mononucleosis without complications
B27.11	Cytomegaloviral mononucleosis with polyneuropathy
B27.12	Cytomegaloviral mononucleosis with meningitis
B27.19	Cytomegaloviral mononucleosis with other complication
T86.03	Bone marrow transplant infection
T86.822	Skin graft infection
T86.892	Other transplanted tissue infection
T86.93	Unspecified transplant organ and tissue infection
T86.23	Heart transplant infection
T86.812	Lung transplant infection
T86.13	Kidney transplant infection
T86.43	Liver transplant infection
T86.33	Heart-lung transplant infection
T86.852	Intestine transplant infection
T86.5	Complications of stem cell transplant

BILLING CODE 4120–01–C

The applicant identified 1,435 claims mapping to 108 MS–DRGs. For MS–DRGs where the case volume was below 11, the applicant imputed a count of 11 cases. The table lists the nine MS–DRGs with the highest volume of cases.

MS-DRG	Description
699	Other Kidney and Urinary Tract Diagnoses with CC
698	Other Kidney and Urinary Tract Diagnoses with MCC
205	Other Respiratory System Diagnoses with MCC
919	Complications of Treatment with MCC
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC
206	Other Respiratory System Diagnoses without MCC
920	Complications of Treatment with CC
166	Other Respiratory System O.R. Procedures with MCC
865	Viral Illness with MCC

The applicant did not remove charges for a prior technology, as the applicant claimed that any current treatment that is used off-label to treat CMV patients post-transplant SOT and HCT may not be reflected in claims data. The applicant further explained that in cases where an off-label treatment is reflected on the claim, LIVTENCITY™ might be used as a second-line treatment rather than to replace the off-label treatment. The applicant then standardized the charges and applied a 4-year inflation factor of 1.281834 or 28.1834%, based on the inflation factor used in the FY 2022 IPPS/LTCH PPS final rule and correction notice to update the outlier threshold (86 FR 45542). The applicant added charges for the new technology by dividing the cost of LIVTENCITY™ by the national average CCR for drugs which is 0.187 (86 FR 44966). The applicant estimated the costs of LIVTENCITY™ based on 8-week dosing regimens to complete the full treatment.

The applicant calculated a final inflated average case-weighted standardized charge per case of $508,855 which exceeded the average case-weighted threshold amount of $76,739.

We invite public comments on whether LIVTENCITY™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that LIVTENCITY™ represents a new treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. To support this claim, the applicant reiterated that there are no existing therapies that are approved by FDA to treat post-transplant patients with refractory or resistant CMV infection or disease. The applicant also asserted that the use of LIVTENCITY™ may significantly improve clinical outcomes by improving efficacy and reducing adverse effects compared to available therapies.

To support the claim of improved efficacy, the applicant cited results from SOLSTICE, a phase III, open-label, randomized controlled trial in which 352 transplant recipients [HCT (n=211) and SOT (n=141)] with refractory [266] or resistant [267] CMV were assigned 2:1 to receive 400 mg of LIVTENCITY™ twice daily (n=235) or investigator-assigned therapy (IAT) with drug-specific dosing (n=117) for 8 weeks, with 12 weeks of follow-up.[268] The choice of specific IAT was at the investigators' discretion and included mono- or combination therapy (≤2 drugs) with intravenous (IV) ganciclovir, oral valganciclovir, IV foscarnet or IV cidofovir, where switching between ganciclovir and valganciclovir was permitted. The median (range) duration of exposure was 57 (2–64) days in the LIVTENCITY™ arm and 34 (4–64) days with IAT. The primary endpoint was the proportion of patients achieving CMV clearance at 8 weeks, and the key secondary endpoint was achievement of CMV clearance [269] and symptom control [270] at the end of week 8, maintained through week 16. With respect to the primary endpoint, the applicant indicated that CMV clearance at 8 weeks was achieved in 55.7% (n=131/235) of the LIVTENCITY™ group and 23.9% (n=28/117) of the IAT group with an adjusted difference of 32.8%, where the results achieved statistical significance [95% CI, 22.8–42.7%, p<0.001]. With respect to the secondary endpoint, the applicant indicated that 18.7% (n=44/235) of the LIVTENCITY™-treated group and 10.3% (n=12/117) of IAT-treated group maintained CMV viremia clearance and symptom control through week 16 (p=0.013).[271] The applicant stated that, based on these results, LIVTENCITY™ is superior to conventional antiviral therapies in achieving and maintaining CMV viremia clearance and symptom control.

The applicant also claimed that the efficacy of LIVTENCITY™ is consistent across SOT types, as evidenced by an unpublished subgroup analysis by Avery et al.[272] which evaluated 211 SOT patients from the SOLSTICE trial for CMV clearance (LIVTENCITY™ vs. conventional) by transplant type, with the following results: Heart: 42.9% (n=6/14) vs. 11.1% (n=1/9) (adjusted difference: 30.7% [95% CI, −1.72–63.15%]); lung: 47.5% (n=19/40) vs. 13.6% (n=3/22), adjusted difference: 38.2% [95% CI, 16.89–59.53%]; kidney: 59.5% (n=44/74) vs. 34.4% (n=11/32); adjusted difference: 26.7% [95% CI, 7.48–45.85%].

Finally, with regard to efficacy, the applicant stated that LIVTENCITY™ is active against refractory or resistant CMV infections and tolerable across doses. To support this claim, the applicant pointed to a randomized, dose-ranging, open-label, phase II study by Papanicolaou et al.,[273] in which HCT

[266] Failure to achieve >1 $\log_{10}$ decrease in CMV DNA after at least 14 days of anti-CMV treatment.

[267] At least 1 genetic mutation associated with resistance to ganciclovir/valganciclovir, foscarnet, and/or cidofovir.

[268] Avery RK, Alain S, Alexander B, et al. Maribavir for refractory cytomegalovirus infections with or without resistance post-transplant: Results from a phase 3 randomized clinical trial (accepted manuscript). *Clin Infect Dis.* 2021; ciab988, *https://doi.org/10.1093/cid/ciab988.*

[269] Measured as CMV DNA level less than lower limit of quantification.

[270] Resolution or improvement in tissue-invasive CMV disease or syndrome for participants symptomatic at baseline or no new symptoms of tissue-invasive CMV disease or syndrome for participants asymptomatic at baseline.

[271] Avery RK, Alain S, Alexander B, et al. Maribavir for refractory cytomegalovirus infections with or without resistance post-transplant: Results from a phase 3 randomized clinical trial (accepted manuscript). *Clin Infect Dis.* 2021; ciab988, *https://doi.org/10.1093/cid/ciab988.*

[272] Avery RK, Blumberg EA, Florescu D, et al. A randomized phase 3 open-label study of maribavir vs. investigator-assigned therapy for refractory/resistant cytomegalovirus infection in transplant recipients: Subgroup analyses of efficacy by organ. in: *The 2021 American Transplant Congress;* 2021. Abstract LB 9.

[273] Papanicolaou GA, Silveira FP, Langston AA, et al. MBV for r/r CMV infections in HCT or SOT

and SOT recipients with refractory or resistant CMV infections (n=120) were randomized 1:1:1 to twice-daily LIVTENCITY™ doses of 400 mg (n=40), 800 mg (n=40), or 1,200 mg (n=40) for up to 24 weeks. The primary efficacy endpoint was the proportion of patients with confirmed undetectable plasma CMV DNA within 6 weeks of treatment. About two-thirds (n=80/120) of the patients achieved undetectable plasma CMV DNA within 6 weeks of treatment among all doses [95% CI, 57–75%], and 70% of patients receiving 400 mg of LIVTENCITY™ twice daily [95% CI, 53–83]; 62% of patients receiving 800 mg twice daily [95% CI, 46–77%], and 68% of patients receiving 1,200 mg twice daily [95% CI, 51–81%] achieved the primary endpoint. About a third of patients experienced recurrent CMV infection while on LIVTENCITY™ (n=25) and 13 patients developed mutations conferring LIVTENCITY™ resistance.

To support the claim of decreased adverse effects, the applicant cited the results of two secondary endpoints from the SOLSTICE trial. Per the applicant, neutropenia and acute kidney injury are known, common adverse effects associated with valganciclovir/ganciclovir and foscarnet, respectively. The applicant noted that the rates of treatment-related neutropenia and acute kidney injury were both 1.7% (n=4/234), separately, in the LIVTENCITY™ treatment group. The applicant also noted that the rate of neutropenia was 25% (n=14/56) in the valganciclovir/ganciclovir group, and the rate of acute kidney injury was 19.1% (n=9/47) in the foscarnet group.[274] The applicant maintained that the rate of treatment-related neutropenia and acute kidney injury was lower in the LIVTENCITY™ group vs. conventional therapy group. The applicant asserted that, based on these results, LIVTENCITY™ has a lower incidence of treatment-related toxicities than existing therapies.

The applicant more specifically claimed that transplant patients treated with LIVTENCITY™ for CMV infection experienced a lower incidence of treatment-related neutropenia compared with valganciclovir. To support this claim, the applicant cited the primary safety endpoint from Maertens et al.,[275] a parallel-group, phase II study. In this open-label, LIVTENCITY™-blinded trial, 120 HCT or SOT recipients with CMV reactivation were randomly assigned to receive LIVTENCITY™ at a dose of 400 mg (n=40), 800 mg (n=40), or 1,200 mg (n=40) twice daily or the standard dose of valganciclovir for 12 weeks for preemptive treatment. The primary efficacy endpoint was the percentage of patients with a response to treatment, defined as confirmed undetectable CMV DNA in plasma, within 3 weeks and 6 weeks after the start of treatment. The primary safety endpoint was the incidence of adverse events that occurred or worsened during treatment. Specifically, the applicant cited the rate of treatment-emergent neutropenia in this study which was identified in 4% (n=5/118) of patients administered LIVTENCITY™ versus 15% (n=6/39) of patients administered valganciclovir through week 6. Similar results were found through week 12: 5% (n=6/118) vs. 18% (n=7/39). The statistical significance of the difference in treatment-emergent neutropenia between the two groups was not reported in the study.

Finally, the applicant stated that LIVTENCITY™ had a lower incidence of adverse events leading to discontinuation. To support this assertion, the applicant cited the rate of treatment-emergent adverse effects (TEAEs) leading to discontinuation from SOLSTICE, which was lower in the LIVTENCITY™ group (13.2% (n=31/324)) vs. the conventional group (31.9% (n=37/116)).[276]

After reviewing the information provided by the applicant, we have the following concerns regarding whether LIVTENCITY™ meets the substantial clinical improvement criterion. First, while the applicant provided data to demonstrate that the proportion of patients achieving CMV clearance at 8 weeks was higher among patients using LIVTENCITY™, we note similar rates of mortality and new-onset CMV between the 2 treatment groups in this trial: LIVTENCITY™ vs. comparator: 11% (n=27/235) vs. 6% (n=13/117) and 6% (n=14/235) vs. 6% (n=7/113), respectively.[277] We also note that it is unclear whether the SOLSTICE study was sufficiently powered to detect a difference in CMV viremia clearance at week 16, one of the study's secondary endpoints.[278] We further note that while the rate of TEAEs leading to discontinuation was lower in the LIVTENCITY™ group, the rate of overall TEAEs and serious TEAEs in the SOLSTICE trial was similar between the two treatment groups [LIVTENCITY™ vs. comparator: Any TEAE: 97.4% (n=229/234) vs. 91.4% (n=106/116), serious TEAE: 38.5% vs. 37.1%].[279] Furthermore, we would appreciate additional information from the applicant regarding safeguards taken to minimize or prevent bias from the treating physician in choosing the conventional therapy for patients in the investigator-assigned therapy group of the phase III trial.

We are inviting public comments on whether LIVTENCITY™ meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for LIVTENCITY™.

f. Mosunetuzumab

Genentech, Inc. submitted an application for new technology add-on payments for mosunetuzumab for FY 2023. According to the applicant, mosunetuzumab is an investigational drug that is anticipated to be a novel first-in class therapy for the treatment of any non-Hodgkin lymphoma (NHL). The applicant stated that it intends to seek FDA approval for the use of mosunetuzumab in adults with relapsed or refractory (r/r) follicular lymphoma (FL) who have received at least two prior systemic therapies.

According to the applicant, mosunetuzumab is a humanized bispecific monoclonal antibody (BsAb) that exhibits potential antineoplastic activity. The applicant stated that mosunetuzumab contains two antigen-recognition sites: One for human CD3 (a T cell surface antigen) and one for human CD20 (a tumor-associated antigen expressed on B cells, and often overexpressed in B cell malignancies). Per the applicant, mosunetuzumab binds to both patients' existing T cells and CD20-expressing tumor cells, linking them, which can cause a cytotoxic T-lymphocyte response against CD20-expressing tumor B cells. According to the applicant, mosunetuzumab's dual targeting design,

recipients: A randomized, dose-ranging, double-blind, phase 2 study. *Clin Infect Dis.* 2019;68(8):1255–1264. doi:10.1093/cid/ciy706.

[274] Avery RK, Alain S, Alexander B, et al. Maribavir for refractory cytomegalovirus infections with or without resistance post-transplant: Results from a phase 3 randomized clinical trial (accepted manuscript). *Clin Infect Dis.* 2021; ciab988, *https://doi.org/10.1093/cid/ciab988.*

[275] Maertens J, Cordonnier C, Jaksch P, et al. Maribavir for preemptive treatment of cytomegalovirus reactivation. *N Engl J Med.* 2019;381(12):1136–1147. doi:10.1056/NEJMoa1714656.

[276] Avery RK, Alain S, Alexander B, et al. Maribavir for refractory cytomegalovirus infections with or without resistance post-transplant: Results from a phase 3 randomized clinical trial (accepted manuscript). *Clin Infect Dis.* 2021; ciab988, *https://doi.org/10.1093/cid/ciab988.*

[277] Ibid.

[278] Ibid.

[279] Ibid.

due to two fragment antigen-binding or 'Fab' binding regions, activates and redirects engagement of a lymphoma patient's T cells to eliminate malignant B cells by releasing cytotoxic proteins into the B cells. The applicant further stated that target B cell killing occurs only upon simultaneous binding to both targets, as it is a conditional agonist. According to the applicant, clinical trials of mosunetuzumab are ongoing with different dosing regimens including subcutaneous and intravenous administration.

FL is the second most prevalent form of non-Hodgkins lymphoma (NHL), affecting approximately 16,000 individuals annually in the US.[280] According to the National Institute of Health (NIH), the rate of new cases of FL was 2.7 per 100,000 men and women per year based on 2014–2018 cases, age-adjusted.[281] According to the applicant, the vast majority of patients treated for FL will have an initial response to therapy with 40 to 80 percent demonstrating a complete response, depending on the initial regimen used. In addition, less than 10 percent of patients treated with initial chemoimmunotherapy will not respond to treatment (that is, have refractory disease).[282]

According to the applicant, FL is an indolent, incurable disease and patients are expected to have relapses. Based on a 10-year retrospective study of follicular NHL patients treated with first line (1L) therapy between 1998–2009, 50% progressed to second line (2L) therapy. Of those who completed 2L treatment, 65% progressed to third line (3L) therapy, and 65% of those patients then progressed to fourth line (4L).[283] An observational National LymphoCare Study also noted that of patients undergoing 1L, 37% progressed to 2L, 18% received 3L, and 9% and 5% went on to 4L and 5L, respectively.[284] The applicant stated that multiply relapsed FL has a high unmet medical need especially in patients who are relapsed or refractory to different classes of agents and have limited treatment options with challenging safety profiles. Therefore, per the applicant, novel treatments with improved efficacy and tolerability are needed.

The applicant stated that the NCCN provides suggested treatment regimens for existing agents in FL. According to the applicant, choice of therapy requires consideration of several factors, including age and comorbidities, as well as refractory status to prior therapies. However, per the applicant, there is no established standard of care for FL in third-line or later (3L+) settings. The applicant stated that the currently FDA approved treatments for r/r FL include anti-CD20-based treatment regimens (including the combination of lenalidomide + rituximab known as the R2 regimen), phosphatidylinositol 3-kinase (PI3K) inhibitors, enhancer of zeste homolog 2 (EZH2) inhibitors, and CAR T-cell therapy.

According to the applicant, chemoimmunotherapy with anti-CD20 monoclonal antibodies (mAb) approved for FL includes rituximab, a Type I antibody, and obinutuzumab, a Type II antibody.[285] The applicant stated that while the anti-CD20 antibodies are NCCN Guidelines Preferred treatments for 2L and subsequent therapy, they are not considered the most beneficial treatment for 3L+ FL; most patients are treated with rituximab-based therapies in the early lines (1L and 2L) of treatment, which the applicant stated leads to decreasing duration of response (DOR) and increasing refractoriness to therapies in the later lines of treatment. The applicant further asserted that the predominantly elderly FL population, together with the fact that many patients have typically been through multiple rounds of therapy, limits their ability to tolerate anti-CD20 mAb plus chemotherapy-based regimens.

According to the applicant, since anti-CD20 mAbs alone or with chemotherapy are not curative, show decreasing efficacy with repeated administrations, and because chemotherapy-based regimens are associated with long-term toxic effects, leading to limited tolerability especially for the elderly population, different targets were sought in the treatment of r/r FL.[286] Per the applicant, the FDA has granted accelerated approval for idelalisib[287] [288] copanlisib,[289] and duvelisib[290] as single agent inhibitors of PI3K delta, alpha/delta, and delta/gamma isoforms, respectively, for the treatment of patients with r/r FL who have received ≥2 prior therapies. More recently, the dual PI3K delta and casein kinase 1 epsilon inhibitor umbralisib[291] gained accelerated approval for treatment of patients with r/r FL who have received at least three prior lines of systemic therapy. The applicant asserted that balancing tumor target inhibition with dose-limiting toxicities has presented a challenge for PI3K inhibitors, and that although these PI3K inhibitors have shown efficacy, they have also been associated with significant toxicities. The applicant further stated that these treatments provide important options to physicians and patients, but their side-by-side evaluation for FL in cross-trial comparisons is challenging due to variability in patient selection and treatments. The applicant noted that both duvelisib and idelalisib have recently been voluntarily withdrawn from the US market for the treatment of FL.[292] [293]

[280] Shi Q, Flowers CR, Hiddemann W, Marcus R, Herold M, Hagenbeek A, Kimby E, Hochster H, Vitolo U, Peterson BA, Gyan E, Ghielmini M, Nielsen T, De Bedout S, Fu T, Valente N, Fowler NH, Hoster E, Ladetto M, Morschhauser F, Zucca E, Salles G, Sargent DJ. Thirty-Month Complete Response as a Surrogate End Point in First-Line Follicular Lymphoma Therapy: An Individual Patient-Level Analysis of Multiple Randomized Trials. J Clin Oncol. 2017 Feb 10;35(5):552–560. doi: 10.1200/JCO.2016.70.8651.

[281] *https://seer.cancer.gov/statfacts/html/nhl.html.*

[282] Freedman, A.S., Friedberg, Jonathan, et.al. (2022). Treatment of relapsed or refractory follicular lymphoma. UpToDate. Retrieved February 7, 2022, from *https://www.uptodate.com/contents/treatment-of-relapsed-or-refractory-follicular-lymphoma?search=relapsed%20refractory%20follicular%20lymphoma&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.*

[283] Hubel K, Ghielmini M, Ladetto M, Gopal A. Controversies in the Treatment of Follicular Lymphoma. HemaSphere. 2020;4(1): e317. doi:10.1097/HS9.0000000000000317.

[284] Link et al. Br. J. Haematol. 2019;184:634–696 *https://doi.org/10.1111/bjh.15149.*

[285] Salles GA, Morschhauser F, Solal-Ce´ligny P, et al. obinutuzumab (GA101) in patients with relapsed/refractory indolent non-Hodgkin lymphoma: Results from the phase II GAUGUIN study. J. Clin. Oncol. 2013;31(23):2920–2926. doi:10.1200/JCO.2012.46.9718.

[286] Bachy E, Houot R, Morschhauser F, et al. Long-term follow up of the FL2000 study comparing CHVP-interferon to CHVP-interferon plus rituximab in follicular lymphoma. Haematologica. 2013;98(7):1107–1114. doi:10.3324/haematol.2012.082412.

[287] Gopal AK, Kahl BS, de Vos S, et al. PI3Kδ inhibition by idelalisib in patients with relapsed indolent lymphoma. N. Engl. J. Med. 2014;370:1008–1018. doi:10.1056/NEJMoa1314583.

[288] Salles G, Schuster SJ, de Vos S, et al. Efficacy and safety of idelalisib in patients with relapsed, rituximab-and alkylating agent-refractory follicular lymphoma: A subgroup analysis of a phase 2 study. Haematologica. 2017;102:156–159. doi:10.3324/haematol.2016.151738.

[289] Dreyling M, Santoro A, Mollica L, et al. Phosphatidylinositol 3-kinase inhibition by copanlisib in relapsed or refractory indolent lymphoma. J. Clin. Oncol. 2017;35:3898–3905. doi:10.1200/JCO.2017.75.4648.

[290] Flinn IW, Miller CB, Ardeshna KM, et al. DYNAMO: A phase II study of duvelisib (IPI–145) in patients with refractory indolent non-Hodgkin lymphoma. J. Clin. Oncol. 2019;37(11):912–922. doi:10.1200/JCO.18.00915. Erratum in: J. Clin. Oncol. 2019;37(16):1448. doi:10.1200/JCO.19.00976.

[291] Fowler NH, Samaniego F, Jurczak W, et al. umbralisib, a dual PI3Kδ/CK1ε inhibitor in patients with relapsed or refractory indolent lymphoma. J. Clin. Oncol. 2021;39:1609–1618. doi:10.1200/JCO.20.03433,

[292] Gilead statement on zydelig® U.S. indication for follicular lymphoma and small lymphocytic leukemia. *https://www.gilead.com/news-and-press/company-statements/gilead-statement-on-zydelig-us-indication-for-follicular-lymphoma-and-small-lymphocytic-leukemia.* Accessed January 25, 2022.

According to the applicant, a newer therapeutic approach to treat FL includes EZH2 inhibitor therapy, a catalytic subunit of the chromatin remodeling Polycomb Repressive Complex 2 (PRC2).[294] According to the applicant, the FDA granted accelerated approval to tazemetostat,[295] a first-in-class EZH2 inhibitor for patients with r/r FL who received ≥2 prior therapies whose tumors are positive for an EZH2 mutation, and for patients with r/r FL who have no satisfactory alternative treatment options. The applicant stated that EZH2 exhibits somatic, gain-of-function activating mutations in 7–29% of FL patients.[296] [297] [298] EZH2 mutations represent an early event in FL, and in the majority of cases are maintained throughout disease transformation. The applicant further stated that considering the high overall incidence of EZH2 mutations in FL, their stability during disease progression, and that EZH2 selective inhibitors can be made, it follows that efforts would be placed on developing FL therapies targeting the inhibition of EZH2.

The applicant stated that recent developments have supported the effectiveness of therapies that utilize T cells in the treatment of B-cell malignancies, such as the ex vivo manipulation of T lymphocytes to express chimeric antigen receptors (CARs) that target lineage-specific surface molecules such as CD19.[299] According to the applicant, axicabtagene ciloleucel (YESCARTA®) was the second approved gene-altering cancer treatment, first-in-class for aggressive lymphoma, and was approved by FDA based on clinical study results [300] for the treatment of patients with r/r FL who have received ≥2 prior therapies. The applicant asserted that while offering strong efficacy, CAR T-cell therapy has significant limitations as it adds complexities in manufacturing and treatment which the applicant states negatively impact patient access significantly. The applicant stated that CAR T-cell therapy requires mandatory hospitalization and is only available at one of only approximately 100 authorized treatment centers (ATCs) across the United States,[301] adding cost and travel burdens on patients, particularly older patients who may be on limited incomes and have difficulty traveling long distances. Per the applicant, CAR T-cell therapy also raises risks for serious toxicities and prominent side effects like neurotoxicity and cytokine release syndrome (CRS).[302]

The applicant stated that for these reasons, there is a high unmet need for patients with r/r FL who have received ≥2 prior therapies, particularly for patients who are refractory to different classes of agents and are left with limited treatment options that may have challenging safety profiles. Per the applicant, new treatment options are needed that will significantly extend the duration of remission and can overcome resistance to existing therapies, while providing acceptable safety and tolerability.

With respect to the newness criterion, the applicant stated that mosunetuzumab was granted Breakthrough Therapy designation by FDA. The applicant indicated that it expects to receive FDA approval by June 30, 2022 and stated that the final review pathway has yet to be determined. Additionally, the applicant stated they may be limited in their ability to make mosunetuzumab available immediately following FDA approval and pointed to printing and labeling requirements as the reason. Per the applicant, while the drug has not yet been FDA-approved, the recommended dosage is presented in the following table.

Day of Treatment		Dosage of Mosunetuzumab	Rate of Infusion
Cycle 1	Day 1	1 mg	Administer over a minimum of 4 hours
	Day 8	2 mg	
	Day 15	60 mg	
Cycle 2	Day 1	60 mg	Administer over 2 hours if infusions from cycle 1 were well-tolerated
Cycles 3+	Day 1	30 mg	

The applicant described a dose escalation for mosunetuzumab to be administered intravenously for eight cycles unless there is unacceptable toxicity or disease progression. For patients who achieve a complete response (CR), no further treatment beyond eight cycles is required. For patients who achieve a partial response

[293] Inc SB. Secura bio announces copiktra® (Duvelisib) strategic focus on t-cell lymphoma and voluntary U.S. withdrawal of the relapsed or refractory follicular lymphoma indication. *https://www.prnewswire.com/news-releases/secura-bio-announces-copiktra-duvelisib-strategic-focus-on-t-cell-lymphoma-and-voluntary-us-withdrawal-of-the-relapsed-or-refractory-follicular-lymphoma-indication-301436834.html.* Accessed January 25, 2022.

[294] Morin RD, Johnson NA, Severson TM, et al. Somatic mutations altering EZH2 (Tyr641) in follicular and diffuse large B-cell lymphomas of germinal-center origin. Nat. Genet. 2010;42:181–185. doi: 10.1038/ng.518

[295] Morschhauser F, Tilly H, Chaidos A, et al. tazemetostat for patients with relapsed or refractory follicular lymphoma: An open-label, single-arm, multicentre, phase 2 trial. Lancet Oncol. 2020;21:1433–1442. doi:10.1016/S1470–2045(20)30441–1.

[296] Morin RD, Johnson NA, Severson TM, et al. Somatic mutations altering EZH2 (Tyr641) in follicular and diffuse large B-cell lymphomas of germinal-center origin. Nat. Genet. 2010;42:181–185. doi: 10.1038/ng.518.

[297] Bödör C, Grossmann V, Popov N, et al. EZH2 mutations are frequent and represent an early event in follicular lymphoma. Blood. 2013;122:3165–3168. doi:10.1182/blood-2013–04–496893.

[298] Huet S, Xerri L, Tesson B, et al. EZH2 alterations in follicular lymphoma: Biological and clinical correlations. Blood Cancer J. 2017;7:e555. doi:10.1038/bcj.2017.32.

[299] Viardot A, Wais V, Sala E, et al. Chimeric antigen receptor (CAR) T-cell therapy as a treatment option for patients with B-cell lymphomas: Perspectives on the therapeutic potential of axicabtagene ciloleucel. Cancer Manag. Res. 2019;11:2393–2404. doi:10.2147/CMAR.S163225.

[300] Jacobson C, Chavez JC, Sehgal AR, et al. Primary analysis of zuma-5: A phase 2 study of axicabtagene ciloleucel (axi-cel) in patients with relapsed/refractory (r/r) indolent non-hodgkin lymphoma (iNHL). Blood. 2020;136 (Supplement 1):40–41. doi:10.1182/blood-2020–136834.

[301] Yescarta® (axicabtagene ciloleucel) Authorized Treatment Centers. YESCARTA HCP website, 10 Sept. 2021, *https://www.yescartahcp.com/large-b-cell-lymphoma/authorized-treatment-centers.*

[302] Jacobson C, Chavez JC, Sehgal AR, et al. Primary analysis of zuma-5: A phase 2 study of axicabtagene ciloleucel (axi-cel) in patients with relapsed/refractory (r/r) indolent non-hodgkin lymphoma (iNHL). Blood. 2020;136(Supplement 1):40–41. doi:10.1182/blood-2020–136834.

(PR) or have stable disease control in response to treatment with mosunetuzumab after eight cycles, an additional nine cycles of treatment (17 cycles total) should be administered. Additionally, if there is any dose delay >7 days in cycle 1, the previous tolerated dose should be repeated prior to resuming the planned treatment schedule. If a dose interruption occurs between cycles 1 and 2 that results in a treatment-free interval of ≥6 weeks, mosunetuzumab is recommended to be administered as 1 mg on day 1 and 2 mg on day 8, and then the planned cycle 2 treatment of 60 mg is resumed on day 15. If a dose interruption occurs that results in a treatment-free interval of ≥6 weeks between any cycles in cycle 3 onwards, mosunetuzumab is to be administered at 1 mg on day 1 and 2 mg on day 8, and then the planned treatment schedule of 30 mg is resumed on day 15.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify procedures involving administration of mosunetuzumab. The applicant submitted a request for approval for a unique ICD–10–PCS code to identify procedures involving the administration of mosunetuzumab for FY 2023. The applicant also listed the following diagnosis codes that could be used to identify the indications associated with the technology:

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ICD-10-CM	Description
C82.00	FL grade I, unspecified site
C82.01	FL grade I, lymph nodes of head, face, and neck
C82.02	FL grade I, intrathoracic lymph nodes
C82.03	FL grade I, intra-abdominal lymph nodes
C82.04	FL grade I, lymph nodes of axilla and upper limb
C82.05	FL grade I, lymph nodes of inguinal region and lower limb
C82.06	FL grade I, intrapelvic lymph nodes
C82.07	FL grade I, spleen
C82.08	FL grade I, lymph nodes of multiple sites
C82.09	FL grade I, extranodal and solid organ sites
C82.10	FL grade II, unspecified site
C82.11	FL grade II, lymph nodes of head, face, and neck
C82.12	FL grade II, lymph nodes of head, face, and neck
C82.13	FL grade II, intra-abdominal lymph nodes
C82.14	FL grade II, lymph nodes of axilla and upper limb
C82.15	FL grade II, lymph nodes of inguinal region and lower limb

ICD-10-CM	Description
C82.16	FL grade II, intrapelvic lymph nodes
C82.17	FL grade II, spleen
C82.18	FL grade II, lymph nodes of multiple sites
C82.19	FL grade II, extranodal and solid organ sites
C82.20	FL grade III, unspecified, unspecified site
C82.21	FL grade III, unspecified, lymph nodes of head, face, and neck
C82.22	FL grade III, unspecified, intrathoracic lymph nodes
C82.23	FL grade III, unspecified, intra-abdominal lymph nodes
C82.24	FL grade III, unspecified, lymph nodes of axilla and upper limb
C82.25	FL grade III, unspecified, lymph nodes of inguinal region and lower limb
C82.26	FL grade III, unspecified, intrapelvic lymph nodes
C82.27	FL grade III, unspecified, spleen
C82.28	FL grade III, unspecified, lymph nodes of multiple sites
C82.29	FL grade III, unspecified, extranodal and solid organ sites
C82.30	FL grade IIIa, unspecified site
C82.31	FL grade IIIa, lymph nodes of head, face, and neck
C82.32	FL grade IIIa, intrathoracic lymph nodes
C82.33	FL grade IIIa, intra-abdominal lymph nodes
C82.34	FL grade IIIa, lymph nodes of axilla and upper limb
C82.35	FL grade IIIa, lymph nodes of inguinal region and lower limb
C82.36	FL grade IIIa, intrapelvic lymph nodes
C82.37	FL grade IIIa, spleen
C82.38	FL grade IIIa, lymph nodes of multiple sites
C82.39	FL grade IIIa, extranodal and solid organ sites
C82.40	FL grade IIIb, unspecified site
C82.41	FL grade IIIb, lymph nodes of head, face, and neck
C82.42	FL grade IIIb, intrathoracic lymph nodes
C82.43	FL grade IIIb, intra-abdominal lymph nodes
C82.44	FL grade IIIb, lymph nodes of axilla and upper limb
C82.45	FL grade IIIb, lymph nodes of inguinal region and lower limb
C82.46	FL grade IIIb, intrapelvic lymph nodes
C82.47	FL grade IIIb, spleen
C82.48	FL grade IIIb, lymph nodes of multiple sites
C82.49	FL grade IIIb, extranodal and solid organ sites
C82.80	Other types of FL, unspecified site
C82.81	Other types of FL, lymph nodes of head, face, and neck
C82.82	Other types of FL, intrathoracic lymph nodes
C82.83	Other types of FL, intra-abdominal lymph nodes
C82.84	Other types of FL, lymph nodes of axilla and upper limb
C82.85	Other types of FL, lymph nodes of inguinal region and lower limb
C82.86	Other types of FL, intrapelvic lymph nodes
C82.87	Other types of FL, spleen
C82.88	Other types of FL, lymph nodes of multiple sites
C82.89	Other types of FL, extranodal and solid organ sites
C82.90	FL, unspecified, unspecified site
C82.91	FL, unspecified, lymph nodes of head, face, and neck

ICD-10-CM	Description
C82.92	FL, unspecified, intrathoracic lymph nodes
C82.93	FL, unspecified, intra-abdominal lymph nodes
C82.94	FL, unspecified, lymph nodes of axilla and upper limb
C82.95	FL, unspecified, lymph nodes of inguinal region and lower limb
C82.96	FL, unspecified, intrapelvic lymph nodes
C82.97	FL, unspecified, spleen
C82.98	FL, unspecified, lymph nodes of multiple sites
C82.99	FL, unspecified, extranodal and solid organ sites

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As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant stated that mosunetuzumab does not use the same or a similar mechanism of action when compared to other therapies approved in the treatment of 3L+ r/r FL. The applicant stated that mosunetuzumab is a bispecific CD20xCD3 monoclonal antibody. The applicant asserted that mosunetuzumab has a mechanism of action that is unique and different from that of existing technologies used to treat FL. The applicant asserted that mosunetuzumab is a novel, full-length, humanized, IgG1 bispecific antibody that concomitantly binds CD3 on T-cells and CD20 on malignant B-cells. Importantly, according to the applicant, 98–100% of FL cases are positive for CD20.[303] [304] Per the applicant, crosslinking leads to T-cell activation, which redirects T-cells to engage and eliminate malignant B-cells. The applicant stated that an amino acid substitution in the Fc region of mosunetuzumab results in a non-glycosylated heavy chain with minimal binding to Fc-γ receptors, significantly reducing Fc effector functions.

The applicant provided a summary of the currently available treatments, their respective mechanisms of action and FDA approval dates in the following table:

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[303] Ray S, Craig FE, Swerdlow SH. Abnormal patterns of antigenic expression in follicular lymphoma: A flow cytometric study. Am. J. Clin. Pathol. 2005;124(4):576–583. doi:10.1309/2GFKU23XA1DH38L7.

[304] Liu Q, Weaver LS, Liewehr D, Venzon D, Stetler-Stevenson M, Yuan CM. Increased expression of CD20 and CD45 and diminished expression of CD19 are features of follicular lymphoma. PLMI. 2013;5:21–30. doi:10.2147/PLMI.S43597.

Non-Proprietary Technology Name	Class	Mechanism of Action	FDA Approval Date for r/r FL
rituximab	Anti-CD20 mAb	Chimeric anti-CD20 antibody that induces B-cell destruction through three proposed mechanisms: antibody-dependent cellular cytotoxicity (ADCC), complement-dependent cytotoxicity (CDC), and classical apoptosis.	November 26, 1997
obinutuzumab	Anti-CD20 mAb	Mediates B-cell lysis through engagement of immune effector cells, direct activation of intracellular death signaling pathways, and/or activation of the complement cascade.	February 26, 2016
idelalisib	PI3K inhibitor	Inhibitor of PI3Kδ kinase, expressed in normal and malignant B cells; inhibits several cell-signaling pathways, including B-cell receptor (BCR) signaling and the CXCR4 and CXCR5 signaling, which are involved in trafficking and homing of B-cells to the lymph nodes and bone marrow.	July 23, 2014
copanlisib	PI3K inhibitor	Inhibitor of PI3K with inhibitory activity predominantly against PI3K-α and PI3K-δ isoforms expressed in malignant B cells; inhibits several key cell-signaling pathways, including BCR signaling, CXCR12 mediated chemotaxis of malignant B cells, and NFκB signaling in lymphoma cell lines.	September 14, 2017
duvelisib	PI3K inhibitor	Inhibitor of PI3K with inhibitory activity predominantly against PI3K-δ and PI3K-γ isoforms expressed in normal and malignant B-cells; inhibits several key cell-signaling pathways, including BCR signaling and CXCR12-mediated chemotaxis of malignant B-cells; inhibits CXCL12-induced T cell migration and M-CSF and IL-4 driven M2 polarization of macrophages.	September 24, 2018
umbralisib (4L+ only	PI3K inhibitor	Inhibitor of PI3Kδ and casein kinase CK1ε. Inhibitor of a mutated form of ABL1 in biochemical assays; inhibits cell proliferation, CXCL12-mediated cell adhesion, and CCL19-mediated cell migration in lymphoma cell lines in studies conducted in vitro.	February 5, 2021

Non-Proprietary Technology Name	Class	Mechanism of Action	FDA Approval Date for r/r FL
tazemetostat	EZH2 inhibitor	Inhibitor of the methyltransferase, EZH2, and some EZH2 gain-of-function mutations including Y646X and A687V.	June 18, 2020
axicabtagene ciloleucel	Gene therapy	CD19-directed, genetically modified, autologous T cell immunotherapy.	March 5, 2021

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The applicant stated that regimens using monospecific, anti-CD20 antibodies, including lenalidomide + rituximab (R2), are approved for r/r FL, but data for R2 was derived from less pre-treated and refractory patients. According to the applicant, rituximab alone, or anti-CD20 mAbs combined with chemotherapy, are critical mainstay therapies used in earlier lines of FL, but patients become refractory or have short DOR to them as they go through relapses. According to the applicant, PI3K inhibitors, EZH2 inhibitors, and CAR T-cell therapies all have different mechanisms of action when compared to mosunetuzumab.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that with the exception of CAR T-cell therapies, which are assigned to a separate MS–DRG (MS–DRG 018 Chimeric Antigen Receptor (CAR) T-cell Immunotherapy and Other Immunotherapies), mosunetuzumab may be assigned to the same MS–DRG as existing technologies. The applicant stated that with respect to PI3K inhibitors, however, they are often provided in outpatient care and it is unlikely that they would be used in inpatient care such that they would be wrapped into an existing MS–DRG. The applicant stated that although mosunetuzumab might be assigned to the same MS–DRG as existing technologies, this does not mean that mosunetuzumab is not new. The applicant stated that the MS–DRG payment system cannot differentiate between patients with r/r FL who could be grouped to MS–DRGs included in the MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms). The applicant stated they have not requested new or different MS–DRGs for mosunetuzumab for FY 2023. According to the applicant, procedures involving the use of mosunetuzumab are expected to map to the following MS–DRGs:

MS-DRG	Description
823	Lymphoma and Non-Acute Leukemia with Other Procedures with MCC
824	Lymphoma and Non-Acute Leukemia with Other Procedures with CC
825	Lymphoma and Non-Acute Leukemia with Other Procedures without CC/MCC
840	Lymphoma and Non-Acute Leukemia with MCC
841	Lymphoma and Non-Acute Leukemia with CC

The applicant further noted that MDC 17 includes ICD–10 CM diagnosis codes that are not specific to FL and that for patients diagnosed with FL, according to the applicant, the current MS–DRG payment system does not factor in whether the patient has received previous treatment.[305] As a result, according to the applicant, mosunetuzumab and an existing technology used to treat r/r FL could be assigned to any of the aforementioned MS–DRGs. The applicant asserted that the assignment of mosunetuzumab to the same MS–DRGs mentioned previously is a result of the lack of specificity in the current MS–DRG system with respect to its classification of lymphomas rather than because mosunetuzumab is not new.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated that mosunetuzumab will not involve the treatment of the same type of disease and the same or similar patient population when compared to existing technologies. The applicant asserted that mosunetuzumab would treat FL 3+ line patients for whom there is no current standard of care. The applicant asserted that in the U.S., there are no therapies with full FDA approval for the specific indication of r/r FL patients who have received 2 or more prior systemic therapies.[306] [307] [308] [309] [310] The applicant further stated that available options used in practice are primarily composed of approved therapies in earlier lines,

[305] MDC 17 Myeloproliferative Diseases & Disorders, Poorly Differentiated Neoplasm. In: ICD–10–CM/PCS MS–DRGv37.2 Definitions Manual. Centers for Medicare & Medicaid Services. *https://www.cms.gov/icd10m/version372-fullcode-cms/fullcode_cms/P0309.html.* Accessed September 09, 2021.

[306] Freedman, A, Jacobsen, E. Follicular lymphoma: 2020 update on diagnosis and management. Am. J. Hematol. 2020; 95:316–327.doi:10.1002/ajh.25696.

[307] Luminari S, Trotman J, Federico M. Advances in Treatment of Follicular Lymphoma. Cancer J. 2020; 26(3):231–240 doi:10.1097/PPO.0000000000000444.

[308] Carbone A, Roulland S, Gloghini A, et al. Follicular lymphoma. Nat. Rev. Dis. Primers. 2019;(5):83. doi:10.1038/s41572–019–0132–x.

[309] Batlevi CL, Sha F, Alperovich A, et al. Follicular lymphoma in the modern era: survival, treatment outcomes, and identification of high-risk subgroups. Blood Cancer J. 2020;10:74. doi:10.1038/s41408–020–00340–z.

[310] Matasar MJ, Luminari S, Barr PM, et al. Follicular Lymphoma: Recent and Emerging Therapies, Treatment Strategies, and Remaining Unmet Needs. The Oncol. 2019;24:e1236–e1250. doi:10.1634/theoncologist.2019–0138.

including anti-CD20 monoclonal antibody plus chemotherapy or lenalidomide, or therapies under accelerated approval including pathway inhibitors and cellular therapies.[311] According to the applicant, each of these options presents several limitations for the treatment of multiple relapsed FL, particularly for patients who are relapsed or refractory to different classes of agents.[312] [313] [314] [315] [316]

In summary, the applicant asserted that mosunetuzumab is new because it does not use the same or a similar mechanism of action compared to other technologies currently available to Medicare beneficiaries to treat FL, and that upon FDA approval, mosunetuzumab would treat FL in 3L+ settings, for which there is no established standard of care. According to the applicant, all existing options have limitations that emphasize the need for a better solution.

We note that the applicant asserted that use of mosunetuzumab will not involve the treatment of the same or similar type of disease and the same or similar patient population when compared to existing technologies. The applicant asserted that mosunetuzumab would treat FL in 3L+ settings, for which there is no established standard of care and that there are no therapies with full FDA approval for the specific indication of r/r FL patients who have received 2 or more prior systemic therapies. We note that FL in 3L+ settings is not a new population because there are FDA approved therapies indicated in the treatment of patients with r/r FL after two or more lines of systemic therapy. We also note that CAR T-cell therapies, such as Yescarta®, are FDA approved therapies. We believe that mosunetuzumab would be used for the same disease and patient population when compared to other therapies approved to treat FL in 3L+ settings. We are inviting public comments on whether mosunetuzumab is substantially similar to existing technologies and whether mosunetuzumab meets the newness criterion.

With respect to the cost criterion, the applicant presented the following analyses to demonstrate that mosunetuzumab meets the cost criterion across four different cohorts. For each cohort, the applicant searched the FY 2019 MedPAR database for cases representing patients who may be eligible for mosunetuzumab. To identify cases for patients with a diagnosis of FL, the applicant searched for claims with ICD–10–CM diagnosis codes C82.00–C82.99. Per the applicant, because a potential patient would need to fail an established prior therapy and not be engaged in active treatment, the applicant then removed cases with the following ICD–10–CM diagnosis codes to exclude cases for patients still actively in the bone marrow transplant process for all four cohorts:

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ICD-10-CM	Description
T86.0	Complications of bone marrow transplant
T86.00	Unspecified complication of bone marrow transplant
T86.03	Bone marrow transplant infection
T86.09	Other complications of bone marrow transplant
T86.5	Complications of stem cell transplant

Per the applicant, as mosunetuzumab would not be administered concomitant to an allogenic bone marrow transplant or CAR T-cell therapy, the applicant also excluded cases with the following ICD–10–PCS procedure codes related to allogenic bone marrow transplants or CAR T-cell therapy for all four cohorts.

[311] National Comprehensive Cancer Network B-cell Lymphomas (version 5 2021) *https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf.* Accessed Oct 27, 2021 [i] National Comprehensive Cancer Network. B-Cell Lymphomas (Version 5.2021). *https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf.* Accessed Oct 27, 2021.

[312] Freedman, A, Jacobsen, E. Follicular lymphoma: 2020 update on diagnosis and management. Am. J. Hematol. 2020; 95:316–327.doi:10.1002/ajh.25696.

[313] Luminari S, Trotman J, Federico M. Advances in Treatment of Follicular Lymphoma. Cancer J. 2020; 26(3):231–240. doi:10.1097/PPO.0000000000000444.

[314] Carbone A, Roulland S, Gloghini A, et al. Follicular lymphoma. Nat. Rev. Dis. Primers. 2019;(5):83. doi:10.1038/s41572–019–0132–x.

[315] Batlevi CL, Sha F, Alperovich A, et al. Follicular lymphoma in the modern era: Survival, treatment outcomes, and identification of high-risk subgroups. Blood Cancer J. 2020;10:74. doi:10.1038/s41408–020–00340–z.

[316] Matasar MJ, Luminari S, Barr PM, et al. Follicular Lymphoma: Recent and Emerging Therapies, Treatment Strategies, and Remaining Unmet Needs. The Oncol. 2019;24:e1236–e1250. doi:10.1634/theoncologist.2019–0138.

ICD-10-PCS	Description
30230G2	Transfusion of allogeneic related bone marrow into peripheral vein, open approach
30230G3	Transfusion of allogeneic unrelated bone marrow into peripheral vein, open approach
30230G4	Transfusion of allogeneic unspecified bone marrow into peripheral vein, open approach
30233G2	Transfusion of allogeneic related bone marrow into peripheral vein, percutaneous approach
30233G3	Transfusion of allogeneic unrelated bone marrow into peripheral vein, percutaneous approach
30233G4	Transfusion of allogeneic unspecified bone marrow into peripheral vein, percutaneous approach
30240G2	Transfusion of allogeneic related bone marrow into central vein, open approach
30240G3	Transfusion of allogeneic unrelated bone marrow into central vein, open approach
30240G4	Transfusion of allogeneic unspecified bone marrow into central vein, open approach
30243G2	Transfusion of allogeneic related bone marrow into central vein, percutaneous approach
30243G3	Transfusion of allogeneic unrelated bone marrow into central vein, percutaneous approach
30243G4	Transfusion of allogeneic unspecified bone marrow into central vein, percutaneous approach
30230Y2	Transfusion of allogeneic related hematopoietic stem cells into peripheral vein, open approach
30230Y3	Transfusion of allogeneic unrelated hematopoietic stem cells into peripheral vein, open approach
30230Y4	Transfusion of allogeneic unspecified hematopoietic stem cells into peripheral vein, open approach
30233Y2	Transfusion of allogeneic related hematopoietic stem cells into peripheral vein, percutaneous approach
30233Y3	Transfusion of allogeneic unrelated hematopoietic stem cells into peripheral vein, percutaneous approach
30233Y4	Transfusion of allogeneic unspecified hematopoietic stem cells into peripheral vein, percutaneous approach
30240Y2	Transfusion of allogeneic related hematopoietic stem cells into central vein, open approach
30240Y3	Transfusion of allogeneic unrelated hematopoietic stem cells into central vein, open approach
30240Y4	Transfusion of allogeneic unspecified hematopoietic stem cells into central vein, open approach
30243Y2	Transfusion of allogeneic related hematopoietic stem cells into central vein, percutaneous approach
30243Y3	Transfusion of allogeneic unrelated hematopoietic stem cells into central vein, percutaneous approach
30243Y4	Transfusion of allogeneic unspecified hematopoietic stem cells into central vein, percutaneous approach
30230U2	Transfusion of allogeneic related T-cell depleted hematopoietic stem cells into peripheral vein, open approach
30230U3	Transfusion of allogeneic unrelated T-cell depleted hematopoietic stem cells into peripheral vein, open approach
30230U4	Transfusion of allogeneic unspecified T-cell depleted hematopoietic stem cells into peripheral vein, open approach
30233U2	Transfusion of allogeneic related T-cell depleted hematopoietic stem cells into peripheral vein, percutaneous approach
30233U3	Transfusion of allogeneic unrelated T-cell depleted hematopoietic stem cells into peripheral vein, percutaneous approach
30233U4	Transfusion of allogeneic unspecified T-cell depleted hematopoietic stem cells into peripheral vein, percutaneous approach
30240U2	Transfusion of allogeneic related T-cell depleted hematopoietic stem cells into central vein, open approach
30240U3	Transfusion of allogeneic unrelated T-cell depleted hematopoietic stem cells into central vein, open approach
30240U4	Transfusion of allogeneic unspecified T-cell depleted hematopoietic stem cells into central vein, open approach

Per the applicant, as mosunetuzumab is being evaluated as a monotherapy for 3L+ r/r FL, cases with at least one ICD–10–PCS procedure code related to chemotherapy administration were removed in Cohort 1 and Cohort 2. Cases with these ICD–10–PCS procedure codes related to chemotherapy administration were maintained in Cohort 3 and Cohort 4. Per the applicant, as the exclusion criteria for one portion of one clinical trial excluded grade IIIb FL patients, cases with at least one ICD–10–CM diagnosis code associated with grade IIIb FL were removed in Cohort 2 and Cohort 4. Cases with these ICD–10–CM diagnosis codes associated with grade IIIb FL were maintained in Cohort 1 and Cohort 3.

Cohort	Cohort Description	Number of MS-DRGs	Number of Cases
1	ALL Follicular Lymphoma Diagnosis Codes and No Chemotherapy Administration Codes	11	9,790
2	ALL Follicular Lymphoma Diagnosis Codes Excluding IIIb and No Chemotherapy Administration Codes	10	9,526
3	ALL Follicular Lymphoma Diagnosis Codes Including Chemotherapy Administration Codes	13	11,330
4	ALL Follicular Lymphoma Diagnosis Codes Excluding IIIb Including Chemotherapy Administration Codes	12	11,055

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Per the applicant, the top five MS–DRGs covering the greatest case volume in each of the four cohorts were 840 (Lymphoma and Non-Acute Leukemia with MCC), 841 (Lymphoma and Non-Acute Leukemia with CC), 824 (Lymphoma and Non-Acute Leukemia with Other Procedure with CC), 823 (Lymphoma and Non-Acute Leukemia with Other Procedure with MCC), and 825 (Lymphoma and Non-Acute Leukemia with Other Procedure without CC/MCC).

The applicant did not remove charges for prior technology. The applicant stated that the predominate prior technologies identified were associated with pain and inflammation relief or contrast agents for radiology, and patients receiving mosunetuzumab may also benefit from the use of these technologies. The applicant standardized the charges across all four cohorts using the FY 2019 IPPS/LTCH PPS final rule and Correction Notice Impact File, and conducted separate analyses on each cohort using both the three-year inflation factor (rounded to 20.5%) and four-year inflation factor (rounded to 28.2%) based on the inflation factor from the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542) to calculate outlier threshold charges. The applicant stated that it did not add any charges for the new technology.

In the first analysis (Cohort 1), the applicant computed a final inflated average case-weighted standardized charge per case of $85,452 using the three-year inflation factor, and $90,912 using the four-year inflation factor, both of which exceeded the average case-weighted threshold amount of $80,433.

In the second analysis (Cohort 2), the applicant computed a final inflated average case-weighted standardized charge per case of $84,849 using the three-year inflation factor, and $90,271 using the four-year inflation factor, both of which exceeded the average case-weighted threshold amount of $80,008.

In the third analysis (Cohort 3), the applicant computed a final inflated average case-weighted standardized charge per case of $103,236 using the three-year inflation factor, and $109,833 using the four-year inflation factor, both of which exceeded the average case-weighted threshold amount of $82,688.

In the fourth analysis (Cohort 4), the applicant computed a final inflated average case-weighted standardized charge per case of $102,520 using the three-year inflation factor, and $109,071 using the four-year inflation factor, both of which exceeded the average case-weighted threshold amount of $82,325.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount under all analyses without the addition of any costs related to the new technology, the applicant asserted that the technology meets the cost criterion.

Based on the information provided by the applicant, we have the following concerns regarding the cost criterion. We note that the applicant did not specify the list of ICD–10–PCS procedure codes noted in its analysis related to chemotherapy administration used for exclusion of cases. Separately, while the applicant provided ICD–10–CM diagnosis codes listed previously, the applicant did not specifically list out which diagnoses were used to exclude grade IIIb FL from Cohort 2 and Cohort 4. We invite public comments on whether mosunetuzumab meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that mosunetuzumab represents a substantial clinical improvement over existing technologies because—(1) mosunetuzumab offers a treatment option for patients with r/r FL who are relapsed or refractory to different classes of agents and are left with limited treatment options; and (2) mosunetuzumab significantly improves clinical outcomes relative to previously available therapies, demonstrating high overall and CR rates, high DOR, deep durable responses, and safety.

According to the applicant, mosunetuzumab demonstrates robust efficacy and complete response rates in the context of the r/r FL after two or more prior lines of therapy, a disease setting with high unmet medical need for which novel treatments are needed. According to the applicant, mosunetuzumab also demonstrates complete response (CR) and overall response rates (ORR) approaching those observed with CAR T-cell therapy. The applicant asserted that mosunetuzumab demonstrates efficacy for those who have had prior systemic therapies, including an anti-CD20 (aCD20) antibody, alkylator, PI3K inhibitor, immunomodulatory drug (IMiD), and/or CAR T-cell therapy, as well ≥2 prior therapies, and that the therapy also shows antitumor response for those having prior autologous stem cell transplant (ASCT). According to the applicant, mosunetuzumab demonstrates efficacy for those who are refractory to their last prior therapy, refractory to any prior aCD20, or double refractory to any prior aCD20 therapy + alkylator therapy. The applicant further stated that mosunetuzumab shows responses for FL patients who experience progression of disease within 2 years of initial chemoimmunotherapy.

To support the assertion that mosunetuzumab offers a treatment option for patients who are relapsed or refractory to different classes of agents and are left with limited treatment options, the applicant described an abstract and presentation from Budde, et al. of an open-label, uncontrolled pivotal Phase II trial of 90 patients with r/r FL (Grade 1 to 3a) and >2 prior therapies that were treated with mosunetuzumab.[317] [318] The median age of enrolled patients was 60 years (range 29 to 90), and these patients had a median of 3 prior therapies (range 2–10). Mosunetuzumab doses started with 1 mg on days 1 and 8, stepping up dosing to mitigate CRS. On day 15 of the first 21-day cycle, 60 mg was administered. In the second cycle, 60 mg was administered, but on subsequent cycles, the day 1 dose was 30 mg. This could be repeated up to 17 cycles, depending upon whether a patient had a CR, a PR, or stable disease. The response was assessed both by the investigators and by an independent reviewer. The investigators noted that there was no mandatory hospitalization for administration of mosunetuzumab.[319] The authors noted that the CR rate assessed by PET/CT was 60% (n=54; CI 49%, 70%) as compared to a historical control of 14% CR rate

[317] Budde LE, et al. Mosunetuzumab Monotherapy is an Effective and Well-Tolerated Treatment Option for Patients with Relapsed/Refractory (r/r) Follicular Lymphoma (FL) who have Received ≥2 Prior Lines of Therapy: Pivotal Results from a Phase I/II Study. Oral Presentation at the 63rd ASH Annual Meeting and Exposition. 2021.

[318] Budde E, et al. ASH Abstract 2021. Mosunetuzumab Monotherapy Is an Effective and Well-Tolerated Treatment Option for Patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL) Who Have Received ≥2 Prior Lines of Therapy: Pivotal Results from a Phase I/II Study. *https://ash.confex.com/ash/2021/webprogram/Paper145872.html.*

[319] Budde LE, et al. Mosunetuzumab Monotherapy is an Effective and Well-Tolerated Treatment Option for Patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL) who have Received ≥2 Prior Lines of Therapy: Pivotal Results from a Phase I/II Study. ASH Presentation. 2021.

(from a 2017 article on copanlisib [320]). The ORR was 80% (n=72). The median DOR in complete responders was 22.8 months (CI 18.7, NE) and the same for all responders (CI 9.7, NE). The median progression free survival (PFS) was 17.9 months (CI 10.1, NE).

To support the assertion that monsunetuzumab is efficacious in high-risk subgroups and in patients with prior systemic therapies, the applicant pointed to a CR of 74% and ORR of 85% among patients who have had 2 prior therapies (n=34), and a CR of 52% and ORR of 77% among patients who have had >3 prior therapies (n=56).[321] According to the applicant, mosunetuzumab demonstrated responses for FL patients who experience progression of disease within 2 years of initial chemoimmunotherapy (POD24) (N=47, CR =57% and ORR = 85%) and those who were not POD24 (N=43, CR = 63%,ORR=74%). The applicant also asserted that mosunetuzumab demonstrated efficacy for patients who are refractory to their last prior therapy (N=62, CR =52% and ORR = 77%) and those who were not refractory (N=28, CR =79% and ORR= 86%). The applicant asserted that mosunetuzumab demonstrated efficacy for patients who are double refractory to any prior aCD20 therapy + alkylator therapy (N=48, CR =50% and ORR =71%) and those who were not double refractory to any prior aCD20 therapy + alkylator therapy (N=42, CR = 71% and ORR =71%). Lastly, the applicant asserted that mosunetuzumab demonstrated efficacy for elderly patients (≤ 65 years) (N=30, CR of 70% and ORR = 87%).

To support the assertion that mosunetuzumab offers a manageable safety profile with fewer discontinuations or treatment-ending toxicities when compared to PI3K inhibitors, as well as a low rate of CRS and neurotoxicity when compared to CAR T-cell therapies, the applicant again cited data from the Budde et al. pivotal Phase II trial, in which 83 patients had mosunetuzumab-related adverse events. The most common were CRS, fatigue, pyrexia, pruritus, neutropenia, hypophosphatemia, and headache. None of the mosunetuzumab-related adverse events were fatal; however, 30 were described as serious and 2 led to the discontinuation of mosunetuzumab. The applicant also cited the Budde et al. article to support features of access to treatment, wide availability, off-the-shelf therapy, potential for administration without mandatory hospitalization, fixed treatment duration, and no requirement of lymphodepleting chemotherapy. The applicant asserted that mosunetuzumab will be immediately available for patients and avoids the ex-vivo T-cell manipulation and the resulting delay in treatment that may be prohibitive in patients with rapidly progressing disease.

According to the applicant, while the therapies used in the treatment of r/r FL have not been tested in a head-to-head trial, when looking at the independent results in the treatment of patients with r/r FL after ≥2 prior systemic therapies, the CR rate and ORR achieved by mosunetuzumab (N=90, CR=60% and ORR=80%) are greater than those for the PI3K and EZH2 inhibitors (N=72, CR=6% and ORR=54%) and are approaching the response rates observed with CAR T-cell therapy (N=84, CR= 80% and ORR =94%).[322] The applicant states, compared to the CAR T-cell therapy axicabtagene ciloleucel, CRS events reported for mosunetuzumab were less frequent and less severe, and that the management of CRS in patients treated with mosunetuzumab enabled more than 95% of affected patients to continue therapy and potentially benefit from its efficacy.[323]

According to the applicant, compared to axicabtagene ciloleucel, which the applicant asserts is only available at authorized treatment centers, mosunetuzumab may potentially be available in community clinics and hospital-based outpatient departments (HOPDs) with the potential for AEs that can be treated at local hospitals. Therefore, according to the applicant, mosunetuzumab is not expected to present significant barriers for widespread implementation of emerging cellular therapies such as CAR T-cell. In addition, the applicant stated that since mosunetuzumab may potentially be administered in a local community setting with no mandatory hospitalization, those unable to travel may still obtain treatment. The applicant states mosunetuzumab is an immediately available, off-the-shelf therapy, enabling critically ill patients with urgent need of treatment access to the drug without delay administered as a fixed treatment duration regimen.

To support the claim that mosunetuzumab improves clinical outcomes, the applicant cited data from the Budde et al. pivotal Phase II trial of mosunetuzumab. The applicant stated that mosunetuzumab showed a complete response (CR) of 60% [324] as compared to 14% for historical control,[325] 1.2% for duvelisib,[326] 6% for P13k,[327] 20.2% for copanlisib,[328] 5.1% for umbralisib,[329] and 6% for idelalisib.[330]

[320] Dreyling M, et al. Phosphatidylinositol 3-kinase inhibition by copanlisib in relapsed or refractory indolent lymphoma. J. Clin. Oncol. 2017; 35:3898–3905.

[321] Budde LE, et al. Mosunetuzumab Monotherapy is an Effective and Well-Tolerated Treatment Option for Patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL) who have Received ≥2 Prior Lines of Therapy: Pivotal Results from a Phase I/II Study. ASH Presentation. 2021.

[322] Jacobson C, Chavez JC, Sehgal AR, et al. Primary analysis of zuma-5: A phase 2 study of axicabtagene ciloleucel (axi-cel) in patients with relapsed/refractory (R/R) indolent non-hodgkin lymphoma (iNHL). Blood. 2020; 136(Supplement 1):40–41. doi:10.1182/blood–2020–136834.

[323] Budde LE, et al. Mosunetuzumab Monotherapy is an Effective and Well-Tolerated Treatment Option for Patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL) who have Received ≥2 Prior Lines of Therapy: Pivotal Results from a Phase I/II Study. ASH Presentation. 2021.

[324] Budde LE, et al. Mosunetuzumab Monotherapy is an Effective and Well-Tolerated Treatment Option for Patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL) who have Received ≥2 Prior Lines of Therapy: Pivotal Results from a Phase I/II Study. ASH Presentation. 2021.

[325] Dreyling M, et al. Phosphatidylinositol 3-kinase inhibition by copanlisib in relapsed or refractory indolent lymphoma. J. Clin. Oncol. 2017; 35:3898–3905.

[326] Flinn IW, Miller CB, Ardeshna KM, et al. DYNAMO: A Phase II Study of Duvelisib (IPI–145) in Patients With Refractory Indolent Non-Hodgkin Lymphoma [published correction appears in J Clin Oncol. 2019 Jun 1;37(16):1448]. J Clin Oncol. 2019; 37(11):912–922. doi:10.1200/JCO.18.00915.

[327] Gopal AK, Kahl BS, de Vos S, et al. PI3Kδ inhibition by idelalisib in patients with relapsed indolent lymphoma. N Engl J Med. 2014; 370(11):1008–1018. doi:10.1056/NEJMoa1314583.

[328] Dreyling M, Santoro A, Mollica L, et al. Long-term safety and efficacy of the PI3K inhibitor copanlisib in patients with relapsed or refractory indolent lymphoma: 2-year follow-up of the CHRONOS–1 study. Am J Hematol. 2020; 95(4):362–371. doi:10.1002/ajh.25711.

[329] Fowler NH, Samaniego F, Jurczak W, et al. Umbralisib, a Dual PI3Kδ/CK1ε Inhibitor in Patients With Relapsed or Refractory Indolent Lymphoma. J Clin Oncol. 2021; 39(15):1609–1618. doi:10.1200/JCO.20.03433.

[330] Gopal AK, Kahl BS, de Vos S, et al. PI3Kδ inhibition by idelalisib in patients with relapsed indolent lymphoma. N Engl J Med. 2014; 370(11):1008–1018. doi:10.1056/NEJMoa1314583.

The applicant stated that mosunetuzumab showed an ORR of 80% [331] as compared to 42.2% for duvelisib,[332] 54% for P13k,[333] 58.7% for copanlisib,[334] 45.3% for umbralisib,[335] and 54.0% for idelalisib.[336] The applicant stated that mosunetuzumab showed an mDOR of 22.8 months [337] as compared to 10.0 months for duvelisib,[338] 12.5 months for P13k,[339] 14.1 months for copanlisib,[340] 11.1 months for umbralisib,[341] and 12.5 months for idelalisib.[342] According to the applicant, while the mDOR for mosunetuzumab is still maturing, the estimate of patients who remain in remission at 12 months compares favorably with mDORs ranging from 10–13 months for therapies under accelerated approval to treat patients with r/r FL after ≥2 prior systemic therapies.

According to the applicant, the overall safety profile of mosunetuzumab appears manageable with no unexpected safety signals, considering the advanced nature of the disease and the heavily pretreated patient population under study. The applicant asserted that the tolerability of mosunetuzumab is evident by the lack of mandatory hospitalization, the low proportion of patients who discontinue mosunetuzumab due to AEs, and the ability to adequately manage and resolve AEs. As an example, the applicant states, CRS events, as the most common AE, were generally low-grade (Gr 1 or 2), mostly confined to cycle 1, manageable, and resolved after a median duration of three days.[343] According to the applicant, dose interruptions generally do not prevent patients continuing to receive their planned mosunetuzumab dose for most of the duration of treatment.

To support the claim that mosunetuzumab improves clinical outcomes related to safety, the applicant asserted that mosunetuzumab has a manageable safety profile with grade 3/4 AEs at 51.1%, SAEs at 33.3% and no grade 5 (fatal) AEs.[344] According to the applicant, mosunetuzumab had fewer discontinuations of treatment at 4.4% as compared to idelalisib at 20.0%,[345] copanlisib at 21.1%,[346] duvelisib at 31.0%,[347] umbralisib at 14.9% [348] and EZH2 inhibitors at 8.0%.[349] According to the applicant, mosunetuzumab has a lower rate of CRS and severe neurotoxicity in comparison to CAR T-cell therapy as evidenced by a CRS adverse event rate of any grade at 44.0% compared to 99% for axicabtagene ciloleucel.[350] [351]

The applicant summarized that fixed-duration mosunetuzumab monotherapy results in high response rates and durable disease control with a tolerable safety profile in heavily pretreated, multiply relapsed patients with FL, including known high-risk subgroups. According to the applicant, mosunetuzumab offers a new treatment option with a novel mechanism of action and demonstrates clinically meaningful advantages over available therapies for the treatment of patients with r/r FL who have received ≥2 prior therapies, a patient population with a high unmet medical need for which novel treatments are needed. The applicant asserted that the benefit-risk assessment of mosunetuzumab is considered to be positive based on the high unmet need in this disease setting and the compelling results from the Budde et.al. study compared to available therapies, in particular the complete response rates and durable remissions observed with current study follow-up. The applicant asserted that mosunetuzumab demonstrates high clinical efficacy and tolerability in 3L+ r/r FL and is a substantial clinical improvement. According to the applicant it is the first T-cell-engaging bispecific antibody to demonstrate clinically meaningful outcomes for patients with r/r FL who have received ≥2 prior lines of therapy in the pivotal Phase II setting, and offers potentially promising off-the-shelf, outpatient therapy.

After review of the information provided by the applicant, we have the following concerns regarding whether

[331] Budde LE, et al. Mosunetuzumab Monotherapy is an Effective and Well-Tolerated Treatment Option for Patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL) who have Received ≥2 Prior Lines of Therapy: Pivotal Results from a Phase I/II Study. ASH Presentation. 2021.

[332] Flinn IW, Miller CB, Ardeshna KM, et al. DYNAMO: A Phase II Study of Duvelisib (IPI–145) in Patients With Refractory Indolent Non-Hodgkin Lymphoma [published correction appears in J Clin Oncol. 2019 Jun 1;37(16):1448]. J Clin Oncol. 2019; 37(11):912–922. doi:10.1200/JCO.18.00915.

[333] Gopal AK, Kahl BS, de Vos S, et al. PI3Kδ inhibition by idelalisib in patients with relapsed indolent lymphoma. N Engl J Med. 2014; 370(11):1008–1018. doi:10.1056/NEJMoa1314583.

[334] Dreyling M, Santoro A, Mollica L, et al. Long-term safety and efficacy of the PI3K inhibitor copanlisib in patients with relapsed or refractory indolent lymphoma: 2-year follow-up of the CHRONOS–1 study. Am J Hematol. 2020; 95(4):362–371. doi:10.1002/ajh.25711.

[335] Fowler NH, Samaniego F, Jurczak W, et al. Umbralisib, a Dual PI3Kδ/CK1ε Inhibitor in Patients With Relapsed or Refractory Indolent Lymphoma. J Clin Oncol. 2021; 39(15):1609–1618. doi:10.1200/JCO.20.03433.

[336] Gopal AK, Kahl BS, de Vos S, et al. PI3Kδ inhibition by idelalisib in patients with relapsed indolent lymphoma. N Engl J Med. 2014; 370(11):1008–1018. doi:10.1056/NEJMoa1314583.

[337] Budde LE, et al. Mosunetuzumab Monotherapy is an Effective and Well-Tolerated Treatment Option for Patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL) who have Received ≥2 Prior Lines of Therapy: Pivotal Results from a Phase I/II Study. ASH Presentation. 2021.

[338] Flinn IW, Miller CB, Ardeshna KM, et al. DYNAMO: A Phase II Study of Duvelisib (IPI–145) in Patients with Refractory Indolent Non-Hodgkin Lymphoma [published correction appears in J Clin Oncol. 2019 Jun 1;37(16):1448]. J Clin Oncol. 2019; 37(11):912–922. doi:10.1200/JCO.18.00915.

[339] Gopal AK, Kahl BS, de Vos S, et al. PI3Kδ inhibition by idelalisib in patients with relapsed indolent lymphoma. N Engl J Med. 2014; 370(11):1008–1018. doi:10.1056/NEJMoa1314583.

[340] Dreyling M, Santoro A, Mollica L, et al. Long-term safety and efficacy of the PI3K inhibitor copanlisib in patients with relapsed or refractory indolent lymphoma: 2-year follow-up of the CHRONOS–1 study. Am J Hematol. 2020; 95(4):362–371. doi:10.1002/ajh.25711.

[341] Fowler NH, Samaniego F, Jurczak W, et al. Umbralisib, a Dual PI3Kδ/CK1ε Inhibitor in Patients With Relapsed or Refractory Indolent Lymphoma. J Clin Oncol. 2021; 39(15):1609–1618. doi:10.1200/JCO.20.03433.

[342] Gopal AK, Kahl BS, de Vos S, et al. PI3Kδ inhibition by idelalisib in patients with relapsed indolent lymphoma. N Engl J Med. 2014; 370(11):1008–1018. doi:10.1056/NEJMoa1314583.

[343] Budde LE, et al. Mosunetuzumab Monotherapy is an Effective and Well-Tolerated Treatment Option for Patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL) who have Received ≥2 Prior Lines of Therapy: Pivotal Results from a Phase I/II Study. ASH Presentation. 2021.

[344] Budde LE, et al. Mosunetuzumab Monotherapy is an Effective and Well-Tolerated Treatment Option for Patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL) who have Received ≥2 Prior Lines of Therapy: Pivotal Results from a Phase I/II Study. ASH Presentation. 2021.

[345] Gopal AK, Kahl BS, de Vos S, et al. PI3Kδ inhibition by idelalisib in patients with relapsed indolent lymphoma. *N Engl J Med.* 2014; 370(11):1008–1018. doi:10.1056/NEJMoa1314583.

[346] Dreyling M, Santoro A, Mollica L, et al. Long-Term Efficacy and Safety from the Copanlisib CHRONOS–1 Study in Patients with Relapsed or Refractory Indolent B-Cell Lymphoma. *Blood.* 2018; 132:1595. doi:10.1182/blood–2018–99–114842.

[347] Flinn IW, Miller CB, Ardeshna KM, et al. DYNAMO: A Phase II Study of Duvelisib (IPI–145) in Patients with Refractory Indolent Non-Hodgkin Lymphoma [published correction appears in J Clin Oncol. 2019 Jun 1;37(16):1448]. J Clin Oncol. 2019; 37(11):912–922. doi:10.1200/JCO.18.00915.

[348] Fowler NH, Samaniego F, Jurczak W, et al. Umbralisib, a Dual PI3Kδ/CK1ε Inhibitor in Patients with Relapsed or Refractory Indolent Lymphoma. J Clin Oncol. 2021; 39(15):1609–1618. doi:10.1200/JCO.20.03433.

[349] Morschhauser F, Tilly H, Chaidos A, et al. Tazemetostat for patients with relapsed or refractory follicular lymphoma: An open-label, single-arm, multicentre, phase 2 trial. Lancet Oncol. 2020; 21(11):1433–1442. doi:10.1016/S1470–2045(20)30441–1.

[350] Budde LE, et al. Mosunetuzumab Monotherapy is an Effective and Well-Tolerated Treatment Option for Patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL) who have Received ≥2 Prior Lines of Therapy: Pivotal Results from a Phase I/II Study. *ASH Presentation.* 2021.

[351] Jacobson C, Chavez JC, Sehgal AR, et al. Primary analysis of zuma-5: A phase 2 study of axicabtagene ciloleucel (axi-cel) in patients with relapsed/refractory (R/R) indolent non-hodgkin lymphoma (iNHL). *Blood.* 2020; 136(Supplement 1):40–41. doi:10.1182/blood–2020–136834.

mosunetuzumab meets the substantial clinical improvement criterion. We note that the applicant provided the abstract for one single-arm, phase II trial of 90 patients to support all of its claims of substantial clinical improvement. The applicant compared outcomes of the phase II trial with mosunetuzumab to outcomes, including CR and ORR, from background studies of other technologies. However, we note limitations in comparing to rates found in other clinical trials that were conducted in earlier time periods and under different circumstances of patient enrollment and treatment options. Additionally, the historical rates were compared directly to those from mosunetuzumab, without more detailed adjustment for patient characteristics. As an example, the applicant compared rates of AEs to NHL patients in trials for idelalisib, copanlisib, and duvelisib. In those studies, FL subtype data was not available for direct comparison and we are concerned that there may be potential for selection bias. Without a direct comparison of outcomes between these therapies, we are concerned as to whether the differences in outcomes such as CR, ORR, mDOR, AEs and treatment discontinuation identified by the applicant translate to clinically meaningful differences or improvements for patients treated with mosunetuzumab as compared to historical rates for other treatments. In addition, durability of response is still maturing per the applicant, and we would appreciate additional information regarding treatment durability when available. We note that the applicant stated that mosunetuzumab has a lower rate of CRS and severe neurotoxicity in comparison to CAR T-cell therapy as evidenced by a CRS adverse event rate of any grade at 44.0% compared to 99% for axicabtagene ciloleucel. However, the study provided by the applicant to support this claim, Jacobson et.al., referenced an any-grade AE rate of 99% for axicabtagene ciloleucel and did not include a value for any-grade CRS for axicabtagene ciloleucel. We would appreciate further clarification of this claim. Lastly, while we understand that there may be potential benefits related to mosunetuzumab potentially being available in community clinics and HOPDs, we question if the benefits are related only to the outpatient administration of the medication and whether they would demonstrate improved clinical outcomes that represent a substantial clinical improvement in the inpatient setting.

We are inviting public comments on whether mosunetuzumab meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for mosunetuzumab.

g. Narsoplimab

The Omeros Corporation submitted an application for new technology add-on payments for narsoplimab for FY 2023. Narsoplimab is a fully human monoclonal antibody for the treatment of hematopoietic stem cell transplantation-associated thrombotic microangiopathy (HSCT–TMA), also known as transplant-associated thrombotic microangiopathy (TA–TMA).

According to the applicant, narsoplimab inhibits mannan-binding lectin serine protease 2 (MASP–2), the effector enzyme of the lectin pathway of the complement system, and activation of the lectin pathway that prevents complement-mediated inflammation and exhibits anticoagulant effects while leaving intact the respective functions of the classical and alternative pathways of innate immunity. According to the applicant, there are currently no FDA-approved products indicated for the treatment of HSCT–TMA. We note that the Omeros Corporation previously submitted an application for new technology add-on payments for narsoplimab for FY 2022, as summarized in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25282 through 25286), that it withdrew prior to the issuance of the FY 2022 IPPS/LTCH PPS final rule (86 FR 44979).

According to the applicant, HSCT–TMA is a lethal complication of hematopoietic stem cell transplantation (HSCT) that results in thrombosis in the small blood vessels, leading to organ failure.[352] [353] [354] According to the applicant, clinical guidelines for the treatment of HSCT–TMA are being developed by members of the American Society for Transplant and Cellular Therapy (ASTCT) and are expected to be published in 2021. The applicant stated that current management of HSCT–TMA includes modification or cessation of any immune-suppressive regimen, appropriate treatment of infections and/or graft-versus-host disease (GvHD) if present, aggressive control of hypertension, and other supportive therapy as deemed appropriate by the treating physician.[355] However, according to the applicant, the withdrawal of immunosuppressive therapies and ongoing monitoring for resolution of TMA symptoms has been determined to be ineffective.[356] The applicant stated that there are multiple off-label treatments for HSCT–TMA which have either not been reviewed by FDA or have been reviewed and not deemed adequate for registration purposes; these unapproved treatments include therapeutic plasma exchange (TPE), eculizumab, defibrotide sodium, rituximab, and vincristine sulfate. The applicant asserted that available evidence for agents used off-label to treat HSCT–TMA is derived from observational studies and case series with mixed results, and none of the agents have been evaluated for efficacy or safety in a robust clinical trial in patients with HSCT–TMA.[357] In summary, the applicant stated with regard to these unapproved therapies that: (1) The use of TPE is based on the extrapolation of its effectiveness for thrombocytopenic purpura with poor outcomes leading the Blood and Marrow Transplant Clinical Trials Network Toxicity Committee in 2005 to recommend that TPE not be considered as a standard of care for HSCT–TMA; [358] (2) eculizumab is a C5 inhibitor that blocks activation of the terminal cascade of complement,[359] the use of which is constrained by lack of efficacy and

[352] Gavriilaki, E et al. Transplant-associated thrombotic microangiopathy: Opening Pandora's box. Bone Marrow Transplantation (2017) 52, 1355–1360.

[353] Jodele, S et al (2016). New approaches in the diagnosis, pathophysiology, and treatment of pediatric hematopoietic stem cell transplantation-associated thrombotic microangiopathy. Transfus Apher Sci. 2016 April; 54(2): 181–190.

[354] Rosenthal, J Hematopoietic cell transplantation-associated thrombotic microangiopathy: A review of pathophysiology, diagnosis, and treatment. Journal of Blood Medicine 2016:7 181–186.

[355] Khosla J et al. Hematopoietic stem cell transplant-associated thrombotic microangiopathy: Current paradigm and novel therapies. Bone Marrow Transplant. 2018; 53(2):129–137.

[356] Li A et al. Transplant-associated thrombotic microangiopathy is a multifactorial disease unresponsive to immunosuppressant withdrawal. Biol Blood Marrow Transplant. 2019;25(3):570–576.

[357] Li A et al. Transplant-associated thrombotic microangiopathy is a multifactorial disease unresponsive to immunosuppressant withdrawal. Biol Blood Marrow Transplant. 2019;25(3):570–576.

[358] Schwatz, J et al. Guidelines on the Use of Therapeutic Apheresis in Clinical Practice—Evidence-Based Approach from the Writing Committee of the American Society for Apheresis: The Seventh Special Issue. Journal of Clinical Apheresis 31:149–338 (2016).

[359] FDA. (2019, June). *Soliris Prescribing Information.* Retrieved from Highlights of Prescribing Information: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125166s431lbl.pdf.*

safety evaluations by FDA [360] and associated increased susceptibility to infections; [361] [362] (3) defibrotide (Defitelio®), an oligonucleotide mixture with profibrinolytic properties whose mechanism of action has not been fully elucidated [363] is not approved by FDA for the treatment of HSCT–TMA nor considered a standard of care; (4) rituximab (Rituxan®), a monoclonal antibody that targets the CD20 antigen expressed on the surface of pre-B and mature B-lymphocytes,[364] is not approved by FDA for the treatment of HSCT–TMA; and (5) vincristine sulfate, a vinca alkaloid isolated as a 1:1 sulfate salt from the periwinkle plant is not approved by FDA for the treatment of HSCT–TMA.[365]

With respect to the newness criterion, the applicant stated in its application that FDA has accepted the Biologics License Application (BLA) for narsoplimab for the treatment of HSCT–TMA with a PDUFA date of October 17, 2021. The applicant stated that as of November 2021 they have received a Complete Response Letter (CRL) from FDA regarding the BLA for narsoplimab. The applicant stated they intend to resubmit the pending application soon. According to the applicant, narsoplimab has received Orphan Drug designation, Breakthrough Therapy Designation, and Priority Review. The applicant stated that the recommended dosage of narsoplimab is 4 mg/kg given as a 30-minute intravenous infusion (up to a maximum of 370 mg per infusion) once weekly. The applicant stated that effective October 1, 2021, the following ICD–10–PCS codes may be used to uniquely describe procedures involving the use of narsoplimab: XW03357 (Introduction of narsoplimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 7) and XW04357 (Introduction of narsoplimab monoclonal antibody into central vein, percutaneous approach, new technology group 7). The applicant stated that effective October 1, 2021, the following ICD–10–CM code is used to identify the indication of narsoplimab: M31.11 (Hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT–TMA)).

If a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that narsoplimab has a unique mechanism of action which inhibits the key effector enzyme of the lectin pathway of complement, MASP–2, provides an upstream (relative to other complement inhibitors) and targeted effect inhibiting complement-mediated inflammation and coagulation while leaving fully intact the alternative and classical pathways to fight infection. The applicant stated that narsoplimab binds with high affinity and specificity to, and blocks, MASP–2, the key effector enzyme of the lectin pathway of complement, inhibiting the inflammatory and pro-thrombotic responses to endothelial injury found in HSCT–TMA.[366] [367] The applicant stated that although all pathways of complement (lectin, alternative, and classical) result in production of pro-inflammatory anaphylatoxins and activation of membrane attack complex on targeted cells, each pathway is triggered in a unique manner.[368]

According to the applicant, the lectin pathway of complement has a role that is different from the classical and alternative pathways in that it serves as a ''surveillance system'' responsible for the identification and removal of damaged host cells or microbes. The applicant asserted that upon host tissue injury or microbe exposure, lectins (MBLs and other pattern recognition molecules including ficolins and collections) recognize damage-associated molecular patterns (DAMPs) on the surface of injured cells or pathogen-associated molecular patterns on microbes, initiating the lectin cascade.[369] [370] [371] [372] According to the applicant, the alternative pathway is a signal amplification system that is consistently engaged at low levels through the presence of a small amount of autoactivated C3 in the blood, so-called ''C3 tickover''.[373] Lastly, the applicant stated the classical pathway is mainly responsible for the antigen-antibody innate immune response necessary to protect against infection and is activated by antibody-antigen complexes recognized by complement component C1q.[374]

The applicant stated that MASP–2 inhibition specifically blocks the lectin pathway of complement but does not inhibit the classical and alternative pathways, leaving the complement system's effector function in adaptive immunity intact, which is important for fighting infection.[375] [376] According to the

[360] Li A et al. Transplant-associated thrombotic microangiopathy is a multifactorial disease unresponsive to immunosuppressant withdrawal. Biol Blood Marrow Transplant. 2019;25(3):570–576.

[361] Bohl SR, Kuchenbauer F, von Harsdorf S, Kloevekorn N, Schonsteiner SS, Rouhi A, et al. Thrombotic Microangiopathy after Allogeneic Stem Cell Transplantation: A Comparison of Eculizumab Therapy and Conventional Therapy. Biol Blood Marrow Transplant. 2017;23(12):2172–7.

[362] Khosla J et al. Hematopoietic stem cell transplant-associated thrombotic microangiopathy: Current paradigm and novel therapies. Bone Marrow Transplant. 2018; 53(2):129–137.

[363] FDA. (2016, March). *Defitelio Prescribing Information*. Retrieved from Highlights of Prescribing Information: *https://www.accessdata.fda.gov/drugsatfdadocs/label/2016/208114lbl.pdf* Defitelio PI. 3/2016.

[364] FDA. (2019, September). Rituxan *Prescribing Information*. Retrieved from Highlights of Prescribing Information: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/103705s5450lbl.pdf* Rituxan PI. 9/2019.

[365] FDA. (2020, July). Vincristine *Prescribing Information*. Retrieved from Highlights of Prescribing Information: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202497s011lbl.pdf* Vincristine PI. 7/2020.

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[375] Rambaldi, A et al. Improved survival following OMS721 treatment following hematopoietic stem cell transplant-associated thrombotic microangiopathy (HCTTMA). European Hematology Society. Stockholm, June 15, 2018. Abstract PF724.

[376] Elhadad, S et al 2020. MASP2 levels are elevated in thrombotic microangiopathies:

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applicant, the mechanism of action of narsoplimab not only results in inhibition of lectin pathway-mediated activation of complement, but also blocks the MASP–2 mediated procoagulant activities in the coagulation cascade. The procoagulant effects of MASP–2, independent of its role in the complement system, include the conversion of prothrombin to thrombin as well as the activation of Factor XII to XIIa.[377] [378] [379] In addition, MASP–2 is activated by fibrin and activated platelets, further augmenting a procoagulant state.[380] The applicant asserted that by inhibiting these procoagulant activities of MASP–2, narsoplimab provides important anticoagulant benefits, without affecting bleeding parameters (that is, prothrombin time, activated partial thromboplastin time, international normalized ratio, or bleeding time). According to the applicant, narsoplimab is the only drug that addresses all the components of HSCT–TMA and is the only product that inhibits complement activation and has anticoagulant activity. Therefore, the applicant asserted that the mechanism of action of narsoplimab differs from that of the products occasionally used off label: Eculizumab, defibrotide sodium, rituximab, and vincristine.

With respect to the second criterion, whether a product is assigned to the same or different MS–DRG, the applicant stated that patients who receive narsoplimab will be assigned to the same DRGs as patients who are diagnosed with HSCT–TMA/TA–TMA regardless of the treatment.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that narsoplimab treats HSCT–TMA, a serious multi-factorial syndrome for which no current FDA-approved technology exists. The applicant asserted that HSCT–TMA is a distinctly different TMA characterized by endothelial injury and microvascular thrombosis caused by pre-HSCT conditioning regimens and exposure to immunosuppressants and is further aggravated by potential complications of HSCT including GVHD and infections.

The applicant next differentiated between thrombotic microangiopathies (TMAs) and HSCT–TMA. According to the applicant, TMAs are a group of disorders with hallmark features of thrombocytopenia, microangiopathic hemolytic anemia (MAHA), and end organ damage. The applicant asserted that two specific TMAs, atypical hemolytic uremic syndrome (aHUS) and thrombotic thrombocytopenic purpura (TTP), exhibit clinical presentations similar to HSCT–TMA; however, their underlying mechanism set their diagnosis and treatment apart from that of HSCT–TMA. The applicant stated that HSCT–TMA is a distinct TMA arising from treatment and complications of HSCT, diagnosis of which requires a constellation of findings. According to the applicant HSCT–TMA is a distinctive endothelial injury syndrome (EIS) commonly associated with transplant conditioning (chemotherapy and total body irradiation), transplant complications such as infection and GVHD, and immunosuppressive agents (CNI and mTOR inhibitors). The applicant asserted that there is no approved treatment for HSCT–TMA.[381]

In summary, the applicant believes that narsoplimab is not substantially similar to other currently available therapies and/or technologies and meets the ''newness'' criterion. Similar to our discussion in the FY 2022 IPPS/LTCH PPS final rule (86 FR 25283–25284), we note that the applicant asserted that there are no FDA-approved products indicated for the treatment of HSCT–TMA and we are inviting public comment on whether narsoplimab therefore has a unique mechanism of action. In addition, we note that although the cause or triggers of thrombotic microangiopathy may be different between HSCT and for example HUS or TTP, the resulting disease may be similar. We welcome public comments on whether HSCT–TMA is a similar disease to other forms of TMA. We are inviting public comments on whether narsoplimab is substantially similar to other currently available therapies and/or technologies and whether this technology meets the newness criterion.

With regard to the cost criterion, the applicant provided the following analysis to demonstrate the technology meets the cost criterion. The applicant used the FY 2019 MedPAR inpatient claims data file released with the FY 2022 IPPS proposed rule to identify patients with a combined diagnosis of history of stem cell transplantation (SCT, ICD–10 code Z94.84) OR complications of stem cell transplant (ICD–10 code T86.5) AND thrombotic microangiopathy (TMA, ICD–10 code M31.1) OR hemolytic-uremic syndrome (HUS, ICD–10 code D59.3). Claims from PPS-exempt hospitals were excluded. The applicant stated that given the nature of HSCT–TMA, patient claims map to many MS–DRGs. The applicant identified a total of 27 MS–DRGs with fewer than 11 patients in any one MS–DRG; the applicant stated the top four MS–DRGs by volume are 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC), 919 (Complications of Treatment with MCC), 546 (Connective Tissue Disorders with CC), and 545 (Connective Tissue Disorders with MCC). In the cost analysis, a total of 54 cases across 27 MS–DRGs were identified. The applicant imputed a case count of 11 for those MS–DRGs with fewer than 11 cases, which increased the number of claims from 54 to 297 because all MS–DRGs had fewer than 11 claims.

The applicant first calculated a case weighted threshold of $89,095 for all scenarios based upon the dollar threshold for each MS–DRG grouping and the proportion of cases in each MS–DRG. The applicant then calculated the average charge per case. The applicant stated that because narsoplimab is an adjunctive therapy, no charges for a prior technology or a technology being replaced were removed. Next the applicant calculated the average standardized charge per case using the FY 2022 IPPS/LTCH PPS final rule Impact file. The 4-year inflation factor of 1.281834 or 28.1834% was obtained from the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542) and applied to the average standardized charge per case.

According to the applicant, because narsoplimab has not yet received FDA approval, the price has not yet been established. Therefore, the applicant did not include the charges for the new technology in the cost analysis. Next, the applicant calculated the final inflated average case-weighted standardized charge per case of $508,855, which exceeded the average

Association with microvascular endothelial cell injury and suppression by anti-MASP2 antibody narsoplimab. Clinical and Experimental Immunology, 0: 2–9.

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[380] Kozarcanin, H et al. The lectin complement pathway serine proteases (MASPs) represent a possible crossroad between the coagulation and complement systems in thromboinflammation. Journal of Thrombosis and Haemostasis, 2016. 14: 531–545.

[381] Li A et al. Transplant-associated thrombotic microangiopathy is a multifactorial disease unresponsive to immunosuppressant withdrawal. Biol Blood Marrow Transplant. 2019;25(3):570–576.

case-weighted threshold amount of $76,739.

We invite public comments on whether narsoplimab meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that narsoplimab represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to currently available treatments due to filling an unmet need for patients with HSCT–TMA where supportive care and/or off-label therapies have been ineffective. The applicant also asserted that narsoplimab has demonstrated a substantial clinical improvement in the treatment of HSCT–TMA in the clinical trial setting and has demonstrated substantial improvement in TMA complete response.

With respect to the assertion that narsoplimab fills an unmet need, the applicant stated that FDA awarded narsoplimab Breakthrough Therapy designation for the treatment of patients with HSCT–TMA who have persistent TMA despite modification of immunosuppressive therapy and if approved by FDA, narsoplimab will be the only drug or biological approved for the treatment of HSCT–TMA.

In support of the assertion that narsoplimab offers a treatment option for patients unresponsive to currently available treatments as demonstrated in the clinical trial setting, the applicant described the pivotal single-arm, open label trial OMS721–TMA–001 which included a high-risk sample (n=28) including patients with persistent TMA following calcineurin inhibitors (CNI) modification and other transplant features or complications such as GVHD, mismatched transplants, female-to-male transplants, and multiple organ involvement. According to the applicant, the study design allowed evaluation of patients at high risk for poor outcomes, including mortality.[382] [383] [384] [385] [386] [387] According to the applicant, 28 patients with HSCT–TMA received narsoplimab intravenously once weekly for four to eight weeks with an eight-week follow-up period. The applicant stated the primary end point of the study was a response defined by improvements in both TMA laboratory markers (LDH and platelet count) and clinical status (improvement in organ function [renal, pulmonary, gastrointestinal, or neurological] or freedom from transfusion). According to the applicant, patients had multiple risk factors for poor outcomes at baseline, including significant infection (85.7%), renal dysfunction (75%), GVHD (67.9%), neurological dysfunction (57.1%), multiple organ involvement (50%), and pulmonary dysfunction (17.9%). Because the primary response endpoint is novel, the applicant asserted that historical response data using the endpoint are not available.

According to the applicant, patients receiving narsoplimab in the full analysis set (FAS) (patients receiving at least 1 dose of narsoplimab) demonstrated a 61% complete response rate (17/28; 95% CI 40.6% to 78.5%), and patients receiving per protocol dosing (≥ 4 doses) demonstrated a 74% complete response rate (17/23; 95% CI 51.6% to 89.8%).[388] [389] [390] [391] [392] [393] The applicant stated that the 100-day survival was demonstrated in 68% (19/28) of narsoplimab-treated patients in the FAS, 83% (19/23) for patients receiving per protocol dosing, and 94% for patients determined to be complete responders (16/17). The applicant added that median overall survival for the full analysis population was demonstrated at 274 days (95% CI 103, NE), 361 days (95% CI 176, NE) for the per protocol analysis, and median survival for the responder population was not reached (95% CI 273, NE) because more than half of the patients were still alive. According to the applicant, similar populations described in the literature have demonstrated much shorter overall survival and much lower 100-day survival rates.

Next the applicant addressed clinical laboratory markers, improvement in clinical status, and key secondary objectives. According to the applicant, statistically significant ($p < 0.01$) and clinically relevant improvements from baseline were observed in platelet count, LDH, and haptoglobin.[394] [395] [396] [397] [398] [399] The

[382] Rambaldi, A et al. ''Improved survival following OMS721 treatment following hematopoietic stem cell transplant associated thrombotic microangiopathy (HCTTMA).'' European Hematology Society. Stockholm, June 15, 2018; Abstract PF724.

[383] Rambaldi, A et al. ''Narsoplimab (OMS721) for the Treatment of Adult Hematopoietic Stem Cell TransplantAssociated Thrombotic Microangiopathy.'' European Hematology Association., June 12, 2020; Abstract S2626.

[384] Rambaldi A, Claes K, Goh YT, et al. ''Narsoplimab (OMS721), a MASP–2 inhibitor, for the treatment of adult hematopoietic stem cell transplantassociated thrombotic microangiopathy (HSCT–TMA): Subgroup analyses.'' Abstracts from the 47th Annual Meeting of the;

[385] Khaled SK, Boelens JJ, Cairo MS, et al. ''Narsoplimab (OMS721), a MASP–2 inhibitor, for the treatment of adult hematopoietic stem cell transplantassociated thrombotic microangiopathy (HSCT–TMA).'' Transplantation and Cellular Therapy. 2021;27(3):S24–S26. h

[386] Perales M, Cairo M, Duarte R, et al. ''Narsoplimab (OMS721) treatment contributes to improvements in organ function in adult patients with high-risk transplant associated thrombotic microangiopathy.'' Presented at: 26th European Hematology Association Congress; June 9–17, 2021. Oral presentation S241. *https://library.ehaweb.org/eha/2021/eha2021-virtualcongress/324649/.*

[387] Whitaker, Steve. OMS721–TMA–001. ''A Phase 2, Uncontrolled, Three-Stage, Dose-Escalation Cohort Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, Immunogenicity, and Clinical Activity of OMS721 in Adults with Thrombotic Microangiopathies''. October 12, 2018.

[388] Rambaldi, A et al. ''Improved survival following OMS721 treatment following hematopoietic stem cell transplant associated thrombotic microangiopathy (HCTTMA).'' European Hematology Society. Stockholm, June 15, 2018; Abstract PF724.

[389] Rambaldi, A et al. ''Narsoplimab (OMS721)for the Treatment of Adult Hematopoietic Stem Cell TransplantAssociated Thrombotic Microangiopathy.'' European Hematology Association., June 12, 2020; Abstract S2626.

[390] Rambaldi A, Claes K, Goh YT, et al. ''Narsoplimab (OMS721), a MASP–2 inhibitor, for the treatment of adult hematopoietic stem cell transplantassociated thrombotic microangiopathy (HSCT–TMA): Subgroup analyses.'' Abstracts from the 47th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT). Bone Marrow Transplant. 2021;56:147–149. *https://doi.org/10.1038/s41409-021-01342-6;*

[391] Khaled SK, Boelens JJ, Cairo MS, et al. ''Narsoplimab (OMS721), a MASP–2 inhibitor, for the treatment of adult hematopoietic stem cell transplantassociated thrombotic microangiopathy (HSCT–TMA).'' Transplantation and Cellular Therapy. 2021;27(3):S24–S26.

[392] Perales M, Cairo M, Duarte R, et al. ''Narsoplimab (OMS721) treatment contributes to improvements in organ function in adult patients with high-risk transplant associated thrombotic microangiopathy.'' Presented at: 26th European Hematology Association Congress; June 9–17, 2021. Oral presentation S241. *https://library.ehaweb.org/eha/2021/eha2021-virtualcongress/324649/.*

[393] Whitaker, Steve. OMS721–TMA–001. ''A Phase 2, Uncontrolled, Three-Stage, Dose-Escalation Cohort Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, Immunogenicity, and Clinical Activity of OMS721 in Adults with Thrombotic Microangiopathies''. October 12, 2018.

[394] Rambaldi, A et al. ''Improved survival following OMS721 treatment following hematopoietic stem cell transplant associated thrombotic microangiopathy (HCTTMA).'' European Hematology Society. Stockholm, June 15, 2018;

[395] Rambaldi, A et al. ''Narsoplimab (OMS721) for the Treatment of Adult Hematopoietic Stem Cell TransplantAssociated Thrombotic Microangiopathy.'' European Hematology Association., June 12, 2020; Abstract S2626.;

[396] Rambaldi A, Claes K, Goh YT, et al. ''Narsoplimab (OMS721), a MASP–2 inhibitor, for the treatment of adult hematopoietic stem cell transplantassociated thrombotic microangiopathy (HSCT–TMA): Subgroup analyses.'' Abstracts from the 47th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT). Bone Marrow Transplant. 2021;56:147–149. *https://doi.org/10.1038/s41409-021-01342-6;*

[397] Khaled SK, Boelens JJ, Cairo MS, et al. ''Narsoplimab (OMS721), a MASP–2 inhibitor, for the treatment of adult hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT–TMA).'' Transplantation and Cellular Therapy. 2021;27(3):S24–S26.

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applicant stated that platelet count increased from baseline over time. The applicant stated that LDH, an adverse predictor for HSCT outcomes, decreased from baseline with narsoplimab treatment, consistent with clinical improvement. The applicant stated that haptoglobin, a marker for hemolysis which is often decreased in HSCT–TMA, steadily increased from baseline with narsoplimab treatment. The applicant stated that hemoglobin also increased with narsoplimab treatment. According to the applicant, the response across all key laboratory parameters was rapid and progressive over time. The applicant noted that overall freedom from transfusion was 48% in the FAS and 55% in the Per-Protocol Analysis Set (PAS).

The applicant also asserted that narsoplimab was well-tolerated in this very sick population with multiple comorbidities. The applicant stated that the most common adverse events in the pivotal trial were nausea, vomiting, diarrhea, hypokalemia, neutropenia, and fever, which are comparable to those typically seen in the post-transplant population. Six deaths (21%) occurred, collectively, from sepsis, AML progression, and GVHD, which according to the applicant are causes of death common in patients with HSCT. The applicant asserted that across all clinical trials, including trials in aHUS and IgA nephropathy (IgAN), with narsoplimab, no safety signal of concern has been observed.

With respect to the claim that use of narsoplimab significantly improves clinical outcomes relative to existing treatments, the applicant stated that there is a lack of effective treatment options for TMA following HSCT. Per the applicant, in order to provide a comparison group for the HSCT–TMA patients treated in the narsoplimab study, a protocol-driven systematic (retrospective) literature review was conducted evaluating clinical outcomes in adult patients with HSCT–TMA following allogeneic transplant. The applicant stated that publications dating from 2000–2020 which described the clinical course and outcomes of HSCT–TMA patients were identified by electronic database search (PubMed) using pre-specified search terms. The applicant stated the literature search identified 459 papers of which 25 manuscripts describing 149 patient outcomes in HSCT–TMA were identified. The applicant stated that to facilitate data comparisons with the narsoplimab clinical trial, random effects logistic regression and propensity score analyses were performed. The applicant stated that they examined various imputation methods to ensure the robustness of findings and then evaluated the following: Age and days from HSCT to TMA diagnosis as continuous variables, and GVHD, infection, renal dysfunction, and neurologic dysfunction as categorical variables.

According to the applicant, where only a minority of patients responded to treatment in the literature review, a majority of patients responded to narsoplimab. The applicant asserted that the comparison was conservative and biased toward the literature group, since the endpoint used in the narsoplimab pivotal trial is novel and rigorous, requiring a composite of laboratory and clinical measures, and none of the literature studies used this response endpoint. According to the applicant, many of the studies identified in the literature review used only one or two components of the narsoplimab primary endpoint or simply reported ''response''. According to the applicant, narsoplimab-treated patients had an overall response rate of 61% (95% CI 40.6% to 78.5%) for the full analysis set as compared to the literature-reported results with 23.3% (95% CI, 15.1% to 34.2%) response. According to the applicant, 62.5% of narsoplimab-treated patients had significant infection and responded to treatment as compared to 23.9% of the literature review dataset. The applicant asserted that propensity score analyses and sensitivity analyses, including all 4 imputation methods, comparing response rates of the narsoplimab-treated patients to those in the literature-based group, yielded odds ratios (ORs) that are all greater than 1 (2- to 8-fold and, with few exceptions, p-values < 0.05), supporting superiority of narsoplimab. The applicant concluded that the results demonstrate that the response observed with narsoplimab is a marked deviation from the natural history of HSCT–TMA, and is especially notable given that the patients in the narsoplimab pivotal trial were at high risk for poor outcomes, yet the majority achieved a complete response with significant improvement in laboratory markers and in clinical status.

In support of the application, the applicant submitted three new references in the form of abstracts.[400] [401] [402] The first abstract discusses results from the single-arm open-label pivotal trial (NCT02222545) (n=28) involving adult TA–TMA patients.[403] The authors stated that patients were at high risk for poor outcomes and had multiple comorbidities. Patients received 6.3 doses on average (2 to 8 range) of narsoplimab for a median duration of treatment of 8 weeks. The authors discussed many of the outcomes discussed by the applicant previously adding that six patients died during the core study period: 1 of septic shock, 2 of progressive AML, 2 of neutropenic sepsis, and 1 of GVHD and TMA. The authors stated that these deaths occurred 3–42 days following the last narsoplimab dose. The second and third abstracts also discuss the single-arm open-label pivotal trial (NCT02222545) (n=28) involving adult TA–TMA patients, as previously described.[404] [405]

After review of the information provided by the applicant, we have

[398] Perales M, Cairo M, Duarte R, et al. ''Narsoplimab (OMS721) treatment contributes to improvements in organ function in adult patients with high-risk transplant associated thrombotic microangiopathy.'' Presented at: 26th European Hematology Association Congress; June 9–17, 2021. Oral presentation S241. *https://library.ehaweb.org/eha/2021/eha2021-virtualcongress/324649/.*

[399] Whitaker, Steve. OMS721–TMA–001. ''A Phase 2, Uncontrolled, Three-Stage, Dose-Escalation Cohort Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, Immunogenicity, and Clinical Activity of OMS721 in Adults with Thrombotic Microangiopathies''. October 12, 2018.

[400] Perales M, Cairo M, Duarte R, et al. ''Narsoplimab (OMS721) treatment contributes to improvements in organ function in adult patients with high-risk transplant-associated thrombotic microangiopathy.'' Presented at: 26th European Hematology Association Congress; June 9–17, 2021. Oral presentation S241. *https://library.ehaweb.org/eha/2021/eha2021-virtual-congress/324649/.*

[401] Rambaldi A, Claes K, Goh YT, et al. ''Narsoplimab (OMS721), a MASP–2 inhibitor, for the treatment of adult hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT–TMA): Subgroup analyses.'' Abstracts from the 47th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT). Bone Marrow Transplant. 2021;56:147–149. *https://doi.org/10.1038/s41409-021-01342-6.*

[402] Khaled SK, Boelens JJ, Cairo MS, et al. ''Narsoplimab (OMS721), a MASP–2 inhibitor, for the treatment of adult hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT–TMA).'' Transplantation and Cellular Therapy. 2021;27(3):S24–S26.

[403] Perales M, Cairo M, Duarte R, et al. ''Narsoplimab (OMS721) treatment contributes to improvements in organ function in adult patients with high-risk transplant-associated thrombotic microangiopathy.'' Presented at: 26th European Hematology Association Congress; June 9–17, 2021. Oral presentation S241. *https://library.ehaweb.org/eha/2021/eha2021-virtual-congress/324649/.*

[404] Rambaldi A, Claes K, Goh YT, et al. ''Narsoplimab (OMS721), a MASP–2 inhibitor, for the treatment of adult hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT–TMA): Subgroup analyses.'' Abstracts from the 47th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT). Bone Marrow Transplant. 2021;56:147–149. *https://doi.org/10.1038/s41409-021-01342-6.*

[405] Khaled SK, Boelens JJ, Cairo MS, et al. ''Narsoplimab (OMS721), a MASP–2 inhibitor, for the treatment of adult hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT–TMA).'' Transplantation and Cellular Therapy. 2021;27(3):S24–S26.

concerns with regard to the substantial clinical improvement criterion. As we noted in the FY 2022 IPPS/LTCH PPS proposed rule, first, the sample from which the applicant draws conclusions is small (sample size of pivotal trial 28, plus five case studies previously discussed in the FY 2022 proposed rule (86 FR 25285 through 25286)). We question whether the sample and these results are generalizable to the greater Medicare population.

As we discussed in the FY 2022 IPPS/LTCH PPS proposed rule, with regard to methodological concerns, the authors pool data from an historical cohort of patients drawn from published literature to calculate survival rates in patients with HSCT–TMA and then retrospectively compare these rates to the survival in their treated cohort. We note the applicant has in their current application provided some insight into how the historical control was evaluated in comparison to narsoplimab outcomes, as previously discussed. We appreciate the greater detail provided by the applicant but without information regarding how the systematic review was designed and performed, we question the appropriateness of the sample used to identify a historical comparator. We question whether this systematic review and analysis sufficiently establish differences between various studies and whether they are sufficient to show that the difference between outcomes is due to differences in treatments as opposed to study design, samples, and so forth.

As we also noted in the FY 2022 IPPS/LTCH PPS proposed rule, the study described in the pivotal trial, upon which the applicant bases its claims for substantial clinical improvement, was not appropriately designed to test for comparisons with another treatment such as an historical control; a historical control was only assessed in post hoc analyses and was not incorporated in the initial study design. Furthermore, the methods utilized in the pivotal trial do not lend themselves to making statistical inferences based on the provided protocol (for example, no power assessment performed, no assessment for multiple comparisons, no pre-identified alpha). We note that the applicant stated that the trial's composite endpoint of laboratory and clinical measures is novel and rigorous, and has not been previously used in the literature. We would appreciate additional information on the clinical significance of this endpoint as compared to others in the literature referenced by the applicant, and whether the composite endpoint has been clinically validated and is demonstrative of durable clinical benefit. Specifically, we note that in some cases, measures used as indicators for patient improvement such as haptoglobin initially showed increases at early time points (for example, 1–10 weeks) but began to decrease at later time points (for example, 13–15 weeks).

We are inviting public comments on whether narsoplimab meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for narsoplimab.

h. Spesolimab

Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI), submitted an application for new technology add-on payments for spesolimab for FY 2023. According to the applicant, spesolimab is a humanized antagonistic monoclonal immunoglobulin G1 antibody blocking human IL36R signaling currently under investigation for the treatment of flares in adult patients with generalized pustular psoriasis (GPP). The applicant stated that binding of spesolimab to IL36R prevents the subsequent activation of IL36R by cognate ligands (IL36 α, β and γ) and downstream activation of pro-inflammatory and pro-fibrotic pathways. Per the applicant, genetic human studies have established a strong link between IL36R signaling and skin inflammation.

According to the applicant, GPP is a rare, heterogeneous, and potentially life-threatening neutrophilic skin disease, with an estimated prevalence of 1/10,000 in the United States.[406] The applicant noted that a flare entails widespread formation of pustules that may occur with or without systemic inflammation. Per the applicant, GPP causes significant morbidity and, in some cases, mortality; infectious, metabolic, cardiac, liver, respiratory, and neurological comorbidities have been reported.[407] The applicant also stated that various factors have been reported to trigger a GPP flare, including pregnancy, severe injury, or viral and bacterial infections. Per the applicant, the use and subsequent withdrawal of systemic corticosteroids is a key contributing factor.[408] [409] [410]

According to the applicant, GPP can be distinguished from plaque psoriasis based on clinical, pathologic, and genetic features in GPP. The applicant asserted that although there are shared pathways between GPP and plaque psoriasis, the IL–36 pathway is predominantly involved in the pathogenesis of GPP, while the IL–23 axis drives plaque psoriasis. Per the applicant, binding of spesolimab to IL36R prevents the subsequent activation of IL36R by cognate ligands (IL36 α, β and γ) and downstream activation of pro-inflammatory and pro-fibrotic pathways. The applicant also stated that IL–36R signaling is differentiated from TNF-α, integrin and IL–23 inhibitory pathways by directly and simultaneously blocking both inflammatory and pro-fibrotic pathways.

The applicant stated that in the absence of an FDA-approved therapy specifically indicated for GPP, immunomodulatory therapies, including biologics, are used in the treatment of GPP based on clinical experience in patients with plaque psoriasis. The applicant further noted that there is limited evidence on the efficacy and safety of these therapies in the treatment of GPP. Per the applicant, due to the rarity of the disease, there are no high-quality clinical trials providing evidence for treatment options in GPP.[411] [412] The applicant also stated that the National Psoriasis Foundation treatment recommendations include cyclosporine, retinoids, infliximab and methotrexate as first-line therapies [413] but that current treatments are associated with slow resolution of GPP flares, and complete clearance of

[406] Strober B., Kotowsky N, Medeiros R., et al., Unmet Medical Needs in the Treatment and Management of Generalized Pustular Psoriasis Flares: Evidence from a Survey of Corrona Registry. Dermatologists Dermatol Ther (Heidelb) (2021) 11:529–541.

[407] Ibid.

[408] Zelickson BD, et al. Generalized Pustular Psoriasis. Arch Dermatol 1991;127:1339–1345.

[409] Choon SE, et al. Clinical profile, morbidity, and outcome of adult-onset generalized pustular psoriasis: Analysis of 102 cases seen in a tertiary hospital in Johor, Malaysia. Int J Dermatol 2014;53:676–684.

[410] The applicant referred to a third citation here, as ''Goiriz 2007,'' but we are unable to identify the citation based upon the information provided by the applicant.

[411] Robinson A, et al. Treatment of pustular psoriasis: From the Medical Board of the National Psoriasis Foundation. J Am Acad Dermatol 2012; 67:279–288.

[412] Choon et al. Study protocol of the global Effisayil 1 Phase II, multicentre, randomised, double-blind, placebo-controlled trial of spesolimab in patients with generalized pustular psoriasis presenting with an acute flare. BMJ Open 2021; 11:e043666.

[413] Robinson A, et al. Treatment of pustular psoriasis: From the Medical Board of the National Psoriasis Foundation. J Am Acad Dermatol 2012; 67:279–288.

pustules and skin is not always achieved.[414]

With respect to the newness criterion, the applicant is pursuing FDA approval of a Biologics License Application (BLA). We note that a December 15, 2021, press release indicates that FDA has accepted a BLA and granted Priority Review for spesolimab for the treatment of flares in patients with GPP.[415] The applicant indicated that it expects to receive FDA approval prior to the July 1 deadline. According to the applicant, the product will be available on the market 1 week post FDA approval. According to the applicant, spesolimab is administered as a single 900 mg (2 x 450 mg/7.5 mL vials) intravenous infusion over 90 minutes, and an additional intravenous 900 mg dose may be administered 1 week after the initial dose if flare symptoms persist. According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify spesolimab. The applicant submitted a request for approval of a unique ICD–10–PCS code to identify cases involving the administration of spesolimab beginning in FY 2023.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant stated that spesolimab does not use the same or similar mechanism of action when compared to an existing technology. The applicant stated that spesolimab inhibits IL–36R signaling which is differentiated from TNF-α, integrin and IL–23 inhibitory pathways by directly and simultaneously blocking both inflammatory and pro-fibrotic pathways. The applicant described first line therapies that include acitretin, cyclosporine, methotrexate, infliximab, oral prednisone, topical corticosteroids, topical calcipotriene, and etanercept. As second line, the applicant cited adalimumab, etanercept, psoralen and long-wave ultraviolet light A (PUVA), ultraviolet light B (UVB) phototherapy, topical corticosteroids, topical calcipotriene, topical tacrolimus, and infliximab. The applicant stated there is limited evidence on the efficacy and safety of these therapies in the treatment of GPP. The applicant reported that due to the rarity of the disease, there are no high-quality clinical trials providing evidence for treatment options in GPP.[416] [417]

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that there is no MS–DRG for spesolimab. We note that the applicant also stated that spesolimab currently maps to the following MS–DRGs: 603 (Cellulitis without MCC), 607 (Minor Skin Disorders without MCC), 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC), and 872 (Septicemia or Severe Sepsis without MV >96 Hours without MCC) under the MS–DRG grouper for FY 2022.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated the clinical, pathological, and genetic features associated with GPP establish it as a distinct disease entity from plaque psoriasis, which is managed with existing therapies.

In summary, the applicant asserted that spesolimab is not substantially similar to other currently available therapies and/or technologies because it does not use the same or similar mechanism of action, there is no MS–DRG, and the features of GPP establish it as a distinct disease entity from plaque psoriasis and that therefore, the technology meets the ''newness'' criterion. However, we have the following concerns with regard to the newness criterion. First, we note that the applicant stated that there are no FDA-approved therapies specifically indicated for GPP. However, we question whether there are any treatments that may be indicated for psoriasis generally that may therefore be considered an on-label use for subtypes of psoriasis such as GPP, and request additional information on any such treatments. We also note that while the applicant stated that spesolimab has no DRG to which it maps, the applicant also provided a list of four MS–DRGs that cases eligible for the use of the technology would map to, and we believe these are the same MS–DRGs to which other treatments for GPP would map.

We are inviting public comments on whether spesolimab is substantially similar to existing technologies and whether spesolimab meets the newness criterion.

With respect to the cost criterion, the applicant presented the following analysis. The applicant first searched the FY 2019 MedPAR for cases representing patients who may be eligible for spesolimab. The applicant selected claims with a diagnosis code of L40.1 (Generalized pustular psoriasis) and limited the data to PPS hospitals. The applicant removed HMO cases, cases with total charges or covered charges less than zero, and cases with a length of stay of zero. After imputing a value of 11 cases for MS–DRGs with a case volume less than 11, the applicant identified 101 claims mapping to 4 MS–DRGs under the MS–DRG grouper for FY 2022: MS–DRG 603 (Cellulitis without MCC), MS–DRG 607 (Minor Skin Disorders without MCC), MS–DRG 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC), and MS–DRG 872 (Septicemia or Severe Sepsis without MV >96 Hours without MCC).

The applicant did not remove charges for prior technology as the applicant stated it did not believe that it was applicable for this product. The applicant standardized the charges and applied a 4-year inflation factor of 1.281834 based on the inflation factor used in the FY 2022 IPPS/LTCH PPS final rule and correction notice to calculate outlier threshold charges. The applicant then added charges for the new technology by dividing the cost of spesolimab by the national average CCR for drugs which is 0.187 from the FY 2022 IPPS/LTCH PPS final rule (86 FR 44966). The applicant stated that the final inflated average case-weighted standardized charge per case of $359,404 exceeded the average case-weighted threshold amount of $41,595. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that spesolimab meets the cost criterion.

We note the applicant's statement that removing charges for prior technology was not applicable to spesolimab; however, the applicant did not provide

[414] Strober B, et al. Unmet medical needs in the treatment and management of generalized pustular psoriasis flares: Evidence from a survey of corrona registry dermatologists. Dermatol Ther (Heidelb) 2021.

[415] Boehringer Ingelheim, *https://www.boehringer-ingelheim.us/press-release/us-fda-grants-priority-review-spesolimab-treatment-flares-patients-generalized.* Accessed 1/18/2022.

[416] Robinson A, et al. Treatment of pustular psoriasis: From the Medical Board of the National Psoriasis Foundation. J Am Acad Dermatol 2012; 67:279–288.

[417] Choon et al. Study protocol of the global Effisayil 1 Phase II, multicentre, randomised, double-blind, placebo-controlled trial of spesolimab in patients with generalized pustular psoriasis presenting with an acute flare. BMJ Open 2021; 11:e043666.

an explanation as to why. We would be interested in additional detail regarding the applicant's decision not to remove charges for prior technology. We invite public comment on whether spesolimab meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that spesolimab represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments and significantly improves clinical outcomes relative to services or technologies previously available.

With respect to the claim that spesolimab offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, the applicant stated that there are no FDA-approved therapies specifically indicated for GPP. The applicant further stated that current treatments are associated with slow resolution of GPP flares, and complete clearance of pustules and skin is not always achieved.[418] In support of this claim, the applicant submitted a study describing a structured survey which was purposed to gauge unmet needs for GPP. The study results of the survey of 29 dermatologists were published regarding the range and adequacy of GPP treatment options.[419] Dermatologists were identified by the Corrona Psoriasis Registry as likely to be currently treating patients with GPP, with a history of having treated at least one patient in the Corrona Registry. The survey was made up of 28 multiple choice questions regarding GPP flares, diagnosis, and treatment options. The authors found that all surveyed dermatologists believed that pustules were necessary to diagnose a GPP flare. Most surveyed dermatologists responded that treatment options for all flare frequencies were adequate ''most'' (79%) or ''all'' (14%) of the time, and 83% reported that treatments for residual disease for all flare frequencies are adequate ''most of the time.'' According to the applicant, this survey established the need for new therapies. The applicant stated that while the study results suggest that moderately effective therapies may exist, the need for GPP-specific treatments remains.

With respect to the claim that spesolimab improves outcomes, the applicant restated that there are no FDA-approved therapies specifically indicated for GPP, current treatments are associated with slow resolution of GPP flares, and complete clearance of pustules and skin is not always achieved.[420] The applicant also stated that spesolimab, as compared to placebo, leads to rapid pustular clearance and rapid skin clearance; clinically significant improvements in patient-reported pain, psoriasis symptoms, and fatigue; and significant decreases in markers of systemic inflammation. The applicant provided three data submissions in support of their claims of improved outcomes.

The applicant submitted a published letter to the editor describing a phase I, proof-of-concept trial in 7 patients who were given a single intravenous dose of spesolimab 10mg/kg and followed for 20 weeks, to establish the results of spesolimab in a study. The authors noted that most adverse events were mild or moderate in nature and that a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of 0 or 1 (clear or almost clear skin) was achieved in five patients by week 1 and in all patients by week 4. Complete pustular clearance was achieved in three patients within 48 hours after treatment (n=3; 42.9%), in five patients by week 1 (n=5; 71.4%) and in six patients by week 2 (n=6; 85.7%).[421] According to the applicant, this proof-of-concept study demonstrated that spesolimab could achieve clear or almost clear skin with no serious adverse effects.

The applicant also submitted a published study protocol describing Effisayil-1, a phase 2 multicenter, randomized, placebo-controlled trial designed to support the use of spesolimab for GPP in a double-blind study. The protocol aimed to randomize at least 51 patients with an acute GPP flare in 2:1 fashion for a single 900 mg intravenous dose of spesolimab or placebo. Inclusion criteria included patients with a GPPGA score 0 or 1 and documented history of GPP; or acute GPP with moderate to severe intensity flare; or first episode acute GPP with moderate to severe intensity with diagnosis to be confirmed retrospectively. According to the protocol, patients would be followed for up to 28 weeks and the primary endpoint would be achievement of GPPGA pustulation subscore of 0 (pustule clearance) at Week 1. A secondary endpoint of GPPGA score of 0 or 1 (clear or almost clear) at Week 1 would also be assessed. Patients not qualifying to enter the open label extension study would be followed for an additional 16 weeks. In addition to photographs, exam, vitals, safety laboratory testing, the IL36RN mutation status would be determined for all patients. Finally, safety would be assessed along with data collection of blood and skin biopsies.[422]

Finally, the applicant summarized unpublished data from Effisayil-1, described previously to demonstrate that spesolimab improves outcomes as compared to placebo.[423] According to the applicant, 54.3% of the treatment arm (19/35) achieved pustule clearance, as assessed by GPPGA pustulation subscore one week after treatment, compared to approximately 5.6% (1/18) of patients in the placebo arm (p<0.001), demonstrating rapid pustular clearance. The applicant also noted a secondary endpoint of clear or almost clear skin one week after treatment. The applicant stated that spesolimab also demonstrated rapid skin clearance, with 42.9% (15/35) of the treatment arm, compared to 11.1% (12/18) of patients treated with placebo (p=0.012) achieving clear or almost clear skin as indicated by a total GPPGA score of 0 or 1 at week 1.

With respect to the claim that spesolimab improved patient-reported outcomes, the applicant stated that patients in the Effisayil-1 trial discussed previously used a visual analog scale to measure their pain. According to the applicant, a significantly greater reduction in pain was measured in patients receiving spesolimab at Week 4 as compared to those receiving placebo (p=0.001). In addition, the applicant stated that patients receiving spesolimab reported significantly greater reductions in psoriasis symptoms (including pain, redness, itching, and burning) as indicated by the psoriasis symptom scale (PSS) by Week 4 (p=0.004). The applicant also noted significantly greater reductions in fatigue by the Functional Assessment of Chronic Illness Therapy (FACIT) scores in the spesolimab group as compared to placebo (p=0.001) at Week 4.

Lastly, the applicant stated that the Effisayil-1 study also demonstrated significant decreases in markers of systemic inflammation. According to the applicant, serum biomarker data

[418] Strober B, et al. Unmet medical needs in the treatment and management of generalized pustular psoriasis flares: Evidence from a survey of corrona registry dermatologists. Dermatol Ther (Heidelb) 2021.

[419] Ibid.

[420] Ibid.

[421] Bachelez H, et al. Inhibition of the Interleukin-36 Pathway for the Treatment of Generalized Pustular Psoriasis. N Engl J Med 2019; 380:981–983.

[422] Choon et al. Study protocol of the global Effisayil 1 Phase II, multicentre, randomised, double-blind, placebo-controlled trial of spesolimab in patients with generalized pustular psoriasis presenting with an acute flare. BMJ Open 2021; 11:e043666.

[423] Bachelez et al., in print.

showed that treatment with spesolimab led to normalization of C-reactive protein (CRP) and neutrophil values that had been above the upper limit of normal at baseline within 2 weeks for CRP and within 1 week for neutrophils. The applicant further stated that this effect was sustained through to Week 12.

After review of the information provided by the applicant, we have the following concerns regarding whether spesolimab meets the substantial clinical improvement criterion. We note that the results of the Effisayil-1 trial are not included in the application. As the applicant references the Effisayil-1 trial in support of its assertions regarding improved outcomes we are concerned that our analysis of the clinical benefit of spesolimab relies entirely on the applicant's summary of the unpublished trial. To the extent that Bachelez et al., matched to the previously published protocol, it does not appear that the unpublished study met the goal of recruiting 51 patients and therefore we question if the study was adequately powered. In addition, the patient demographics, excluded cases, and details of adverse events are unable to be determined. We therefore question the generalizability of the Effisayil-1 trial outcomes to the Medicare population.

With regard to the Effisayil-1 protocol and the unpublished data,[424] [425] we note that the protocol is not designed to compare spesolimab to current treatment options. While the applicant states that spesolimab will be the first GPP treatment targeting the IL–36 pathway, we note that the applicant previously described other treatments that are available, which include TNF-α inhibitors, etanercept, and others. We also question whether there are any treatments that may be indicated for psoriasis generally that may therefore be considered an on-label use for subtypes of psoriasis such as GPP, as discussed previously. In addition, we note that the dermatology survey results supplied by the applicant seem to indicate that there is perceived efficacy in current treatments.[426] Most of the surveyed dermatologists indicated that treatment options for all flare frequencies were adequate ''most'' (79%) or ''all'' (14%) of the time, and 83% reported that treatments for residual disease for all flare frequencies are adequate ''most of the time.'' Given this, we question whether placebo is the most appropriate comparator for spesolimab.

We also note that there does not appear to be a standard way to assess GPP severity and response to treatment. Though the studies described in the application used GPPGA to assess these outcomes, because there are multiple assessment tools such as the Psoriasis Area and Severity Index (PASI), the GPPGA adapted from the Psoriasis Physician Global Assessment (PGA), the Clinical Global Impression (CGI) scale, the Japanese Dermatological Association Severity Index (JDA–SI), patient reported outcomes, and others, we question the extent of response and comparability to other therapies. We also question if skin manifestations correlate with systemic symptoms and laboratory values as those outcomes would also be of interest.

We are inviting public comments on whether spesolimab meets the substantial clinical improvement criterion.

In this section, we summarize and respond to written public comments received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for spesolimab.

Comment: The applicant provided supplemental written responses to questions by CMS during the FY 2022 Town Hall meeting regarding the Effisayil-1 study. First, in response to a question regarding how the results of the Effisayil-1 trial align to labs and other findings, the applicant clarified that among patients with elevated baseline neutrophils in the Effisayil-1 trial, counts were normalized within one week of receiving spesolimab while median C-reactive protein (CRP) normalized within two weeks in patients with elevated baseline CRP (≥ 10mg/L).

Second, in response to a question regarding whether safety data is available based on impact to the immune system, the applicant also stated that a comparison of safety data among patients with or without measurable changes to immune response cannot be answered since treatment with spesolimab consistently resulted in normalization of inflammatory markers among patients with elevated baseline values. Per the applicant, during the 1-week placebo-controlled period in Effisayil-1, infections were reported in 17.1% of patients treated with spesolimab compared with 5.6% of patients treated with placebo. Serious infection (urinary tract infection) was reported in one patient (2.9%) in the spesolimab group and no patients in the placebo group. The applicant also stated that infections observed were mild to moderate with no distinct pattern regarding pathogen or type of infection.

Third, in response to a question regarding whether older adults were studied in the trial, the applicant stated that among patients enrolled in the Effisayil-1 study, the mean age was 43 years and the median age was 41 years, thirteen patients (24.5%) were 50 to <65 years of age and two patients (3.8%) were ≥65 years of age. Per the applicant, the age distribution observed in the Effisayil-1 study is similar to what is known for the US population with GPP [427] but market research has suggested a larger impact on the Medicare population. In utilizing IQVIA claims data, the applicant estimated that approximately 40% of GPP claims are adjudicated as Medicare.[428]

Fourth, in response to a request for the inclusion and exclusion criteria, the applicant clarified that patients aged 18–75 years were eligible for enrollment if they had a history of GPP consistent with criteria for diagnosis according to European Rare and Severe Psoriasis Expert Network (ERASPEN) criteria. The applicant further stated that patients had to have a GPP flare of moderate-to-severe intensity (defined as total GPPGA score ≥3, new or worsening pustules, a GPPGA pustulation subscore ≥2, and ≥5% body surface area with erythema and the presence of pustules). Per the applicant, key exclusion criteria included patients with plaque psoriasis without pustules or with pustules restricted to psoriatic plaques, drug-triggered acute generalized exanthematous pustulosis, immediate life-threatening flare of GPP requiring intensive care treatment, and requirement for current treatment with methotrexate, cyclosporine, or retinoids, or any restricted medication.

Fifth, in response to a question regarding whether the primary endpoint reached statistical significance, the applicant asserted that the Effisayil-1 study met its primary endpoint and achieved statistical significance with the following results: At week one, 19 patients (54.3%) receiving spesolimab versus one patient (5.6%) receiving placebo, achieved a GPPGA pustulation subscore of 0; (risk difference: 48.7%

[424] Choon SE, et al. Clinical profile, morbidity, and outcome of adult-onset generalized pustular psoriasis: Analysis of 102 cases seen in a tertiary hospital in Johor, Malaysia. Int J Dermatol 2014;53:676–684.

[425] Bachelez et al., in print.

[426] Strober B, et al. Unmet medical needs in the treatment and management of generalized pustular psoriasis flares: Evidence from a survey of corrona registry dermatologists. Dermatol Ther (Heidelb) 2021.

[427] Noe MH et al. JAMA Dermatol. doi:10.1001/jamadermatol.2021.4640.

[428] IQVIA Longitudinal Access and Adjudicated Data 2016–2019.

with a 95% confidence interval [CI] 21.5–67.2; one-sided p<0.001).

Sixth, in response to a question regarding how IL–36R signaling could be utilized for other indications, the applicant stated that spesolimab is also under investigation for the prevention of GPP flares and for the treatment of other neutrophilic skin diseases, such as palmoplantar pustulosis (PPP) and hidradenitis suppurativa (HS).

Seventh, in response to a question regarding when the published results of Effisayil-1 and Effisayil-2 are expected, the applicant stated that the primary results of Effisayil-1 were previously presented at the World Psoriasis and Psoriatic Arthritis Conference in June 2021, and the full manuscript has been accepted in a peer-reviewed journal for publication by the end of December 2021. The applicant further noted that the Effisayil-2 study is currently ongoing and publication of the results is to be determined.

Response: We thank the applicant for its comments and will take this information into consideration when deciding whether to approve new technology add-on payments for spesolimab. We note that as of the time of the development of this proposed rule, we have not received the published Effisayil-1 trial results.

i. Teclistamab

Johnson & Johnson submitted an application for new technology add-on payments for teclistamab for FY 2023. Teclistamab is a bispecific antibody (bsAb) that is intended to bind CD3 on T cells and B cell maturation antigen (BCMA) on myeloma cells in the treatment of relapsed or refractory multiple myeloma. The applicant stated that this dual binding brings T cells into proximity with target myeloma cells and triggers T cell activation, leading to a cascade of ''effector'' events, such as cytotoxicity, cytokine production and immune activation, and an overall anti-tumor response.

Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells.[429] Normal plasma cells are found in the bone marrow as part of the immune system and make antibodies that help the body fight infections. According to the applicant, when they become malignant, these plasma cells rapidly spread and replace normal cells in the bone marrow.[430] As indicated by its name, multiple myeloma is characterized by dissemination of multiple tumor cells throughout the bone marrow.[431] The applicant asserted that the median age of onset is 66 years old, and only 2% of patients are less than 40 at the age of diagnosis.[432] In 2020, it is estimated that more than 32,000 people will be diagnosed and nearly 13,000 will die from multiple myeloma in the US.[433] It is associated with substantial morbidity and mortality, and approximately 25% of patients have a median survival of two years or less.[434] [435]

According to the applicant, multiple myeloma is incurable, with most patients relapsing despite current treatments.[436] The applicant stated that immunotherapies, including CAR T-cell therapy and antibody-based therapies, engage the patient's immune system to fight cancer. According to the applicant, new treatment options available in the last two decades have extended the median survival of multiple myeloma patients. The introduction of proteasome inhibitors (PI), histone deacetylase inhibitors, immunomodulatory agents (IMiD), monoclonal antibodies, antibody-drug conjugates, corticosteroids, conventional chemotherapy and cellular therapies like autologous stem cell transplantation (ASCT) have allowed numerous therapeutic options for patients with multiple myeloma. The applicant stated that other currently available treatment options include selective inhibitor of nuclear export (SINES) and melphalan flufenamide. However, the applicant stated that barriers to access and a complex, time-consuming manufacturing process limit access on some therapies. The applicant stated that bsAbs facilitate T cell redirection without the need for patient cell collection and external manipulation as is seen in CAR T-cell therapy.

With respect to the newness criterion, the applicant stated that teclistamab has not yet received FDA marketing authorization but was granted Breakthrough Therapy designation on May 26, 2021. The applicant stated that it is seeking accelerated approval for a Biologics License Application (BLA) for the proposed indication for adult patients with relapsed or refractory multiple myeloma, who have received at least 3 prior therapies including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody, and that it expects FDA approval by June 2022. According to the applicant, teclistamab is designed to be given subcutaneously in two priming doses of 60 ug/kg and 300 ug/kg, then a maintenance dose of 1500 ug/kg. According to the applicant, ICD–10–PCS code 3E01305 (Introduction of other antineoplastic into subcutaneous tissue, percutaneous approach) can be used to identify the technology, but it does not distinctly identify procedures involving the administration of teclistamab. The applicant has submitted a request for approval for a unique ICD–10–PCS code to identify procedures involving the administration of teclistamab. The applicant also stated that the following ICD–10 CM diagnosis codes can be used to identify the proposed indication for teclistamab: C90.00 (Multiple myeloma not having achieved remission), C90.01 (Multiple myeloma in remission), and C90.02 (Multiple myeloma in relapse).

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant

[429] Raab MS, Podar K, Breitkreutz I, Richardson PG, Anderson KC. Multiple myeloma. Lancet. 2009 Jul 25;374(9686):324–39. doi: 10.1016/S0140–6736(09)60221–X. Epub 2009 Jun 21. PMID: 19541364.

[430] Utley A, Lipchick B, Lee KP, Nikiforov MA. Targeting Multiple Myeloma through the Biology of Long-Lived Plasma Cells. Cancers (Basel). 2020 Jul 30;12(8):2117. doi: 10.3390/cancers12082117. PMID: 32751699; PMCID: PMC7466116.

[431] Fairfield H, Falank C, Avery L, Reagan MR. Multiple myeloma in the marrow: Pathogenesis and treatments. Ann N Y Acad Sci. 2016 Jan;1364(1):32–51. doi: 10.1111/nyas.13038. PMID: 27002787; PMCID: PMC4806534.

[432] Kyle RA, Gertz MA, Witzig TE, Lust JA, Lacy MQ, Dispenzieri A, Fonseca R, Rajkumar SV, Offord JR, Larson DR, Plevak ME, Therneau TM, Greipp PR. Review of 1027 patients with newly diagnosed multiple myeloma. Mayo Clin Proc. 2003 Jan;78(1):21–33. doi: 10.4065/78.1.21. PMID: 12528874.

[433] SEER Cancer Stat Facts: Myeloma. National Cancer Institute. Bethesda, MD, *https://seer.cancer.gov/statfacts/html/mulmy.html.*

[434] Cowan AJ, Allen C, Barac A, Basaleem H, Bensenor I, Curado MP, Foreman K, Gupta R, Harvey J, Hosgood HD, Jakovljevic M, Khader Y, Linn S, Lad D, Mantovani L, Nong VM, Mokdad A, Naghavi M, Postma M, Roshandel G, Shackelford K, Sisay M, Nguyen CT, Tran TT, Xuan BT, Ukwaja KN, Vollset SE, Weiderpass E, Libby EN, Fitzmaurice C. Global Burden of Multiple Myeloma: A Systematic Analysis for the Global Burden of Disease Study 2016. JAMA Oncol. 2018 Sep 1;4(9):1221–1227. doi: 10.1001/jamaoncol.2018.2128. PMID: 29800065; PMCID: PMC6143021.

[435] Biran N, Jagannath S, Chari A. Risk stratification in multiple myeloma, part 1: Characterization of high-risk disease. Clin Adv Hematol Oncol. 2013 Aug;11(8):489–503. PMID: 24518420.

[436] Rajkumar SV. Multiple myeloma: Every year a new standard? Hematol Oncol. 2019 Jun;37 Suppl 1(Suppl 1):62–65. doi: 10.1002/hon.2586. PMID: 31187526; PMCID: PMC6570407.

asserts that teclistamab uses a different mechanism of action when compared to existing technologies used to treat myeloma. The applicant stated that teclistamab has a unique mechanism of action with a full-sized antibody containing two distinct binding domains that simultaneously bind the BCMA target on tumor cells and the CD3 T-cell receptor. The applicant stated that teclistamab's mechanism of action is different from CAR T-cell therapies used to treat multiple myeloma such as idecabtagene vicleucel because it does not require cell extraction and engineering. The applicant submitted the following table that compares the mechanism of action for teclistamab to the mechanism of action for existing technologies used to treat multiple myeloma.

Treatment Class	Mechanism of Action
Proteasome inhibitors	Interfere with the degradation of proteins within the cells Myeloma cells are sensitive to this inhibition
Immunomodulatory drugs	Possess multiple antimyeloma properties including immune modulation, antiangiogenic, anti-inflammatory, and antiproliferative effects
Monoclonal antibodies (mABS)	Target specific proteins on myeloma cells, which may activate immune responses
Antibody-drug conjugates	Antibody that specifically recognizes the B-cell maturation antigen (BCMA) — a protein found on the surface of myeloma cells
Histone deacetylase inhibitors (HDACIS)	Can cause apoptosis of myeloma cells through effects on gene regulation
Corticosteroids	Can cause apoptosis of myeloma cells
Conventional chemotherapy	An approach that targets dividing cells
Selective Inhibitor of Nuclear Export (SINES)	Inhibits exportin-1 (XPO) resulting in activation of tumor suppressor proteins, glucocorticoid receptors, and immune response regulators thereby inducing cell cycle arrest and apoptosis
Melphalan flufenamide	Peptidase enhanced cytotoxic (PEnC) that exerts a targeted delivery of melphalan in cells with high expression of aminopeptidases, such as aminopeptidase N.
Autologous CAR T-cells	A myeloma antigen-directed genetically modified autologous T-cell immunotherapy

According to the applicant, there is currently no commercially available bispecific antibody for multiple myeloma: Blinatumomab is a bispecific T cell engager (BiTE) targeting CD3 and CD19 made up of two fragment antigen-binding (Fab) portions held together by a chemical linker that is only approved for pre-B-cell acute lymphoblastic lymphoma, and amivantamab targets two antigens specific to lung cancer cells and does not contain a CD3-binding domain. The applicant stated that teclistamab is not substantially similar to other existing bispecific antibodies like blinatumomab due to teclistamab's duobody structure of BCMA versus CD19, or amivantamab due to targeting of CD3 and BCMA versus the lung cancer antigens, cMET and EGFR. Therefore, the applicant asserted that teclistamab has a novel structure and unique mechanism of action, and is unlike any existing technology utilized to treat multiple myeloma.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that the DRG assignment for treating multiple myeloma is not expected to change with this technology.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated that its proposed indication is for treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least three prior therapies including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. According to the applicant, this indication is similar to belantamab and idecabtagene vicleucel, which are approved for multiple myeloma patients who have failed four prior therapies or lines of therapy, respectively. The applicant asserts that it is likely that teclistamab will be approved for an indication identical or similar to these two other therapies.

In summary, the applicant believes that teclistamab is not substantially similar to other currently available therapies and/or technologies because it uses a new mechanism of action and that therefore, the technology meets the newness criterion.

We are inviting public comments on whether teclistamab is substantially similar to existing technologies and whether teclistamab meets the newness criterion.

With respect to the cost criterion, the applicant presented the following analysis. The applicant searched the FY 2019 MedPAR for cases representing patients who may be eligible for teclistamab based on the presence of the ICD–10–CM diagnosis codes listed.

ICD-10-CM	Description
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse

The applicant limited its case selection to cases mapping to MS–DRGs 846 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC) and 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with CC). The applicant identified 766 claims that mapped to these two MS–DRGs.

Next, the applicant removed all charges in the drug cost center because it stated that it was not possible to differentiate between different drugs on inpatient claims. The applicant noted that the three doses of the drug administered during inpatient hospitalization would replace other therapies, but that removing all charges is likely an overestimation of the charges that would be replaced by use of teclistamab.

The applicant then standardized the charges using the FY 2022 IPPS/LTCH PPS final rule impact file and applied a 4-year inflation factor (1.281834) based on the inflation factor used in the FY 2022 IPPS/LTCH PPS final rule and correction notice (86 FR 45542) to calculate outlier threshold charges. Since the technology is not FDA approved, the cost of teclistamab has not yet been determined. However, the applicant added charges for the new technology by dividing an estimated cost of teclistamab by the national average CCR for drugs (0.187) published in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44966).

The applicant calculated a final inflated average case-weighted standardized charge per case of $101,270, which exceeded the average case-weighted threshold amount of $58,800. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that teclistamab meets the cost criterion. We are inviting public comment on whether teclistamab meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that teclistamab offers a treatment option for patients who are refractory to the three major classes of drugs currently approved for multiple myeloma (IMiDs, PIs, and monoclonal antibodies). The applicant also asserts that teclistamab significantly improves clinical outcomes such as treatment response rates, and minimal residual disease (MRD) rates when compared to currently available treatments.

With respect to the claim that teclistamab provides a treatment option for patients who are refractory to the three major classes of drugs currently approved for multiple myeloma, the applicant asserted that patients treated with teclistamab demonstrate an overall response rate (ORR) of 65%, with 61% of patients who are triple-class refractory exhibiting a response. The applicant stated that while response rates are similar for idecabtagene vicleucel, another BCMA targeting therapy, access may be limited due to inability to secure a CAR T-cell treatment spot due to manufacturing constraints, inability and/or unwillingness to travel to an idecabtagene vicleucel qualified center, or the need to initiate immediate treatment and inability to wait weeks for CAR T-cell manufacturing and/or respond to bridging therapy. Additionally, the applicant stated some patients are not eligible for idecabtagene vicleucel due to fitness/frailty and CAR T-cell manufacturing may be unsuccessful. The applicant described the ''off-the-shelf'' nature of teclistamab providing a more accessible and immediate option for patients, not limited to certified centers, and available to more practitioners. Finally, the applicant asserted that frequency and severity of CRS and neurotoxicity are less with teclistamab than with some other therapies, including CAR T-cell therapies. The applicant asserted that no neurotoxicity was observed at the recommended phase 2 dose (RP2D).[437]

With respect to the claim that teclistamab improves clinical outcomes as compared to existing technologies, the applicant stated that teclistamab demonstrates a high ORR in general as well as in triple-class refractory patients; early and deep clinical responses; MRD at time of complete response and sustained results; good progression-free survival (PFS); predictable, limited, and manageable CRS, and minimal toxicity. To support these claims, the applicant referenced data from the MajesTEC–1 trial, which is an ongoing, open-label, single-arm, phase 1 study of intravenous (IV) or subcutaneous (SQ) teclistamab in 157 patients with multiple myeloma who were relapsed, refractory, or intolerant to established therapies.[438] [439] The primary objectives were to identify the RP2D and its safety and tolerability. The study used a data cutoff date of March 29, 2021. Between June 8, 2017 and March 29, 2021, enrolled patients were administered the study drug at 0.3–19.2 ug/kg once every 2 weeks or 19.2–720 ug/kg once a week in the IV cohort, and 80–3000 ug/kg once a week in the SQ cohort. Teclistamab was given to the 157 subjects by IV (n=84) or SC (n=73) administration. Step-up dosing was employed during the first week to minimize side effects, and the full dose was given weekly beginning on day 1 of week 2. Patients continued treatment until disease progression, unacceptable toxicity, withdrawal of consent, death, or at study completion. Patients who had at least one post-baseline response evaluation after teclistamab administration (n=40) were evaluated for secondary endpoints of ORR, duration of response (DOR), time to response, pharmacokinetic parameters, pharmacodynamics markers, and anti-teclistamab antibodies. The authors did not report PFS and overall survival (OS) because they stated that the data were not mature.

At the cutoff date, median age of enrolled patients was 63, with more elderly patients (≥70 years) in the IV cohort than the SQ cohort. The median lines of therapy received prior to the study were six. All patients enrolled in the study experienced treatment-emergent adverse events (TEAEs), with 85% experiencing grade 3 or 4. At R2PD, the percentage of grade 3 or 4

[437] Usmani et al. Teclistamab, a B-cell maturation antigen x CD3 bispecific antibody, in patients with relapsed or refractory multiple myeloma (MajesTEC–1): A multicentre, open-label, single-arm, phase I study, Lancet. 2021 Aug 21;398(10301):665–674. doi: 10.1016/S0140–6736(21)01338–6. Epub 2021 Aug 10. PMID: 34388396.

[438] Usmani et al., Teclistamab, a B-cell maturation antigen × CD3 bispecific antibody, in patients with relapsed or refractory multiple myeloma (MajesTEC–1): A multicentre, open-label, single-arm, phase 1 study, Lancet. 2021 Aug 21;398(10301):665–674. doi: 10.1016/S0140–6736(21)01338–6. Epub 2021 Aug 10. PMID: 34388396.

[439] *ClinicalTrials.gov*, NCT03145181.

TEAEs dropped to 80%, and 50% of those were believed to be treatment related. The most common hematologic TEAEs were neutropenia, anemia, and thrombocytopenia, whereas the most common non-hematologic TEAE was CRS at grade 1 or 2. TEAEs occurred in 57% of all treated patients, and 70% of those at the R2PD. Median time and duration of CRS was 1 day in IV cohort and 2 days in the SQ cohort. The most common non-hematologic adverse event (AE) was CRS, all grade 1 or 2, which occurred in 60% of all subjects treated with subcutaneous drug and 70% of subjects at the RP2D. Infections were noted in 45% of subjects at the RP2D, including 23% with grade 3/4 infections. Neurotoxicity occurred in 1% of subjects treated with SC drug, including 3% at the RP2D. AEs led to cycle delays or dose reductions in the overall population. No subject discontinued treatment due to CRS. Based on data from this trial, the authors noted a more gradual increase in serum teclistamab in SQ administration compared to IV administration and established a RP2D of 1500 ug/kg SQ. The ORR at the RP2D was 65%, with complete response (CR) and very good partial response (VGPR) rates of 40% and 58%, respectively. After a median follow-up of 7.1 months, 22/26 (85%) responders continued on therapy. In a small subgroup of 33 triple-class refractory patients, the ORR was 61%. Authors noted that, in contrast, studies of selinexor and belantamab mafodotin at approved doses had response rates of 26% and 31%, respectively.

The applicant also provided updated results that were presented at the American Society for Hematology in December 2021.[440] This data, up to clinical cut-off date September 7, 2021, included longer follow-up of the phase 1 trial (median 5.9 months, 0.2–18 month range in the safety analysis) as well as initial data from the phase 2 trial at median follow-up of 7.8 months (range 0.5+ − 18 months). The pivotal cohort now included 165 patients, with 40 in the phase 1 cohort and 125 in the phase 2 cohort. According to the applicant, the phase 1 patients were relapsed, refractory, or intolerant to established therapies. The phase 2 patients received >3 prior lines of therapy and both cohorts received R2PD. There were discontinuations in both groups due to progressive disease, physician decision, patient withdrawal, AE, and death. At the time of the ASH presentation, authors noted an ORR of 62% (95% CI: 53.7–69.8) with median time to first response of 1.2 months (range 0.2–5.5 months). ORR was slightly higher in patients <75 years old (n=127) compared to patients >75 years (n=23) and in those with baseline renal function >60 ml/min/1.73 m2. Of the 165 patients, serious AEs occurred in 88 patients and there were 9 deaths. CRS events were mostly grade 1/2 with one transient-grade 3 CRS. There was neurotoxicity in 21 patients, with headache being the most common. At a data cut-off of November 7, 2021, the applicant stated that 88.2% of responders were alive without subsequent treatment or progressive disease. Median DOR has not been reached, with a 9-month PFS rate of 59%. The applicant also stated that enrollment in phase 2 expansion cohorts is ongoing, and phase 3 study enrollment has been initiated.

In support of the claim that teclistamab demonstrates a high ORR and early and deep clinical responses, the applicant cited MajesTEC–1 data for 40 patients who received R2PD and were eligible for evaluation of response. The applicant noted that at a median follow-up of 6.1 months, teclistamab was associated with a 65% overall response rate (95% CI 48–79), in patients receiving the RP2D of maintenance dose of 1.5 mg/kg SQ weekly (n=40). Approximately 58% achieved VGPR or better, and 40% achieved complete response or better. For the subgroup of triple-class refractory patients (n=33), the applicant cited a 61% ORR at R2PD. Regarding early and deep clinical responses, the applicant noted that of the 40 patients receiving R2PD, the median time to first confirmed response was 1 month (IQR 1.0–1.6), very good partial response or better was 1 month (1.0–3.1), first confirmed complete response or better was 3.0 months (1.7–3.7).

In support of the assertions that teclistamab is associated with high levels of response, the applicant stated that most patients at RP2D attained a status of MRD-negativity by the time they were evaluable for a CR. The applicant also stated that teclistamab demonstrated responses wherein myeloma cells were not detected in a background of 105 or 106 cells. The applicant also cited a 6-month PFS of 67% (95% CI 49–80) for those treated at R2PD.

Lastly, in support of the claim that teclistamab results in predictable, limited, and manageable CRS and minimal toxicity, the applicant cited hematological and nonhematological TEAEs described earlier in the MajesTEC–1 trial summary. The applicant also stated that CRS was of limited severity, with consistent, predictable time to onset (median 2 days) and duration of CRS (median 2 days). Teclistamab-related toxicity was manageable, including CRS, and did not result in discontinuation of therapy. In review of the applicant's data, neurotoxicity occurred in 4% of patients (n=7), with higher grade neurotoxicity (3 or 4) occurring in the IV cohort.

The applicant also provided preclinical data regarding the development of JNJ–7957 (teclistamab), a novel BCMAxCD3 bispecific antibody.[441] In the first paper, authors evaluated activity of this antibody in cell lines and bone marrow samples from patients with multiple myeloma and refractory disease. It was noted that JNJ–7957 was associated with anti-tumor activity in 48 of 49 bone marrow samples from multiple myeloma patients and in 5 of 6 bone marrow samples from primary plasma cell leukemia patients. In daratumumab-exposed effector cells, there appeared to be enhanced JNJ–7957 activity. The authors used this data to support further studies on JNJ–7957 in patients with multiple myeloma (MM). In a second preclinical paper, authors described the development of a BCMAxCD3 bispecific antibody (teclistamab [JNJ–64007957]) to recruit and activate T cells to kill BCMA-expressing multiple myeloma cells.[442] This study noted that teclistamab was associated with cytotoxicity of BCMA+ MM cell lines in vitro (H929 cells, 50% effective concentration [EC50] = 0.15 nM; MM.1R cells, EC50 = 0.06 nM; RPMI 8226 cells, EC50 = 0.45 nM) with concomitant T-cell activation (H929 cells, EC50 = 0.21 nM; MM.1R cells, EC50 = 0.1 nM; RPMI 8226 cells, EC50 = 0.28 nM) and cytokine release. According to the applicant, teclistamab also depleted BCMA+ cells in bone marrow samples from MM patients in an ex vivo assay with an average EC50 value of 1.7 nM. Under more physiological conditions using healthy human whole blood, teclistamab mediated dose-dependent lysis of H929 cells and activation of T

[440] Moreau P, Usmani S, Garfall A, et al., Updated Results From MajesTEC–1: Phase 1/2 Study of Teclistamab, a B-Cell Maturation Antigen x CD3 Bispecific Antibody, in Relapsed/Refractory Multiple Myeloma. 63rd American Society of Hematology (ASH) Annual Meeting & Exposition, Atlanta, GA/Virtual, December 11–14, 2021.

[441] Frerichs et al., Preclinical Activity of JNJ–7957, a Novel BCMA×CD3 Bispecific Antibody for the Treatment of Multiple Myeloma, Is Potentiated by Daratumumab, Clin Cancer Res. 2020 May 1;26(9):2203–2215. doi: 10.1158/1078–0432.CCR–19–2299. Epub 2020 Jan 22. PMID: 31969333.

[442] Pillarisetti et al, Teclistamab is an active T cell-redirecting bispecific antibody against B-cell maturation antigen for multiple myeloma, Blood Adv. 2020 Sep 22;4(18):4538–4549.

cells. Antitumor activity of teclistamab was also observed in 2 BCMA+ MM murine xenograft models inoculated with human T cells (tumor inhibition with H929 model and tumor regression with the RPMI 8226 model) compared with vehicle and antibody controls. According to the applicant, the findings of this study indicate that teclistamab is active against BCMA-expressing cells from MM cell lines, patient samples, and MM xenograft models.

After review of the information provided by the applicant, we have the following concerns regarding whether teclistamab meets the substantial clinical improvement criterion. We note that all substantial clinical improvement claims were based on one small-sized open-label phase 1 study (MajesTEC–1) without control or comparator and that subsequently submitted phase 2 data is still in early phases. The application and MajesTEC–1 manuscript reported outcomes on 26 of the 40 patients at RP2D, but further information on that smaller population and MRD-evaluability would be helpful. There is also no long-term follow-up in the published data. Additionally, of the 40 patients enrolled in the R2PD cohort, 70% had CRS and 18 had discontinued treatment at the time of publication. Updated results presented at ASH demonstrated that 50 patients had discontinued treatment out of the 125 enrolled in the phase 2 cohort. The authors studied both IV and SQ dosing in the MajesTEC–1 trial, but it is unclear if the overall results that include IV doses can be generalizable. We further note that the median age in MajesTEC–1 was 63 years and the majority of elderly patients (≥70 years old) were not in the R2PD cohort. The new data presented at ASH included 24 patients ≥75 years in the safety analysis. The ORR was slightly lower than what was seen in younger patients. It is unclear if this is mainly due to small sample size; the confidence interval is wider in this subgroup.

While the applicant provided data to demonstrate that teclistamab is associated with a 62% ORR, this was done in a single-arm trial which the applicant compared to historically published data of other therapies such as selinexor, belantamab, and idecabtagene vicleucel. We note that this comparison may be subject to sample-selection bias, as without matching of patients or study characteristics, it is unclear whether these differences in ORR are due to the therapy or can be attributed to other factors.

We also note that while the applicant asserted that teclistamab offers a treatment option for patients with limited access to or who are ineligible for CAR T-cell therapy due to wait time, fitness/frailty, and other issues, we question whether there are other available therapies, such as belantamab and selinexor, that may be used to treat patients with multiple relapses or who are refractory to other therapies that also would not have those limitations. We are inviting public comments on whether teclistamab meets the substantial clinical improvement criterion.

We received a written public comment from the applicant in response to the New Technology Town Hall meeting regarding the teclistamab FY 2023 application for new technology add-on payments.

Comment: The applicant responded to questions received at the New Technology Town Hall Meeting. During the Q&A portion of their presentation, the applicant presenter was asked about the status of planned phase 2 studies as the data shown were from the phase I portion of MajesTEC–1, first presented at the American Society of Clinical Oncology Annual Meeting in June 2021. According to the applicant, the data shown were the most recent available at the time of submission of the FY 2023 application and slide for new technology add-on payments. The applicant provided updated data from the phase I and phase 2 cohorts of MajesTEC–1 which, according to the applicant, were presented just the evening before at the American Society for Hematology 2021 Annual Meeting. This update included safety and efficacy data from both cohorts, including longer-term follow for 150 patients at the RP2D. The applicant provided a summary of this update as well as the presentation deck from the ASH oral session. (We note that we have summarized this updated data in the preceding discussion of the substantial clinical improvement criterion for teclistamab.)

Response: We appreciate the applicant's comments and updated data, as previously summarized. We will take these comments into consideration when deciding whether to approve new technology add-on payments for teclistamab.

j. TERLIVAZ® for Injection (Terlipressin)

Mallinckrodt Pharmaceuticals submitted an application for new technology add-on payments for TERLIVAZ® (terlipressin) for FY 2023. Per the applicant, TERLIVAZ® is for intravenous use in the treatment of adults with hepatorenal syndrome type 1 (HRS–1). TERLIVAZ® is a sterile, preservative-free, lyophilized powder for intravenous (IV) administration. We note that Mallinckrodt Pharmaceuticals previously submitted an application for new technology add-on payments for TERLIVAZ™ for FY 2022, as summarized in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25339 through 25344), that it withdrew prior to the issuance of the FY 2022 IPPS/LTCH PPS final rule (86 FR 44979).

The applicant stated that TERLIVAZ® (Na-tryglycl-8-lysinevasopressin) is a pro-drug for the endogenous/natural porcine hormone [Lys8]-vasopressin and a synthetic vasopressin analog derived from the natural/endogenous human hormone [Arg8]-vasopressin.[443] According to the applicant, TERLIVAZ® has greater selectivity for the vasopressin receptors (V1) versus vasopressin receptors (V2) and inhibits portal hypertension with simultaneous reduction of blood circulation in portal vessels.[444] The applicant stated that the V1 receptor mediated vasoconstrictor activity of TERLIVAZ®, particularly in the splanchnic area, results in an increase in effective arterial volume, an increase in mean arterial pressure (MAP), and normalization of endogenous vasoconstrictor systems (renin-angiotensin-aldosterone and sympathetic nervous system) resulting in increased renal blood flow.[445]

The applicant described HRS–1 as a serious, life-threatening condition characterized by development of acute or sub-acute renal failure in patients with advanced chronic liver disease (CLD). The applicant stated that HRS–1 is the leading cause of hospitalizations among all patients with advanced CLD.[446] The applicant explained that HRS–1 most often develops in patients with CLD, including cirrhosis. HRS–1 does not exist in isolation, but as a co-morbidity in very ill patients with CLD. According to the applicant, 43.4% of estimated annual HRS cases in FY 2023 will be Medicare patients. The applicant asserted that the high mortality and significant rates of HRS–1-related readmissions support the need for better disease awareness and more effective

[443] Jamil K, Pappas SC, Devarakonda KR. In vitro binding and receptor-mediated activity of terlipressin at vasopressin receptors V1 and V2. J Exp Pharmacol. 2017;10:1–7.

[444] Wong F. Recent advances in our understanding of hepatorenal syndrome. Nat Rev Gastroenterol Hepatol. 2012;9(7):382–391.

[445] Ibid.

[446] Allegretti AS, Ortiz G, Wenger J, et al. Prognosis of Acute Kidney Injury and Hepatorenal Syndrome in Patients with Cirrhosis: A Prospective Cohort Study. Int J Nephrol. 2015; 2015:108139.

treatment options.[447] [448] The applicant stated that there are currently no FDA-approved medications available in the US indicated specifically for the treatment of HRS–1,[449] but several agents are used off-label. The applicant stated that in the U.S., the standard of care and initial treatment for HRS–1 is a combination of midodrine and octreotide, which are used off-label.[450] [451] According to the applicant, this combination is concomitantly administered with albumin. The applicant also stated that in patients who are admitted to the intensive care unit (ICU), initial treatment with norepinephrine, also used off-label, in combination with albumin is recommended.[452] The applicant stated that the ideal therapy for HRS–1 is improvement of liver function from either recovery of alcoholic hepatitis, treatment of decompensated hepatitis B with effective antiviral therapy, recovery from acute hepatic failure, or liver transplantation.[453] According to the applicant, TERLIVAZ® is approved as the first-line treatment for HRS–1 in European and Asian countries under appropriate marketing authorizations in those countries.[454]

The applicant explained that the goal of HRS–1 treatment is to reverse the underlying hemodynamic instability. According to the applicant, treatment with TERLIVAZ® accomplishes this by decreasing splanchnic vasodilation and improving renal hemodynamics, thereby ameliorating afferent renal vasoconstriction, and improving glomerular filtration rate (GFR). The applicant noted that recent research suggests that increased circulating levels of pro-inflammatory cytokines (which the applicant asserted TERLIVAZ® administration helps to reduce) also play an important role in the development of HRS. The applicant asserted that, overall, treatment with TERLIVAZ® effectively addresses multiple aspects of the fundamental pathophysiology responsible for HRS–1, though it does not treat the underlying liver disease or decompensated cirrhosis. Furthermore, the applicant asserted that effective timely reversal of HRS–1 helps to improve post-liver transplant outcomes, as well as mitigates demand for renal replacement therapy (RRT) and kidney transplant.

With respect to the newness criterion, the applicant explained that TERLIVAZ® has not yet been granted approval from FDA for the proposed indication of treatment of adults with HRS–1. The applicant stated that in 2005, a New Drug Application (NDA) filing for TERLIVAZ® was granted Fast Track designation by FDA and was considered under Priority Review in May 2008, but a Complete Response Letter (CRL) was issued by FDA in November 2009. The applicant also stated that in 2016, Mallinckrodt Pharmaceuticals and FDA reached agreement on their trial protocol design and data analysis under the Agency's special protocol assessment (SPA) process. In April 2020, the applicant submitted the current NDA application with FDA as a Class 2 resubmission of the original NDA. On July 15, 2020, the Cardiovascular and Renal Drugs Advisory Committee of FDA voted to recommend approval of the investigational agent TERLIVAZ® to treat adults with HRS–1; however, on September 11, 2020, Mallinckrodt received a CRL from FDA denying this NDA. The applicant stated that it will work with FDA and anticipates approval prior to July 1, 2022.

According to the applicant, TERLIVAZ® is administered as an IV bolus injection. For the first 3 days, the recommended dosage is 1 mg TERLIVAZ every 6 hours by slow IV bolus injection (over 2 minutes). On day 4, the serum creatinine level is assessed against the baseline level obtained prior to initiating treatment. If the serum creatinine has decreased by 30% or more from the baseline, then 1 mg TERLIVAZ® can continue to be administered every 6 hours. If the serum creatinine has decreased by less than 30% from the baseline, then TERLIVAZ® may be increased to 2 mg every 6 hours. According to the applicant, TERLIVAZ® can continue to be administered until 24 hours after the patient achieves a second consecutive serum creatinine value of ≤1.5mg/dL at least 2 hours apart or for a maximum of 14 days. If, by day 4, serum creatine is at or above the baseline serum creatinine level, then TERLIVAZ® should be discontinued. If a patient develops a recurrence of HRS–1 after discontinuation of initial treatment, TERLIVAZ may be re-administered.

The applicant stated that, effective October 1, 2022, the following ICD–10–PCS codes may be used to uniquely describe procedures involving the administration of TERLIVAZ®: XW03367 (Introduction of terlipressin into peripheral vein, percutaneous approach, new technology group 7) and XW04367 (Introduction of terlipressin into central vein, percutaneous approach, new technology group 7).

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant stated that TERLIVAZ® uses a different mechanism of action than existing, off-label treatments for HRS–1, for example, midodrine, octreotide, and norepinephrine. The applicant explained that TERLIVAZ® has a selective affinity for V1 vasopressin receptors predominantly located in the arterial vasculature in the splanchnic region. The applicant submitted the following table that compares the mechanism of action for TERLIVAZ® to the mechanism of action for existing technologies used off-label to treat HRS–1 including midodrine, octreotide, and norepinephrine.

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[446] Allegretti AS, Ortiz G, Wenger J, et al. Prognosis of Acute Kidney Injury and Hepatorenal Syndrome in Patients with Cirrhosis: A Prospective Cohort Study. Int J Nephrol. 2015; 2015:108139.

[447] Low G, Alexander GJ, Lomas DJ. Hepatorenal syndrome: Aetiology, diagnosis, and treatment. Gastroenterol Res Pract. 2015; 2015:207012.

[448] Angeli P, Bernardi M, Villanueva C, et al. EASL Clinical Practice Guidelines for the management of patients with decompensated cirrhosis. J Hepatol. 2018;69(2):406–460.

[449] Jamil K, Huang X, Lovelace B, Pham AT, Lodaya K, Wan G. The burden of illness of hepatorenal syndrome (HRS) in the United States: A retrospective analysis of electronic health records. J Med Econ. 2019;22(5):421–429.

[450] Mindikoglu AL, Pappas SC. New Developments in Hepatorenal Syndrome [published correction appears in Clin Gastroenterol Hepatol. 2018 Jun;16(6):988]. Clin Gastroenterol Hepatol. 2018;16(2):162–177.e1.

[451] Runyon BA. Hepatorenal syndrome. UpToDate.com. *https://www.uptodate.com/contents/hepatorenal-syndrome.* Updated April 13, 2020. Accessed January 26, 2020.

[452] Ibid.

[453] Ibid.

	Terlipressin	Midodrine and Octreotide	Norepinephrine
Vasoconstrictor class	Non-sympathomimetic drug Vasopressin analogue (Prodrug of lysine-vasopressin)	Sympathomimetic drugs α-adrenergic receptor agonist (midodrine); somatostatin analogue (octreotide)	Sympathomimetic drug α-adrenergic receptor agonist
Mechanism of action	Selective affinity for V1 vasopressin receptors predominantly located in smooth muscles of arterial vasculature in the splanchnic region. Provides potent vasoconstrictor and antidiuretic properties to elevate arterial pressure.	Midodrine binds to α1 adrenoceptors on peripheral vascular smooth muscle, promoting smooth muscle contraction. Octreotide inhibits glucagon-mediated splanchnic vasodilation.	Binds to α1 adrenoceptors on peripheral vascular smooth muscle, promoting smooth muscle contraction.
Drug availability and FDA approval	Not available / not approved for use in U.S.	Available but not approved for use in HRS-1 in U.S.	Available but not approved for use in HRS-1 in U.S.
Administration and special requirements	Intravenous bolus injection (does not need to be infused due to prolonged half-life)	Oral (midodrine) Continuous infusion or subcutaneous (octreotide)	Continuous infusion through dedicated central line

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With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that TERLIVAZ® may be assigned to the same MS–DRG as existing technologies currently used to treat HRS–1. In particular, the applicant stated that cases involving the use of TERLIVAZ® may map to the following three MS–DRGs: (1) MS–DRG 441 (Disorders of Liver Except Malignancy, Cirrhosis or Alcoholic Hepatitis with Major Complication or Comorbidity); (2) MS–DRG 442 (Disorders of Liver Except Malignancy, Cirrhosis or Alcoholic Hepatitis with Complication or Comorbidity); and (3) MS–DRG 443 (Disorders of Liver Except Malignancy, Cirrhosis or Alcoholic Hepatitis without Complication or Comorbidity/Major Complication or Comorbidity). The applicant stated that although TERLIVAZ® may be assigned to the same MS–DRG when compared with an existing technology, this does not mean that TERLIVAZ® is not ''new'' for the purposes of new technology add-on payments because, according to the applicant, the existing technologies are not specifically indicated for the treatment of HRS–1. The applicant stated that none of the current standard-of-care drugs used to treat HRS–1, namely midodrine, octreotide, and norepinephrine, are FDA-approved for the treatment of this disease. The applicant referenced the discussion in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49445) of BLINCYTO®, as an example of another technology that was the only FDA-approved product available on the U.S. market to treat the relevant indication, and stated that CMS agreed that eligible cases involving the BLINCYTO technology would map to a different MS–DRG than cases treated with similar technologies. The applicant also stated that the MS–DRG system does not differentiate between patients with HRS and non-HRS conditions that are assigned to the three MS–DRGs included in Major Diagnostic Category (MDC) 7 (Diseases & Disorders of the Hepatobiliary System & Pancreas), and further that the current MS–DRGs do not differentiate between HRS type 1 and type 2. The applicant states that because of this, both TERLIVAZ® and an existing technology used to treat non-HRS conditions may be assigned to MS–DRGs 441, 442, and 443.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated that it is seeking FDA approval for the proposed indication of treatment of adults with HRS–1. Therefore, the applicant explained, TERLIVAZ® will treat the same type of disease when compared to existing technologies. However, the applicant noted that the use of the existing drugs for treatment of HRS–1 is off-label, while Mallinckrodt Pharmaceuticals is

seeking FDA approval of TERLIVAZ® specifically for the proposed indication of treatment of adults with HRS–1. The applicant also asserted that TERLIVAZ® (upon FDA approval) will not treat the same or a similar population when compared to existing technologies currently used to treat HRS–1 in the U.S. The applicant asserted that results from the CONFIRM trial (*ClinicalTrials.gov* number, NCT02770716) indicate there is a subset of patients for whom TERLIVAZ® will have efficacy and for whom current therapies, which are used off-label, are not effective. The applicant asserted that the patient population for which TERLIVAZ® offers a new treatment option (that is, those unresponsive to current standard of care treatments) is a subset of the larger patient population for which TERLIVAZ® will receive an FDA label. Nevertheless, the applicant stated that while the FDA label for TERLIVAZ® is not expected to be reserved for a subset of the patient population that has been diagnosed with HRS–1 and has failed to respond to standard-of-care treatment options, it does not logically follow that because of this label, TERLIVAZ® will not offer a treatment option to a new patient population.

In summary, the applicant stated that TERLIVAZ® is not substantially similar to existing technologies currently available to Medicare beneficiaries to treat HRS–1 because it uses a different mechanism of action and treats a new patient population, and therefore, the technology meets the ''newness'' criterion. However, similar to our discussion in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25340), we note that while TERLIVAZ® may address an unmet need because it will be the first treatment indicated specifically for the treatment of HRS–1, the applicant's assertion that TERLIVAZ® involves the treatment of a different patient population on the basis that there is a subset of patients for whom TERLIVAZ® will have efficacy and for whom current treatments are ineffective does not necessarily speak to the treatment of a new patient population for HRS–1.

We are inviting public comments on whether TERLIVAZ® is substantially similar to existing technologies and whether TERLIVAZ® meets the newness criterion.

With respect to the cost criterion, the applicant presented the following analysis. The applicant searched the FY 2019 MedPAR database for cases representing patients who may be eligible for TERLIVAZ® using patient claims bearing the ICD–10–CM code K76.7 (Hepatorenal syndrome) to identify HRS–1 in the inpatient setting. The applicant stated that it filtered for HRS–1 cases by excluding cases with an inpatient length of stay of under two days. The applicant explained that HRS–1 is diagnosed by the exclusion of other causes of acute kidney injury in cirrhotic patients, and that no response after two consecutive days of diuretic withdrawal and plasma volume expansion with albumin is one of the diagnostic criteria of HRS–1 in patients with cirrhosis. The applicant stated that, accordingly, patients who do not fulfill this criterion cannot be considered HRS–1 cases. The applicant also stated that it differentiated between cases where HRS–1 is the primary and/or admitting diagnosis code and cases where HRS–1 can be the primary, admitting, or any secondary diagnosis. The applicant further defined cohorts using an ICU indicator, explaining that it considered the different clinical presentations of HRS–1, which may at times be treated in the ICU.

The applicant then presented two analyses using six defined cohorts. The applicant considered the following factors in defining the cohorts. For Cohorts 1 and 2, the applicant included cases with an ICU indicator, representing serious cases where the patient needed stabilization procedures and/or conditions needing immediate attention. The applicant stated that these could be conditions related to, caused by, or leading to the HRS–1 diagnosis or having no relationship to HRS–1 other than a concurrent presence. For Cohorts 3 and 4, the applicant also included cases without an ICU indicator. For Cohorts 5 and 6, the applicant included all cases without differentiation in ICU utilization. Cohorts 1, 3, and 5 include cases where HRS is the primary and/or admitting diagnosis code. Cohorts 2, 4, and 6 include cases where HRS can be the primary, the admitting, or any secondary diagnosis. The applicant described the six cohorts as shown in the table.

Cohort	Cohort Description	Number of Cases
1	ICD-10-CM code - K76.7 Primary/Admitting, ICU Indicator, Stays of 2+ Days Only	8,349
2	ICD-10-CM code - K76.7 Any Position, ICU Indicator, Stays of 2+ Days Only	98,131
3	ICD-10-CM code - K76.7 Primary/Admitting, No ICU Indicator, Stays of 2+ Days Only	8,822
4	ICD-10-CM code - K76.7 Any Position, No ICU Indicator, Stays of 2+ Days Only	78,815
5	ICD-10-CM code - K76.7 Primary/Admitting, Stays of 2+ Days Only	16,797
6	ICD-10-CM code - K76.7 Any Position, Stays of 2+ Days Only	170,643
	TOTAL	381,557

The applicant imputed a value of 11 cases for MS–DRGs with a case volume under 11 for use in the weighted average calculations. Using this approach, the applicant identified 318,557 cases mapping to 249 MS–DRGs across the six cohorts. The applicant noted, however, that only 14 MS–DRGs had a case volume ≥ 1% across all cohorts, as shown in the table, and that these MS–DRGs cumulatively represented 77.8% of all cases. The applicant stated that MS–DRG 441 (Disorders of Liver Except Malignancy, Cirrhosis or Alcoholic Hepatitis with MCC) had the highest case volume in each of the six cohorts in the analysis, and that only the first four MS–DRGs listed in the table had a case volume ≥7%.

MS-DRG	Description	% Case Volume
441	Disorders of Liver Except Malignancy, Cirrhosis or Alcoholic Hepatitis with MCC	23.8%
432	Cirrhosis and Alcoholic Hepatitis with MCC	13.5%
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC	12.3%
682	Renal Failure with MCC	7.2%
291	Heart Failure and Shock with MCC or Peripheral Extracorporeal Membrane Oxygenation (ECMO)	3.1%
442	Disorders of Liver Except Malignancy, Cirrhosis or Alcoholic Hepatitis with CC	2.7%
435	Malignancy of Hepatobiliary System or Pancreas with MCC	2.5%
377	G.I. Hemorrhage with MCC	2.5%
005	Liver Transplant with MCC Or Intestinal Transplant	2.3%
853	Infectious and Parasitic Diseases with O.R. Procedure with MCC	2.1%
870	Septicemia or Severe Sepsis with MV >96 Hours	1.9%
371	Major Gastrointestinal Disorders and Peritoneal Infections with MCC	1.5%
673	Other Kidney and Urinary Tract Procedures with MCC	1.2%
981	Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC	1.1%

CC – complication or comorbidity; ECMO – extracorporeal membrane oxygenation; G.I. – gastrointestinal hemorrhage; MCC – major complication or comorbidity; MV – mechanical ventilation; O.R. – operating room

After identifying cases in each of the cohorts, the applicant removed charges for prior technology as follows:

- The applicant subtracted the estimated cost of generic norepinephrine based on HRS–1 dosing regimens, $1,699 (AnalySource 2018 U.S. Pricing), for ICU-only cases (Cohorts 1 and 2).
- The applicant subtracted the estimated cost of midodrine plus octreotide based on HRS–1 dosing regimens, $3,391 (AnalySource 2018 U.S. Pricing), for non-ICU cases (Cohorts 3 and 4).
- The applicant noted that Cohorts 5 and 6 have a mix of both ICU and non-ICU cases. For the ICU cases, the applicant subtracted the estimated cost of generic norepinephrine, $1,699. For non-ICU cases, the applicant subtracted the estimated cost of midodrine plus octreotide, $3,391.

The applicant then standardized the charges across the six cohorts using the FY 2019 impact file in the FY 2022 IPPS/LTCH PPS final rule and correction notice. The applicant presented two scenarios that varied the inflation factor used to update charges from FY 2019. Under the first scenario, the applicant applied the 3-year inflation factor of 20.5% (rounded from 1.204686), which was derived from the inflation factor used to calculate outlier threshold charges in the FY 2022 IPPS/LTCH PPS final rule and correction notice (86 FR 45542), to update the charges from FY 2019 to FY 2022. The applicant asserted that it did not add charges for the new technology, as a price for TERLIVAZ® has not yet been established. Even without the additional charges, the applicant asserted that TERLIVAZ® would meet the cost criterion as the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount across all six cohorts, as summarized in the table.

Cohort	Case-Weighted Threshold	Final Inflated Case-Weighted Standardized Charge
Cohort 1	$71,069	$144,132
Cohort 2	$88,995	$193,687
Cohort 3	$57,341	$63,089
Cohort 4	$64,420	$71,582
Cohort 5	$64,125	$103,160
Cohort 6	$78,597	$141,163
Weighted average	**$77,050**	**$136,886**

Under the second scenario, the applicant applied a 4-year inflation factor of 28.2% (rounded from 1.281834), which was derived from the inflation factor used to calculate outlier threshold charges in the FY 2022 IPPS/LTCH PPS final rule and correction notice (86 FR 45542), to update the standardized charges from FY 2019 to FY 2023. Similar to the first analysis, the applicant did not add charges for the new technology as the applicant asserted that a price for TERLIVAZ® has not yet been established. Again, the applicant asserted that even without the additional charges, TERLIVAZ® would meet the cost criterion as the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount across all six cohorts. We did not receive a weighted average for the final inflated average case-weighted standardized charge per case across the six cohorts for the 4-year inflation factor calculations.

- For Cohort 1, the applicant calculated a final inflated average case-weighted standardized charge per case of $153,342, which exceeded the average case-weighted threshold amount of $71,069.
- For Cohort 2, the applicant calculated a final inflated average case-weighted standardized charge per case of $206,064, which exceeded the average case-weighted threshold amount of $88,995.
- For Cohort 3, the applicant calculated a final inflated average case-

weighted standardized charge per case of $67,120, which exceeded the average case-weighted threshold amount of $57,341.

- For Cohort 4, the applicant calculated a final inflated average case-weighted standardized charge per case of $76,156, which exceeded the average case-weighted threshold amount of $64,420.
- For Cohort 5, the applicant calculated a final inflated average case-weighted standardized charge per case of $109,752, which exceeded the average case-weighted threshold amount of $64,125.
- For Cohort 6, the applicant calculated a final inflated average case-weighted standardized charge per case of $150,184, which exceeded the average case-weighted threshold amount of $78,597.

Because the final inflated average case-weighted standardized charge per case for each of the six cohorts under both scenarios exceeded the average case-weighted threshold amount, the applicant asserted that TERLIVAZ® meets the cost criterion.

We invite public comments on whether TERLIVAZ® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that TERLIVAZ® represents a substantial clinical improvement over existing technologies because (1) it offers a treatment option for HRS–1 patients unresponsive to currently available treatments (for example, midodrine, octreotide, and norepinephrine); and (2) it significantly improves clinical outcomes among HRS–1 patients as compared to placebo as well as currently available treatments.

In support of the claim that the use of TERLIVAZ® offers a treatment option for HRS–1 patients unresponsive to currently available treatments, the applicant cited the results of the CONFIRM trial (ClinicalTrials.gov number, NCT02770716).[455] The CONFIRM study was a randomized (2:1), double-blinded study comparing TERLIVAZ® to placebo in 300 adult patients, 18 years of age or older with HRS–1 (defined as rapidly progressive worsening in renal function to a serum creatinine (SCr) ≥2.25 mg/dL and meeting a trajectory for SCr to double over 2 weeks). TERLIVAZ® or placebo were administered as a 1 mg IV bolus injection every 6 hours for a maximum of 14 days. The primary objective of the study was to confirm the efficacy and safety of TERLIVAZ® versus placebo in the treatment of adult subjects with HRS–1 receiving standard of care albumin therapy. The primary endpoint was the incidence of verified HRS reversal, defined as 2 consecutive serum creatinine values ≤1.5 mg/dL at least 2 hours apart, while on treatment by Day 14 or discharge, whichever came first (on treatment defined as up to 24 hours after the final dose of study drug). To be counted in the primary endpoint, patients needed to be alive without RRT for at least 10 days after achieving verified HRS reversal. The secondary endpoints were as follows: HRS reversal, defined as a serum creatinine level of 1.5 mg per deciliter or less; durability of HRS reversal, defined as HRS reversal without renal-replacement therapy to day 30; HRS reversal among patients with systemic inflammatory response syndrome (SIRS); and verified reversal of HRS without recurrence of HRS by day 30. The applicant explained that patient enrollment criteria for the CONFIRM trial included cirrhosis, ascites, and rapidly progressive kidney failure, with a doubling of the serum creatinine level to at least 2.25 mg per deciliter (199 μmol per liter) within 14 days before randomization.

The applicant stated that patients were excluded if they had a sustained reduction in the serum creatinine level of more than 20% or a decrease to below 2.25 mg per deciliter at least 48 hours after diuretic withdrawal and albumin infusions. The applicant explained that approximately three fourths of the study patients in the CONFIRM trial had received vasopressors prior to randomization and did not respond; these included midodrine, octreotide, and/or norepinephrine. The applicant stated that out of a total of 121 patients, 60 patients (61%) in the TERLIVAZ® group and 61 patients (60%) in the placebo group, had previously received midodrine and octreotide and had failed on that combination before entering the study. Therefore, the applicant explained that well over half of the patients treated in the CONFIRM trial were unresponsive to currently available (off-label) treatment options—the option often used in the ICU setting (norepinephrine) and the options typically used to treat patients on the general medical ward (midodrine and/or octreotide).

In support of the claim that the use of TERLIVAZ® significantly improves clinical outcomes among HRS–1 patients as compared to the currently available treatments, the applicant stated that TERLIVAZ® is associated with a more rapid resolution of the disease process and a reduced rate of mortality compared to placebo, midodrine and octreotide, and norepinephrine. The applicant also stated that the use of TERLIVAZ® is associated with a decreased rate of several subsequent diagnostic or therapeutic interventions, compared with placebo, and that the overall benefit-risk profile of TERLIVAZ® as a treatment for HRS–1 is favorable.

In support of the claim that the use of TERLIVAZ® is associated with a more rapid resolution of the disease process and a reduced rate of mortality compared to placebo, the applicant cited results from the CONFIRM study, previously described, as a well as an abstract of a post-hoc analysis done by Mujtaba et al. on outcomes with TERLIVAZ® in older patients aged ≥65 years.[456] [457] The applicant stated that the incidence of verified HRS reversal was 32% in the TERLIVAZ® (treatment) group and 17% in the placebo (control) group (p=0.006). According to the applicant, the incidence of subjects with the pre-specified secondary endpoint of HRS reversal was 36.2% in the treatment group and 16.8% in the control group (p<0.001). According to the applicant, the incidence of verified HRS reversal without HRS recurrence by Day 30 was 24.1% in the treatment group and 15.8% in the control group (p=0.092). The applicant stated that in the intent-to-treat (ITT) population for patients at least 65 years old, 34.3% of the patients in the TERLIVAZ® group demonstrated the pre-specified secondary endpoint of HRS reversal compared to 16.7% patients in the placebo group.

The applicant noted that the durability of HRS reversal was 31.7% in the treatment group and 15.8% in the control group (p=0.003). In addition, the applicant stated that TERLIVAZ® provided greater durability of HRS reversal in HRS–1 patients who were at least 65 years of age, and that in the ITT population, 31.4% of patients in the TERLIVAZ® arm achieved durable HRS reversal compared to 16.7% in the placebo arm.

The applicant stated that TERLIVAZ® provided greater benefit in HRS–1 patients with SIRS and that the incidence of HRS reversal in the SIRS subgroup was 33.3% (n=28) in the treatment group and 6.3% (n=3) in the control group (p <0.001). In addition,

[454] Sarin S, Sharma P. Terlipressin: An Asset for Hepatologists! Hepatology. 2011;54(2):724–728.

[456] Ibid.

[457] Mujtaba M, Gamilla-Cruda AK, Jamil K, et al. Terlipressin, in Combination with Albumin, Is an Effective Therapy for Hepatorenal Syndrome Type 1 in Patients Aged ≥65 Years. Abstract to be submitted to NKF by November 30, 2021 for presentation at the NKF Spring Clinical Meeting (April 6–10, 2022).

the applicant stated that TERLIVAZ® provided greater benefit in HRS–1 patients with SIRS who were at least 65 years of age, and that in the ITT population, 23.1% of patients with SIRS in the TERLIVAZ® arm achieved HRS reversal compared to 0.0% in the placebo arm.[458]

The applicant also reported that overall survival up to Day 90 was higher in subjects who achieved verified HRS reversal or HRS reversal while receiving treatment than in those who did not (p<0.001). The applicant stated that by Day 90, death occurred in 101 patients (51%) in the TERLIVAZ® group and in 45 patients (45%) in the placebo group (6% difference, 95% CI, −6 to 18). The applicant stated that overall survival was not a primary or secondary endpoint in the CONFIRM trial as the prognosis of patients with HRS–1 is poor, with a reported median survival of ≤ 3 months. The applicant stated that aggregate, published studies and meta-analyses suggest that TERLIVAZ® treatment is likely associated with improved survival for HRS–1 as a cause of death, but not for other causes of death.[459] [460] The applicant also stated that given the high overall mortality in the study population, a total of 146 patients (48.8%) died during the CONFIRM trial.[461] The applicant explained that while TERLIVAZ® improves renal function, patients with end stage liver disease nonetheless may continue to experience and die from other complications of end stage liver disease, unrelated to HRS–1. The applicant further explained that the CONFIRM trial was not powered to show a statistical difference in survival. However, the applicant stated that the TERLIVAZ® plus albumin arm in CONFIRM had a significantly better verified response rate than the albumin arm, and that better response confers better prognosis in these patients.[462] The applicant also mentioned that similar results were seen in previous North American and European trials with TERLIVAZ®.[463] [464] [465]

To support its claim that the use of TERLIVAZ® is associated with a more rapid resolution of the HRS–1 disease process and a reduced rate of mortality compared to norepinephrine, the applicant cited a study conducted by Arora et al.[466] This study was an open-label, randomized controlled trial conducted as a single-center study in India. The study compared a continuous infusion of TERLIVAZ® and albumin to a continuous infusion of norepinephrine and albumin in the management of HRS–AKI in patients with a diagnosis of acute chronic liver failure (ACLF). Patients were randomized to receive either TERLIVAZ® or norepinephrine in a 1:1 ratio.[467] ACLF is a distinct diagnosis where, because of severe acute hepatic injury, a rapid loss of liver function develops in a patient with previous chronic liver disease. In this study, ACLF was defined as an acute hepatic insult manifesting as jaundice (serum bilirubin ≥5 mg/dL) and coagulopathy (international normalized ratio [INR] ≥1.5) complicated within 4 weeks by ascites and/or encephalopathy in a patient with previously diagnosed or undiagnosed CLD or cirrhosis. HRS–AKI was defined as ICA–AKI stage ≥II when other causes of AKI were excluded and the patient was nonresponsive to volume expansion with intravenous albumin.

A total of 120 patients were randomized; 60 patients were allocated to the intention to treat group for both the TERLIVAZ® and norepinephrine arms. Adverse events requiring discontinuation of the drug were reported in 9 of 60 (15%) patients in the TERLIVAZ® arm compared to 5 of 60 (8.3%) in the norepinephrine arm (P=0.39). These events included diarrhea, abdominal pain, atrial fibrillation, cyanosis, and chest pain in the TERLIVAZ® arm. In the norepinephrine arm, patients experienced the previously mentioned adverse events as well as ventricular premature complex (VPCs) and hypertension. The per protocol analysis included 51 patients in the TERLIVAZ® arm and 55 patients in the norepinephrine arm. A response rate of 56% for TERLIVAZ®, a response rate of 43% for norepinephrine, and a 10% noninferiority margin was assumed. For an alpha level of 5% and power of 80%, it was determined that 57 patients were needed in each arm.

According to the applicant, the results showed that a higher percentage of patients achieved HRS reversal at day 14 (primary endpoint) in the TERLIVAZ® group compared to the norepinephrine group in both the ITT analysis and per protocol analysis (PPA) (ITT 40% (n=24) vs. 16.7% (n=10), p=0.004; PPA 43.1% (n=22) vs. 16.3% (n=9), p=0.002). Complete response was defined as return of serum creatinine to a value within 0.3 mg/dL of baseline. The applicant also stated that patients in the TERLIVAZ® group had higher 28-day survival compared to the norepinephrine group (48% versus 20%, respectively; p=0.001).

In support of its claims that TERLIVAZ® is associated with a more rapid resolution of the HRS–1 disease process and a reduced rate of mortality compared to midodrine and octreotide, the applicant summarized the results of the Cavallin et al. study,[468] which compared TERLIVAZ® plus albumin versus midodrine and octreotide (MID/OCT) plus albumin in a multi-center randomized controlled trial. The applicant stated that 27 patients were randomized to receive TERLIVAZ® with albumin and 22 to receive MID/OCT plus albumin. Patients in the study were from eight hospitals in Italy. The researchers hypothesized a response rate of 60% for TERLIVAZ® and of 30% for MID/OCT, with an alpha error of 5% and power of 80%. An interim analysis after enrolling half the sample set a stopping rule for the randomized clinical trial if the difference in renal function recovery was significant at p<0.01. The study was terminated after 49 patients were enrolled according to the a priori determined stopping rule.

The applicant stated that the results showed improvement of renal function was significantly more frequent in patients randomized to the TERLIVAZ® group compared to patients randomized to the MID/OCT group; 70.4% of

[458] Ibid.

[459] Hiremath SB, Srinivas LD. Survival benefits of terlipressin and non-responder state in hepatorenal syndrome: A meta-analysis. Indian J Pharmacol. 2013;45(1):54–60.

[460] Facciorusso A, Chandar AK, Murad MH, et al. Comparative efficacy of pharmacological strategies for management of type 1 hepatorenal syndrome: A systematic review and network meta-analysis. Lancet Gastroenterol Hepatol. 2017; 2: 94–102.

[461] Wong F, Pappas, S.C, Curry M.P, et al. Terlipressin plus Albumin for the Treatment of Type 1 Hepatorenal Syndrome. New England Journal of Medicine. 2021;384(9):818–828. doi: 10.1056/NEJMoa2008290.

[462] Wong F, Pappas, S.C, Curry M.P, et al. Terlipressin plus Albumin for the Treatment of Type 1 Hepatorenal Syndrome. New England Journal of Medicine. 2021;384(9):818–828. doi: 10.1056/NEJMoa2008290.

[463] Sanyal A, Boyer T, Garcia-Taso G, et al. A Randomized, Prospective, Double-Blind, Placebo-Controlled Trial of Terlipressin for Type 1 Hepatorenal Syndrome. Gastroenterology. 2008;134(5):1360–1368.

[464] Martin-Llahi M, Pepin MN, Guevara M, et al. Terlipressin and albumin vs. albumin in patients with cirrhosis and hepatorenal syndrome: A randomized study. Gastroenterology. 2008;134:1352–1359.

[465] Boyer T, Sanyal A, Wong F, et al. Terlipressin Plus Albumin is More Effective Than Albumin Alone in Improving Renal Function in Patients with Cirrhosis and Hepatorenal Syndrome Type 1. Gastroenterology. 2016;150:1579–1589.

[466] Arora V, Maiwall R, Rajan V, et al. Terlipressin Is Superior to Noradrenaline in the Management of Acute Kidney Injury in Acute on Chronic Liver Failure. Hepatology. 2020;71(2):600–610.

[467] Ibid.

[468] Cavallin M, Kamath PS, Merli M, et al. Terlipressin plus albumin versus midodrine and octreotide plus albumin in the treatment of hepatorenal syndrome: A randomized trial. Hepatology. 2015;62:567–574.

patients in the TERLIVAZ® group had a complete or partial response compared with 28.6% in the MID/OCT group (p=0.01); 55.5% of patients in the TERLIVAZ® group had a complete response compared with 4.8% of the MID/OCT group (p<0.001). Complete response was defined as a decrease in serum creatinine to ≤133 mmol/L (≤1.5 mg/dL). Partial response was defined as a ≥50% serum creatinine decrease from baseline to a final value >133 mmol/L (>1.5 mg/dL). No response was defined as a serum creatinine decrease of <50% from baseline. The applicant stated that mean arterial pressure (MAP) was significantly higher in the TERLIVAZ® group compared to the MID/OCT group after 3 days of treatment as well as at the midpoint of the treatment period.

The applicant also stated that response to treatment (complete or partial) was found to be a predictor of 3-month survival in the univariate analysis. The difference in cumulative survival between all responders (partial and full responders) and nonresponders was statistically significant in the TERLIVAZ® group (P<0.001) but not in the MID/OCT group. Some nonresponders to the assigned treatment received a rescue treatment according to the treating physician's decision. Seven of 12 (58.3%) nonresponders in the MID/OCT group received a rescue treatment: Six received TERLIVAZ® plus albumin, and one received dialysis. An improvement of renal function was observed in five of six patients (83.3%) who received TERLIVAZ® plus albumin. Four patients had a complete response and one patient had a partial response. The applicant stated that in patients who did not receive any rescue treatment, the TERLIVAZ® group had a higher 3-month survival rate than the MID/OCT group (55.5% vs. 28.6%, P=0.06).

In support of its claim that TERLIVAZ® is associated with a decreased rate of subsequent diagnostic or therapeutic interventions, compared with placebo, the applicant cited the results of the CONFIRM trial. The applicant noted that there was a lower incidence of RRT through the treatment period (14 days) in patients receiving TERLIVAZ® (23.1% (n=46)) versus the placebo (34.7% (n=35)) (p=0.03).[469]

In addition, according to the applicant, based on the ITT population for the integrated studies for patients at least 65 years old (TERLIVAZ® n=54; placebo n=36), there was a favorable trend of lower incidence of RRT in the subsequent follow-up periods: (1) The use of RRT/dialysis by Day 30 visit was 25.9% (n=14) in TERLIVAZ®-treated patients vs. 44.4% in placebo-treated patients; (2) the use of RRT/dialysis by Day 60 visit was 27.8% in TERLIVAZ®-treated patients vs. 44.4% in placebo-treated patients; and (3) the use of RRT/dialysis by Day 90 visit was 29.6% in TERLIVAZ®-treated patients vs. 47.2% in placebo-treated patients.[470]

The applicant also stated that there was a decreased incidence of RRT after liver transplant in patients treated with TERLIVAZ® (19.6% (n=46)) versus 44.8% (n=29) in the placebo group (p=0.04).[471] The applicant stated that the need for RRT post-transplant is predictive of poor graft function and survival.[472] The applicant stated that in the ITT population, 0 of 8 TERLIVAZ®-treated patients 65 years and older who received liver transplant required RRT and 5 of 6 placebo-treated patients 65 years and older who received liver transplant required RRT.[473]

The applicant also claimed that patients receiving TERLIVAZ® in the CONFIRM trial had shorter lengths of hospitalizations and ICU stays compared to those in the placebo group. The applicant stated that in the ITT population for patients at least 65 years old, the median number of days for hospital length of stay was 18 for TERLIVAZ®-treated patients and 25.5 for placebo-treated patients.[474] In addition, the applicant stated that patients in the TERLIVAZ® group stayed an average of 6.4 days in the ICU versus 13.2 days in the placebo group.[475] The applicant explained that, while in CONFIRM, the overall incidence of admission to ICU was similar in both cohorts given the severe multiple pre-existing comorbidities in patients with decompensated cirrhosis, and that by addressing one severe complication (HRS–1), TERLIVAZ® facilitates management of these patients and reduces the burden of critical care management.

The applicant also asserted that the overall benefit-risk profile of TERLIVAZ® as a treatment for HRS–1 is favorable. In support of this assertion, the applicant cited the results of the CONFIRM trial. The applicant noted that the overall incidence of adverse events (AEs) and serious adverse events (SAEs) were similar between patients receiving TERLIVAZ® (n=200) and those receiving placebo (n=99).[476] The applicant stated that 88.0% (n=176) of patients receiving TERLIVAZ® reported AEs versus 88.9% (n=88) in the placebo group, and that 65.0% (n=130) of patients receiving TERLIVAZ® reported SAEs versus 60.6% (n=60) in the placebo group. The applicant also stated that: (1) The overall incidence of AEs was similar between groups: 91.1% in the TERLIVAZ® group and 90.4% in the placebo group; (2) the incidence of SAEs was similar between groups: 65.0% in the TERLIVAZ® group and 59.8% in the placebo group; and (3) mortality up to 30 days after first treatment was 41.5% in the TERLIVAZ® group and 40.6% in the placebo group.[477]

The applicant stated that, with appropriate labeling to help prevent administration to patients who are known to be at higher risk for SAEs, TERLIVAZ® has an acceptable safety profile for patients at least 65 years old, a high-morbidity patient population. The applicant explained that the safety profile of TERLIVAZ® is well-characterized, with the majority of AEs being predictable, recognizable, and generally manageable in the hospital setting where HRS–1 patients are treated. The applicant further stated that most of the events observed in the company-sponsored clinical studies were expected based on TERLIVAZ®'s V1-receptor activity and consistent with the known experience with TERLIVAZ® outside the US. Regarding the increased risk of serious or fatal respiratory failure, the applicant stated that TERLIVAZ® should not be administered in patients with pulmonary edema,

[469] Jamil, K. Terlipressin, a New Investigational Drug for the Treatment of Hepatorenal Syndrome Type 1. Presented at: New Technology Town Hall Meeting; December 16, 2019; Centers for Medicare & Medicaid Services; Baltimore, MD.

[470] Mujtaba M, Gamilla-Cruda AK, Jamil K, et al. Terlipressin, in Combination with Albumin, Is an Effective Therapy for Hepatorenal Syndrome Type 1 in Patients Aged ≥65 Years. Abstract to be submitted to NKF by November 30, 2021 for presentation at the NKF Spring Clinical Meeting (April 6–10, 2022).

[471] Jamil, K. Terlipressin, a New Investigational Drug for the Treatment of Hepatorenal Syndrome Type 1. Presented at: New Technology Town Hall Meeting; December 16, 2019; Centers for Medicare & Medicaid Services; Baltimore, MD.

[472] Watt KDS, Pedersen RA, Kremers WK, et al. Evolution of Causes and Risk Factors for Mortality Post-Liver Transplant: Results of the NIDDK Long-Term Follow-Up Study. Am. J. Transplant. 2010;10(6)1420–1427.

[473] Mujtaba M, Gamilla-Cruda AK, Jamil K, et al. Terlipressin, in Combination with Albumin, Is an Effective Therapy for Hepatorenal Syndrome Type 1 in Patients Aged ≥65 Years. Abstract to be submitted to NKF by November 30, 2021 for presentation at the NKF Spring Clinical Meeting (April 6–10, 2022).

[474] Ibid.

[475] Jamil, K. Terlipressin, a New Investigational Drug for the Treatment of Hepatorenal Syndrome Type 1. Presented at: New Technology Town Hall Meeting; December 16, 2019; Centers for Medicare & Medicaid Services; Baltimore, MD.

[476] Ibid.

[477] Mallinckrodt Hospital Products Inc. Terlipressin Briefing Document. NDA # 022231. Cardiovascular and Renal Drugs Advisory Committee, July 15, 2020. U.S. Food and Drug Administration. *https://www.fda.gov/media/139965/download.* Accessed September 10, 2020.

pneumonia, dyspnea, or tachypnea until events resolve. The applicant explained that patients with ACLF grade 3 are at significant risk of respiratory failure and fluid overload must be actively managed. Regarding increased mortality in patients with SCr ≥5 mg/dL, the applicant explained that the use of TERLIVAZ® with these patients should be considered only when the anticipated benefit to the patient outweighs the potential risk.

In support of the claim that TERLIVAZ® represents a substantial clinical improvement over existing technologies, based on real-world usage, the applicant noted that TERLIVAZ is the vasoconstrictor of choice for HRS–1 in much of the rest of the world, where it is approved and available due to its direct effect in reversing the fundamental hemodynamic pathophysiology of HRS–1. The applicant stated that both the EASL [478] and the American Association for the Study of Liver Diseases (AASLD) [479] recommend TERLIVAZ® plus albumin as the first-line treatment for the reversal of HRS–1, while other treatment options should only be used if TERLIVAZ® is not available.

The applicant also described a meta-analysis study identifying a total of 377 patients from eight eligible studies, from which the authors found that: (1) TERLIVAZ® reduced the all-cause mortality rate by 15% (Risk Difference: −0.15%, 95% CI: −0.26 to −0.03); and (2) the reduction in the mortality rate due to HRS at three months was 9% (Risk Difference: −0.09%, 95% CI: −0.18 to 0.00).[480] According to the applicant, the authors concluded that TERLIVAZ® has long-term survival benefits of at least up to three months, but only with HRS as a cause of death, not for other causes of death.[481]

In addition, the applicant cited a study by Moore et al. of real-world treatment patterns and outcomes using TERLIVAZ® in 203 patients with HRS–1/HRS-acute kidney injury (AKI) in the United Kingdom.[482] The applicant stated that the authors found that the vast majority of patients with a clinical diagnosis of HRS–AKI were treated with TERLIVAZ® in the United Kingdom, consistent with EASL guidelines. The applicant stated that approximately 50% of patients treated with TERLIVAZ® in the study achieved a complete response, with an additional 23% experiencing partial response, and that initiation of TERLIVAZ® at lower serum creatinine levels was associated with higher rates of treatment response. The applicant stated that complete or partial response to TERLIVAZ® was associated with a higher rate of 90-day survival.

Finally, the applicant asserted that TERLIVAZ® represents a substantial clinical improvement because the totality of the circumstances demonstrates that TERLIVAZ® substantially improves, relative to technologies previously available, the treatment of Medicare beneficiaries. The applicant stated that HRS–1 is a serious, life-threatening condition characterized by development of acute or sub-acute renal failure in patients with advanced CLD. The applicant further emphasized that HRS–1 is the leading cause of hospitalizations among all patients with advanced CLD; therefore, inpatient care management of patients with HRS–1 is time and resource intensive, representing a significant cost to hospitals.[483] Finally, the applicant reiterated that upon FDA approval, TERLIVAZ® will be the only FDA-approved drug for the HRS–1 indication that aligns with the EASL treatment guidelines for HRS–1 and that TERLIVAZ® has now been recommended in guidance from AASLD as first-line treatment for HRS reversal.[484]

After review of the information provided by the applicant, we have the following concerns regarding whether TERLIVAZ® meets the substantial clinical improvement criterion. As we noted in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25344), in the CONFIRM trial the proportion of patients with verified HRS reversal without HRS–1 recurrence by Day 30 was numerically greater in the TERLIVAZ® arm than placebo; however, the difference between groups was not statistically significant (26% vs 17%, p=0.08) [485] and we note that the potential for HRS–1 recurrence among patients treated with TERLIVAZ® after 30 days is unclear. We also noted in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25344) that, although the applicant claimed a reduction in mortality with the use of TERLIVAZ®, the mortality rate at Day 90 was higher in the TERLIVAZ® group vs. the placebo group (51% vs. 45%).[486] We further noted in the FY 2022 IPPS/LTCH PPS proposed rule that the applicant states that survival was not defined as a primary or secondary analysis in the CONFIRM trial and that no overall survival benefit was observed in the CONFIRM trial because survival is confounded by multiple comorbidities in patients with HRS–1.[487]

In addition, we noted in the FY 2022 IPPS/LTCH PPS proposed rule that the primary endpoint of the CONFIRM trial used a surrogate endpoint of serum creatinine as an indicator of HRS reversal, and we questioned whether this correlates to improvements in clinical outcomes such as mortality and time to transplant (86 FR 25344). We also question whether mortality would be a more appropriate endpoint than HRS reversal to demonstrate substantial clinical improvement in clinical outcomes. We note that we were unable to verify the following claims made by the applicant about the ITT population for the integrated studies involving patients at least 65 years old, based on the submitted abstract for Mujtaba et al: (1) That there was a greater benefit in these HRS–1 patients with SIRS, (2) that there was a favorable trend of lower incidence of RRT in these patients, and (3) that there was a shorter median number of days for hospital length of stay in these patients.[488]

With regard to the applicant's claims regarding a similar incidence of AEs and SAEs between groups in the CONFIRM trial, we noted in the FY 2022 IPPS/LTCH PPS proposed rule that the results show that the TERLIVAZ® arm had a higher incidence of SAEs up to 30 days

[478] Angeli P, Bernardi M, Villanueva C, et al. EASL Clinical Practice Guidelines for the management of patients with decompensated cirrhosis. J Hepatol. 2018;69(2):406–460.

[479] Biggins S, Angeli P, Garcia-Tsao G, et al. Diagnosis, Evaluation, and Management of Ascites, Spontaneous Bacterial Peritonitis and Hepatorenal Syndrome: 2021 Practice Guidance by the American Association for the Study of Liver Diseases. Hepatology. 2021;74(2):1014–1048. doi:10.1002/hep.31884.

[480] Hiremath SB, Srinivas LD. Survival benefits of terlipressin and non-responder state in hepatorenal syndrome: A meta-analysis. Indian J Pharmacol. 2013;45(1):54–60.

[481] Ibid.

[482] Moore K, Jamil K, Verleger K, et al. Real-world treatment patterns and outcomes using terlipressin in 203 patients with the hepatorenal syndrome. Aliment Pharmacol. Ther. 2020;00:1–8. doi: 10.1111/apt.15836.

[483] Jamil K, Huang X, Lovelace B, et al. The Burden of Illness of Hepatorenal Syndrome (HRS) in the United States: A Retrospective Analysis of Electronic Health Records. Journal of Medical Economics. 2019;22(5):421–430.

[484] Angeli P, Bernardi M, Villanueva C, et al. EASL Clinical Practice Guidelines for the management of patients with decompensated cirrhosis. Journal of Hepatology. 2018;69(2):406–460.

[485] Wong F, Pappas, S.C, Curry M.P, et al. Terlipressin plus Albumin for the Treatment of Type 1 Hepatorenal Syndrome. New England Journal of Medicine. 2021;384(9):818–828. doi: 10.1056/NEJMoa2008290.

[486] Ibid.

[487] Ibid.

[488] Mujtaba M, Gamilla-Cruda AK, Jamil K, et al. Terlipressin, in Combination with Albumin, Is an Effective Therapy for Hepatorenal Syndrome Type 1 in Patients Aged ≥65 Years. Abstract to be submitted to NKF by November 30, 2021 for presentation at the NKF Spring Clinical Meeting (April 6–10, 2022).

post-treatment (65% of patients receiving TERLIVAZ® reported SAEs vs. 60.6% in the placebo group) related to respiratory failure, serious infections such as sepsis and septic shock, GI bleeding, and abdominal pain[489] (86 FR 25344).

Additionally, we note that death within 90 days due to respiratory disorders occurred in 11% of patients in the TERLIVAZ® group and 2% of patients in the placebo group.[490] Regarding the study conducted by Arora et al., we noted in the FY 2022 IPPS/LTCH PPS proposed rule that this study had an open-label design and included patients with a diagnosis of ACLF as well as HRS–AKI, which may have contributed to the differences observed between the TERLIVAZ® arm and the norepinephrine arm in this study[491] (86 FR 25344). Finally, in the FY 2022 IPPS/LTCH PPS proposed rule, we noted that the results of the Cavallin et al. study submitted by the applicant in support of a substantial clinical improvement over midodrine and octreotide show that there was no survival benefit for the TERLIVAZ® group at months one and three[492] (86 FR 25344).

We are inviting public comments on whether TERLIVAZ® meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for TERLIVAZ®.

k. Treosulfan

Medexus Pharma, Inc. submitted an application for new technology add-on payments for treosulfan for FY 2023. According to the applicant, treosulfan is a prodrug of a bifunctional alkylating agent that is being studied in combination with fludarabine as a preparative regimen for allogenic hematopoietic stem cell transplantation (alloHSCT) in patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS).

The applicant stated that the goal of alloHSCT is to cure patients of their disease by replacing their hematopoietic stem cells (that is, bone marrow stem cells) with stem cells from a healthy related or unrelated donor. The applicant noted that preparative or conditioning treatments are often used to (1) eradicate existing bone marrow tissue to provide space for engraftment of transplanted donor stem cells, (2) prevent rejection of the incoming donor stem cells by host immune cells, and (3) help eradicate existing disease, and that this type of preparation is needed for the alloHSCT process. The applicant explained that there are two types of conditioning regimens, myeloablative conditioning (MAC) and reduced intensity conditioning (RIC). According to the applicant, while standard MAC regimens generally lead to low relapse rates, they are associated with high treatment-related toxicity and transplantation-related mortality (TRM). Thus, patients who are not eligible for MAC regimens due to these risks (for example, the elderly and patients with comorbidities) usually receive a RIC regimen. The applicant described a recent study of patients with acute myeloid leukemia,[493] where RIC resulted in lower treatment related mortality but higher relapse rates compared with MAC, with a statistically significant advantage in relapse-free survival with MAC. However, the applicant stated that certain patients are unable to tolerate MAC, therefore according to the applicant, treosulfan was developed in an effort to address the significant unmet medical need for improved alloHSCT conditioning regimens that can reduce treatment-related toxicity and the risk of TRM without increasing the incidence of relapse. Per the applicant, treosulfan's immunosuppressive effects are due to its toxicity against primitive and committed progenitor cells, T and NK cells, reduction of cellularity of primary and secondary lymphatic organs and a preclusive effect on the 'cytokine storm' that precedes the development of graft-versus-host disease (GVHD). The applicant stated that these events are involved in the pathogenesis of hepatic sinusoidal obstruction syndrome (HSOS).

With respect to the newness criterion, the applicant stated that FDA is still reviewing treosulfan's NDA which has a proposed indication for: (1) Use in combination with fludarabine as a preparative regimen for alloHSCT in adult and pediatric patients older than one year with AML; and (2) use in combination with fludarabine as a preparative regimen for alloHSCT in adult and pediatric patients older than one year with MDS. According to the applicant, FDA approval is anticipated by June 30, 2022. The applicant stated that the drug is designed to be administered intravenously and must be reconstituted prior to infusion. While not yet FDA approved, the applicant noted that the recommended dosage of treosulfan for adult patients is anticipated to be 10 grams per square meter ($10g/m^2$) of body surface area (BSA) per day of treatment, given as a two-hour intravenous infusion, and with treatment provided on three consecutive days (day -4, -3, -2) in conjunction with fludarabine before hematopoietic stem cell infusion (which occurs on day 0).

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify procedures involving the administration of treosulfan. The applicant submitted a request for approval for a unique ICD–10–PCS code for procedures involving the administration of treosulfan beginning in FY 2023. The applicant also stated that the following ICD–10 CM diagnosis codes are potentially applicable for the proposed AML and MDS indications that FDA is currently reviewing:

BILLING CODE 4120–01–P

[489] Ibid.

[490] Ibid.

[491] Arora V, Maiwall R, Rajan V, et al. Terlipressin Is Superior to Noradrenaline in the Management of Acute Kidney Injury in Acute on Chronic Liver Failure. Hepatology. 2020;71(2):600–610.

[492] Cavallin M, Kamath PS, Merli M, et al. Terlipressin plus albumin versus midodrine and octreotide plus albumin in the treatment of hepatorenal syndrome: A randomized trial. Hepatology. 2015;62:567–574.

[493] Scott, BL et al. 2017. Myeloablative Versus Reduced-Intensity Hematopoietic Cell Transplantation for Acute Myeloid Leukemia and Myelodysplastic Syndromes. J. Clin Oncology 11: 1154.

ICD-10-CM	DESCRIPTION
C92 Myeloid Leukemia	
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.01	Acute myeloblastic leukemia, in remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.42	Acute promyelocytic leukemia, in relapse
C92.50	Acute myelomonocytic leukemia, no having achieved remission
C92.51	Acute myelomonocytic leukemia, in remission
C92.52	Acute myelomonocytic leukemia, in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality, not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality, in remission
C92.62	Acute myeloid leukemia with 11q23-abnormality, in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C92.A1	Acute myeloid leukemia with multilineage dysplasia, in remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia, in relapse
C92.90	Myeloid leukemia, unspecified
C92.91	Myeloid leukemia, unspecified in remission
C92.92	Myeloid leukemia, unspecified in relapse
C92.Z0	Other myeloid leukemia not having achieved remission
C92.Z1	Other myeloid leukemia, in remission
C92.Z2	Other myeloid leukemia, in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.01	Acute monoblastic/monocytic leukemia, in remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C93.9	Monocytic leukemia, unspecified
C93.Z0	Other monocytic leukemia not having achieved remission
C93.Z1	Other monocytic leukemia, in remission
C93.Z2	Other monocytic leukemia, in relapse
C94.0	Acute erythroid leukemia
C94.02	Acute erythroid leukemia, in relapse
C94.20	Acute megakaryoblastic leukemia not having achieved remission
C94.21	Acute megakaryoblastic leukemia, in remission
C94.22	Acute megakaryoblastic leukemia, in relapse
C94.30	Mast cell leukemia not having achieved remission
C94.31	Mast cell leukemia, in remission
C94.32	Mast cell leukemia, in relapse
C94.40	Acute panmyelosis with myelofibrosis not having achieved remission
C94.41	Acute panmyelosis with myelofibrosis, in remission
C94.42	Acute panmyelosis with myelofibrosis, in relapse
C94.6	Myelodysplastic disease, not classified
C95.9	Leukemia, unspecified
C95.90	Leukemia, unspecified not having achieved remission
C95.91	Leukemia, unspecified, in remission
C95.92	Leukemia, unspecified, in relapse
D46 Myelodysplastic Syndromes	
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.22	Refractory anemia with excess of blasts 2
D46.4	Refractory anemia, unspecified
D46.9	Myelodysplastic syndrome, unspecified
D46.Z	Other myelodysplastic syndromes

BILLING CODE 4120–01–C

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be

considered substantially similar to an existing technology and would not be considered new for the purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant stated that treosulfan does not use the same or similar mechanism of action to achieve a therapeutic outcome as compared to existing busulfan- and melphalan-based MAC and RIC regimens. The applicant stated that treosulfan differs from both busulfan and melphalan in that it is a separate chemical entity that is pending FDA review for a fully separate and distinct New Drug Application. The applicant further stated that treosulfan differs from other alkylating agents in that it is a prodrug activated under specific pH conditions and that it has its own distinct cytotoxic activity toward hematopoietic precursor cells. The applicant described the pH-dependent conversion into a mono-epoxide intermediate and L-diepoxybutan. The applicant stated that the epoxides form alkylate and cross-link nucleophilic centers of deoxyribonucleic acid (DNA) and other biological molecules, which are involved in various physiological functions, and the alkylation and cross-linking are considered responsible for the stem cell depleting, immune-suppressive and antineoplastic effects of the epoxides. The applicant stated that treosulfan exerts broad antineoplastic and antileukemic activity. In further support of its assertion that treosulfan has a different mechanism of action, the applicant cited an in vitro to in vivo extrapolation (IVIVE) study modeling its potential for drug interactions.[494]

The applicant further stated that treosulfan-based conditioning regimens differ significantly from existing conditioning regimens that commonly utilize busulfan and melphalan. The applicant stated that MAC treatments typically include high-dose TBI and high-dose chemotherapy-based regimens, while in RIC treatments, cytotoxic components of the regimen are reduced or replaced with less toxic but immunosuppressive agents. The applicant noted that busulfan and melphalan are typically the mainstays of MAC chemotherapy-based regimens, while fludarabine combined with busulfan or melphalan is commonly used in RIC regimens.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that treosulfan would be assigned to the same MS–DRG as other agents used for conditioning/preparative treatments, MS–DRG 014 (Allogeneic Bone Marrow Transplant) because, in a majority of cases, it is anticipated that a patient would undergo the treosulfan-based conditioning regimen during the same inpatient admission as alloHSCT itself.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated that treosulfan is designed to address a broader patient population than existing MAC and RIC treatment regimens by providing access to improved alloHSCT conditioning outcomes for patients who may otherwise be ineligible for MAC regimens (for example, the elderly and patients with comorbidities) due to the increased toxicity of those regimens, without increasing risk of relapse. The applicant stated that treosulfan may also be used as a conditioning regimen appropriate for children with malignant and non-malignant disorders that are indicated for alloHSCT.

In summary, the applicant believes that treosulfan is not substantially similar to other currently available therapies and/or technologies because it uses a new mechanism of action and treats a broader patient population as compared to existing technologies and therefore, the technology meets the ''newness'' criterion. However, we have the following concerns regarding whether treosulfan meets the newness criterion. We note that it is unclear how the drug interaction modeling study, and the separate NDA being considered for treosulfan, as cited by the applicant, support the assertion that its mechanism of action is different from other alkylating agents. We note that treosulfan is an alkylating agent like other drugs used in myeloablative conditioning such as busulfan and melphalan. Specifically, treosulfan appears to be structurally similar to busulfan, and we therefore question whether they share a similar mechanism of action. Additionally, we note that the applicant asserts that treosulfan can be used in a broader patient population than that eligible for MAC regimens, without increasing the risk of relapse associated with RIC regimens, but the references presented by the applicant only compare a treosulfan-containing conditioning regimen to another RIC regimen [495] [496] and thus do not demonstrate that treosulfan can be used in different patient populations unable to receive MAC. Specifically, the studies provided by the applicant compare treosulfan to busulfan, both of which are RIC regimens, so this appears to demonstrate that a RIC regimen using treosulfan could be an option for patients who otherwise would have been treated with a busulfan regimen. We are inviting public comments on whether treosulfan is substanially similar to existing technologies and whether treosulfan meets the newness criterion.

With respect to the cost criterion, the applicant presented the following analysis to demonstrate that treosulfan meets the cost criterion. To identify cases representing patients who may be eligible for treatment with treosulfan, the applicant searched the FY 2019 MedPAR dataset from the FY 2022 IPPS/LTCH PPS final rule for claims reporting an ICD–10–PCS procedure code that could potentially be used to identify procedures involving the administration of treosulfan, in conjunction with an ICD–10–CM diagnosis code for AML or MDS. For inclusion in the analysis, the applicant required at least one ICD–10–PCS procedure code and at least one ICD–10–CM diagnosis code from the following tables:

BILLING CODE 4120–01–P

[494] Schaller, S. et al. 2021. Evaluation of the Drug-Drug Interaction Potential of Treosulfan using a Physiologically-Based Pharmacokinetic Modelling Approach. Br. J Clin Pharmacology (first published Sept. 13, 2021), *available at https://bpspubs.onlinelibrary.wiley.com/doi/10.1111/bcp.15081.*

[495] Beelen DW 2019 Treosulfan or busulfan plus fludarabine as conditioning treatment before allogeneic aemopoietic stem cell transplantation for older patients with acute myeloid leukaemia or myelodysplastic syndrome (MC-FludT.14/L): A randomised, non-inferiority, phase 3 trial. The Lancet Haematol *https://doi.org/10.1016/S2352-3026(19)30157-7.*

[496] Beelen D 2019 Final Evaluation of a Clinical Phase III Trial Comparing Treosulfan to Busulfan-Based Conditioning Therapy Prior to Allogeneic Hematopoietic Stem Cell Transplantation of Adult Acute Myeloid Leukemia and Myelodysplastic Syndrome Patients Ineligible to Standard Myeloablative Regimens. Biol Blood Marrow Transplant 25 (2019) S3.

ICD-10-PCS	DESCRIPTION
Central vein, open approach	
30240U2	Transfusion of allogeneic related T-cell depleted hematopoietic stem cells into central vein, open approach
30240U3	Transfusion of allogeneic unrelated T-cell depleted hematopoietic stem cells into central vein, open approach
30240U4	Transfusion of allogeneic unspecified T-cell depleted hematopoietic stem cells into central vein, open approach
30240X2	Transfusion of allogeneic related cord blood stem cells into central vein, open approach
30240X3	Transfusion of allogeneic unrelated cord blood stem cells into central vein, open approach
30240X4	Transfusion of allogeneic unspecified cord blood stem cells into central vein, open approach
30240Y2	Transfusion of allogeneic related hematopoietic stem cells into central vein, open approach
30240Y3	Transfusion of allogeneic unrelated hematopoietic stem cells into central vein, open approach
30240Y4	Transfusion of allogeneic unspecified hematopoietic stem cells into central vein, open approach
Central vein, percutaneous approach	
30243U2	Transfusion of allogeneic related T-cell depleted hematopoietic stem cells into central vein, percutaneous approach
30243U3	Transfusion of allogeneic unrelated T-cell depleted hematopoietic stem cells into central vein, percutaneous approach
30243U4	Transfusion of allogeneic unspecified T-cell depleted hematopoietic stem cells into central vein, percutaneous approach
30243X2	Transfusion of allogeneic related cord blood stem cells into central vein, percutaneous approach
30243X3	Transfusion of allogeneic unrelated cord blood stem cells into central vein, percutaneous approach
30243X4	Transfusion of allogeneic unspecified cord blood stem cells into central vein, percutaneous approach
30243Y2	Transfusion of allogeneic related hematopoietic stem cells into central vein, percutaneous approach
30243Y3	Transfusion of allogeneic unrelated hematopoietic stem cells into central vein, percutaneous approach
30243Y4	Transfusion of allogeneic unspecified hematopoietic stem cells into central vein, percutaneous approach

ICD-10-CM	DESCRIPTION
D46, Myelodysplastic syndromes	
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.22	Refractory anemia with excess of blasts 2
D46.4	Refractory anemia, unspecified
D46.9	Myelodysplastic syndrome, unspecified
D46.Z	Other myelodysplastic syndromes
C92, Myeloid Leukemia	
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.01	Acute myeloblastic leukemia, in remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.42	Acute promyelocytic leukemia, in relapse
C92.50	Acute myelomonocytic leukemia, not having achieved remission
C92.51	Acute myelomonocytic leukemia, in remission
C92.52	Acute myelomonocytic leukemia, in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality, not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality, in remission
C92.62	Acute myeloid leukemia with 11q23-abnormality, in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C92.A1	Acute myeloid leukemia with multilineage dysplasia, in remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia, in relapse
C92.90	Myeloid leukemia, unspecified
C92.91	Myeloid leukemia, unspecified in remission
C92.92	Myeloid leukemia, unspecified in relapse
C92.Z0	Other myeloid leukemia not having achieved remission
C92.Z1	Other myeloid leukemia, in remission
C92.Z2	Other myeloid leukemia, in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission

C93.01	Acute monoblastic/monocytic leukemia, in remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C93.9	Monocytic leukemia, unspecified
C93.Z0	Other monocytic leukemia not having achieved remission
C93.Z1	Other monocytic leukemia, in remission
C93.Z2	Other monocytic leukemia, in relapse
C94.0	Acute erythroid leukemia
C94.02	Acute erythroid leukemia, in relapse
C94.20	Acute megakaryoblastic leukemia not having achieved remission
C94.21	Acute megakaryoblastic leukemia, in remission
C94.22	Acute megakaryoblastic leukemia, in relapse
C94.30	Mast cell leukemia not having achieved remission
C94.31	Mast cell leukemia, in remission
C94.32	Mast cell leukemia, in relapse
C94.40	Acute panmyelosis with myelofibrosis not having achieved remission
C94.41	Acute panmyelosis with myelofibrosis, in remission
C94.42	Acute panmyelosis with myelofibrosis, in relapse
C94.6	Myelodysplastic disease, not classified
C95.9	Leukemia, unspecified
C95.90	Leukemia, unspecified not having achieved remission
C95.91	Leukemia, unspecified, in remission
C95.92	Leukemia, unspecified, in relapse

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Using these case selection criteria, the applicant's search resulted in 549 cases mapping to three MS–DRGs: MS–DRG 014 (Allogeneic Bone Marrow Transplant), MS–DRG 003 (ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures), and MS–DRG 004 (Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck Without Major O.R. Procedures). The applicant noted that they imputed a value of 11 cases for MS–DRGs with a case count lower than 11 for use in the weighted average calculations. The applicant noted that approximately 96% of identified cases were in MS–DRG 014, approximately 2% of identified cases were in MS–DRG 003, and approximately 2% of identified cases were in MS–DRG 004. The applicant stated that the cost threshold would still be exceeded even if the cases from DRGs 003 and 004 were excluded.

The applicant then removed charges for the technology being replaced. According to the applicant, 100% of charges associated with drugs (revenue centers 025X, 026X, and 063X) were removed from the identified claims. The applicant stated that, while some other drugs would still be required for patients treated with treosulfan during their inpatient hospital stay, the applicant removed 100% of total drug charges to be as conservative as possible. Next, the applicant standardized charges using the FY 2022 IPPS/LTCH PPS final rule impact file and applied a 4-year inflation factor (1.281834) based on the inflation factor used in the FY 2022 IPPS/LTCH PPS final rule to calculate outlier threshold charges. As the price of treosulfan has yet to be determined, the applicant did not add charges for the new technology. The applicant indicated that, once the price is determined, it will divide the wholesale acquisition cost (WAC) of treosulfan (per gram) by the national CCR for drugs from the FY 2022 IPPS/LTCH PPS final rule (0.187) to calculate estimated average hospital charges associated with treosulfan. The applicant also noted that no other charges related to the administration of treosulfan are expected to be added.

The applicant calculated a final inflated average case-weighted standardized charge per case of $363,789, which exceeded the average case-weighted threshold amount of $260,833. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that treosulfan meets the cost criterion.

We note that the applicant did not remove claims from PPS-excluded cancer hospitals that can be identified by a ''V'' in the fifth position of their provider number or an ''E'' or ''F'' in the sixth position in their Medicare certification number. We further note that many HSCTs are done by cancer centers not paid under IPPS and typically have higher charges, which may inflate the cost calculation. Since these hospitals are not paid under IPPS, their claims should not be included in the calculation of the charges for cases. We believe estimates from an analysis excluding PPS-exempt hospitals would be more appropriate for this cost analysis. Finally, we also note that the leukemia patients in treosulfan's clinical evidence [497] were in remission and posit that codes only specifying remission should be included in the cost analysis. We invite public comments on whether treosulfan meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that treosulfan represents a substantial clinical improvement over existing technologies because it was designed to provide access to improved alloHSCT conditioning outcomes for patients that may otherwise be ineligible for MAC regimens due to its increased toxicity (for example, the elderly and patients with comorbidities), without the increased risk of relapse that is demonstrated to occur with RIC regimens. The applicant also asserted that treosulfan significantly improves clinical outcomes relative to services or

[497] Beelen DW 2019 Treosulfan or busulfan plus fludarabine as conditioning treatment before allogeneic aemopoietic stem cell transplantation for older patients with acute myeloid leukaemia or myelodysplastic syndrome (MC-FludT.14/L): A randomised, non-inferiority, phase 3 trial. The Lancet Haematol *https://doi.org/10.1016/S2352-3026(19)30157-7.*

technologies previously available, including increased event free survival and overall survival at 24 months post-alloHSCT, reduced cumulative incidence of non-relapse mortality (NRM) at 24 months post-alloHSCT, reduced cumulative incidence of treatment-related mortality (TRM) at 24 months post-alloHSCT, increased rate of graft-versus-host disease (GVHD)-free and relapse/progression-free survival at 24 months post-alloHSCT. To support its claims, the applicant provided two published articles, one published abstract, and two background articles.

To support its claim that treosulfan represents a substantial clinical improvement over existing technologies because it was designed to provide access to improved alloHSCT conditioning outcomes for patients that may otherwise be ineligible for MAC regimens without the increased risk of relapse that is demonstrated to occur with RIC regimens, the applicant asserted that treosulfan-based regimens retain the beneficial properties from both MAC and RIC regimens with an efficacy profile comparable with that of conventional MAC regimens as they are associated with rapid engraftment, high levels of donor chimerism, and relatively low post-transplantation relapse rates.[498] [499] The applicant also cited background studies, which indicated that MAC regimens are currently the preferred standard of care for young patients given the reduced relapse rates for MAC patients as compared to RIC patients showing that MAC regimens produced less recurrence of disease.[500] [501]

To support its claim that treosulfan significantly improves clinical outcomes relative to services or technologies previously available, the applicant provided a phase 3 open-label, non-inferiority, randomized study of the use of treosulfan as part of a conditioning regimen in 31 transplant centers in 5 European countries.[502] The authors compared a RIC regimen of treosulfan 10 gm/m² daily for 3 days (days 4 to 2 prior to the alloHSCT) plus fludarabine 30 mg/m² daily for 5 days (6 to 2 days prior to the alloHSCT) to a RIC regimen containing busulfan (another alkylating agent) 0.8 mg/kg at 6 hour intervals on days 4 and 3 prior to the alloHSCT with the same dose of fludarabine. The initial protocol used a treosulfan dose of 14 gm/m², but the protocol was modified to 10 gm/m², but the protocol was modified to 10 gm/m² daily because of the prolonged neutropenia and subsequent infections with that dose. Eligible patients were aged 18 to 70 years with either AML in a first or complete remission or MDS with bone marrow blast counts >20% who were identified as appropriate for treatment with alloHSCT but were considered high risk for myeloablative conditioning because of age greater than or equal to 50 or comorbidities. 476 patients were enrolled (240 patients in the busulfan group received treatment and transplantation and were included in the full analysis population; 221 patients in the treosulfan group received treatment, but only 220 patients received transplantation and were included in the full analysis population). Study discontinuations were mainly due to disease progression prior to conditioning.

	Treosulfan	Busulfan	Hazard Ratio	P value
Number of patients	220	240		
Follow up months	15.4	17.4		
Deaths	23	41		
Relapse or Progression	45	51		
24 Month Event-Free Survival	64.0%	50.4%	0.65	p<0.0001
24 Month Overall Survival	71.3%	56.4%	0.61	p=0.0082
Cumulative Incidence Relapse or Progression at 24 Months	24.6%	23.3%	0.87	p=0.505
24 Month Transplant Related Mortality	12.1%	28.2%	0.54	p=0.020
24 Month Cumulative Non-Relapse Mortality Incidence	10%	17%	0.60	p=0.0535

The applicant noted that other results from this study demonstrated no significant differences in engraftment with neutrophils, leukocytes, and platelets and graft versus host disease (overall, acute and chronic). The applicant also noted that the treosulfan treated group had higher incidences of complete chimerism at both 28- and 100-days post alloHSCT.

The applicant also submitted an abstract [503] containing a final evaluation of the results from the phase 3 study reported in the earlier publication.[504] The authors of the abstract noted that the previous study was a confirmatory interim analysis (based on 476 patients), and that results of the final analysis of all 570 randomized patients including post surveillance data were provided in this analysis. The full analysis in the abstract consisted of 551 patients: 352 with AML and 199 with MDS. Treosulfan was given to 268 patients and busulfan was given to 283 patients. The median age of patients was 60 years

[498] Dietrich Wilhelm Beelen, et al., Treosulfan or Busulfan plus Fludarabine as Conditioning Treatment Before Allogeneic Haemopoietic Stem Cell Transplantation for Older patients with Acute Myeloid Leukemia or Myelodysplastic Syndrome (MC-Flud.T.14/L): A Randomised, Non-Inferiority, Phase 3 Trial, THE LANCET HAEMATOLOGY, Oct. 9, 2019.

[499] Dietrich Wilhelm Beelen, et al., Final Evaluation of a Clinical Phase III Trial Comparing Treosulfan to Busulfan-Based Conditioning Therapy Prior to Allogeneic Hematopoietic Stem Cell Transplantation of Adult Acute Myeloid Leukemia and Myelodysplastic Syndrome Patients Ineligible to Standard Myeloablative Regimens, BIOLOGY OF BLOOD AND MARROW TRANSPLANTATION, 2019; 25(3): S3.

[500] Scott, BL et al. 2017. Myeloablative Versus Reduced-Intensity Hematopoietic Cell Transplantation for Acute Myeloid Leukemia and Myelodysplastic Syndromes. J. Clin Oncology 11: 1154.

[501] Dhere V et al. 2018. Myeloablative busulfan/cytoxan conditioning versus reduced-intensity fludarabine/melphalan conditioning for allogeneic hematopoietic stem cell transplant in patients with acute myelogenous leukemia Leuk Lymphoma. 2018 April; 59(4): 837–843. doi:10.1080/10428194.2017.1361027.

[502] Beelen DW 2019 Treosulfan or busulfan plus fludarabine as conditioning treatment before allogeneic aemopoietic stem cell transplantation for older patients with acute myeloid leukaemia or myelodysplastic syndrome (MC-FludT.14/L): A randomised, non-inferiority, phase 3 trial. The Lancet Haematol *https://doi.org/10.1016/S2352-3026(19)30157-7*.

[503] Beelen D 2019 Final Evaluation of a Clinical Phase III Trial Comparing Treosulfan to Busulfan-Based Conditioning Therapy Prior to Allogeneic Hematopoietic Stem Cell Transplantation of Adult Acute Myeloid Leukemia and Myelodysplastic Syndrome Patients Ineligible to Standard Myeloablative Regimens. Biol Blood Marrow Transplant 25 (2019) S3.

[504] Beelen DW 2019 Treosulfan or busulfan plus fludarabine as conditioning treatment before allogeneic aemopoietic stem cell transplantation for older patients with acute myeloid leukaemia or myelodysplastic syndrome (MC-FludT.14/L): A randomised, non-inferiority, phase 3 trial. The Lancet Haematol *https://doi.org/10.1016/S2352-3026(19)30157-7*.

(range 21–70). The median follow-up time was 29 months. The findings are shown in the following table.

Parameter	Treosulfan group % (95% CI)	Busulfan group % (95% CI)	Hazard ratio (95% CI)	P value
Number of patients	268	283		
Event-free survival[a]	65.7% (59.5, 71.2)	51.2% (45.0, 57.0)	0.64 (0.49, 0.84)[b]	0.00058[b,d]
Overall survival[a]	72.7% (66.8, 77.8)	60.2% (54.0, 65.8)	0.64 (0.48, 0.87)[b]	0.0037[b]
Cumulative incidence of non-relapse mortality	12.0% (8.0, 15.9)	20.4% (15.5, 25.2)	0.63 (0.41, 0.97)[c]	0.0343[c]
Cumulative incidence of relapse/progression	22.0% (16.9, 27.1)	25.2% (20.0, 30.3)	0.82 (0.59, 1.16)[c]	0.2631[c]
[a] Based on Kaplan-Meier estimates; [b] adjusted for donor type, risk group and center using Cox regression model; [c] adjusted for donor type as factor and risk group as stratum using Fine and Gray model; [d] P value for testing superiority				

The applicant stated that the results of the phase 3 trial demonstrated that the treosulfan treatment group had increased event free survival (EFS) and overall survival (OS), with statistically significant improvements in EFS (p=0.0005787) and OS at 24 months post-alloHSCT (p=0.0037) compared to the busulfan treatment group. The applicant also stated that the results of the phase 3 trial demonstrated that the treosulfan treatment group had reduced cumulative incidence of NRM and TRM, noting a statistically significant reduced cumulative incidence of NRM at 24 months post-alloHSCT (p=0.0343), as well as a reduced cumulative incidence of TRM at 24 months post-alloHSCT (adjusted p value of 0.0043) compared to the busulfan treatment group. The applicant also cited a statistically significantly lower cumulative incidence of TRM caused by infections (adjusted p value of 0.0371) and lower cumulative incidence of TRM related to causes of death other than infections (adjusted p value of 0.0423). Furthermore, the applicant stated that the incidence of complete donor type chimerism was statistically significantly higher in the treosulfan treatment group compared with the busulfan treatment group (adjusted p value of 0.0381). Finally, the applicant stated that the results of the phase 3 trial demonstrated that the treosulfan treatment group had an increased rate of GVHD-free and relapse/progression-free survival at 24 months post-alloHSCT compared to the busulfan treatment group (adjusted p value of 0.00087), as well as a higher chronic GVHD-free and relapse/progression-free survival at 24 months (adjusted p value of 0.003).[505] [506]

After review of the information provided by the applicant, we have the following concerns regarding whether treosulfan meets the substantial clinical improvement criterion. We note that we were unable to verify the applicant's claims that the treosulfan treatment group had a statistically significant increased rate of acute and chronic GVHD-free and relapse/progression-free survival at 24 months post-alloHSCT compared to the busulfan treatment group. We note that the Beelen et al. abstract cited by the applicant only provided an analysis of GVHD rates up to the 28-day follow-up visit, and stated that the incidences of acute and chronic GVHD were comparable between the two regimens (treosulfan and busulfan). We also note that the cumulative incidence of acute GVHD in the Beelen et al. interim analysis of 473 patients submitted by the applicant was only analyzed at 100 days, and did not describe a statistically significant difference between the treosulfan and busulfan groups (acute GVHD grade 2–4, p=0.13; grade 3–4, p=0.21); similarly, the cumulative incidence of chronic GVHD at 24 months were not significantly different (chronic GVHD, p=0.52; extensive chronic GVHD, p=0.11). Furthermore, we note that the treosulfan and busulfan treatment groups did not have a statistically significant difference in cumulative incidence of relapse or progression incidence at 24 months (p=0.50).[507] [508]

Finally, we note that the phase 3 trial [509] was a non-inferiority trial, which is not designed to demonstrate superiority over other regimens, and may be subject to observer bias due to the lack of blinding. We also note that the studies provided were not powered to show that the treosulfan 10mg/m^2 improved outcomes for patients 65 and older, and therefore question whether the results may be generalizable to the Medicare population. Furthermore, the comparison of treosulfan with busulfan represents the testing of only one potential RIC regimen, and we note that there are other possible treatment regimens. For example, the applicant asserted that combination treatments including treosulfan can provide patients who are ineligible for MAC regimens access to a new treatment option. However, the applicant did not provide evidence that this treosulfan treatment combination improved outcomes relative to other current RIC regimens, besides busulfan and fludarabine used in their cited studies. We note that while the applicant stated that treosulfan demonstrates improved outcomes (reduces treatment-related toxicity and risk of TRM without increasing risk of relapse) as compared to MAC regimens and that it therefore offers a treatment option for patients ineligible for MAC, the proposed indications for treosulfan do not limit use to patients ineligible for MAC. We would appreciate additional information comparing outcomes with treosulfan-based regimens to MAC regimens. We are inviting public comments on whether treosulfan meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for treosulfan.

[505] Ibid.

[506] Beelen D 2019 Final Evaluation of a Clinical Phase III Trial Comparing Treosulfan to Busulfan-Based Conditioning Therapy Prior to Allogeneic Hematopoietic Stem Cell Transplantation of Adult Acute Myeloid Leukemia and Myelodysplastic Syndrome Patients Ineligible to Standard Myeloablative Regimens. Biol Blood Marrow Transplant 25 (2019) S3.

[507] Beelen D 2019 Final Evaluation of a Clinical Phase III Trial Comparing Treosulfan to Busulfan-Based Conditioning Therapy Prior to Allogeneic Hematopoietic Stem Cell Transplantation of Adult Acute Myeloid Leukemia and Myelodysplastic Syndrome Patients Ineligible to Standard Myeloablative Regimens. Biol Blood Marrow Transplant 25 (2019) S3.

[508] Beelen DW 2019 Treosulfan or busulfan plus fludarabine as conditioning treatment before allogeneic aemopoietic stem cell transplantation for older patients with acute myeloid leukaemia or myelodysplastic syndrome (MC-FludT.14/L): A randomised, non-inferiority, phase 3 trial. The Lancet Haematol *https://doi.org/10.1016/S2352-3026(19)30157-7*.

[509] Ibid.

l. UPLIZNA® (inebilizumab-cdon)

HTI–DAC, the manufacturer under the distributor Horizon Therapeutics USA, Inc., submitted an application for new technology add-on payment for UPLIZNA® (inebilizumab-cdon) for FY 2023. Per the applicant, UPLIZNA® is the first FDA-approved anti-cluster of differentiation 19 (CD19) B-cell depleter for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adults who are anti-aquaporin-4 (AQP4) antibody positive, for which 80% of all patients with NMOSD test positive.[510] According to the applicant, the goal of UPLIZNA® is to reduce the risk of relapse and disability progression. The applicant explained UPLIZNA® is a CD19+ B cell-directed humanized afucosylated immunoglobulin F1 (IgG1) monoclonal antibody. The applicant further explained that CD19 is a cell surface antigen expressed on a broad range of B lymphocytes. Per the applicant, UPLIZNA® is a B-cell depleter that binds specifically to CD19, allowing it to target an extended range of B-cells that play a role in NMOSD. The applicant stated that following cell surface binding to CD19+ B lymphocytes, UPLIZNA® causes antibody-dependent cellular cytolysis (ADCC), resulting in significant and robust B-cell depletion.

NMOSD is a rare, severe autoimmune disease of the central nervous system that causes damage to the optic nerve, spinal cord, and brain stem. NMOSD affects approximately 10,000–15,000 people in the United States, and the incidence rate may be up to 9 times higher for women than for men, with prevalence approximately 2- to 3-fold higher among Black and Asian populations.[511] According to the applicant, NMOSD is characterized by unpredictable, recurrent attacks of inflammation of the optic nerve (optic neuritis) and/or of the spinal cord (transverse myelitis), and may also affect regions of the brain. The applicant stated that attacks can be severe and result in life-altering permanent disability, such as blindness and paralysis, and that recurring attacks can have cumulative effects resulting in significant morbidity. According to the applicant, aquaporin-4 antibodies are highly specific to NMOSD and AQP4 is expressed on astrocytes throughout the central nervous system. Per the applicant, in NMOSD, AQP4 antibodies bind to AQP4, resulting in astrocyte cell death and inflammation. The applicant stated that a sub-population of B-lineage cells, CD19+ plasmablasts, produce AQP4 antibodies and that certain CD19+ B-cells are increased in the blood of AQP4-seropositive individuals with NMOSD, with the highest levels observed during an attack. According to the applicant, by depleting a wide range of B-cells that express CD19 (including plasmablasts and some plasma cells), UPLIZNA® reduces the risk of relapses or attacks that may lead to permanent disability in NMOSD patients.

With respect to the newness criterion, the applicant stated that UPLIZNA® was designated as a Breakthrough Therapy and received Orphan Drug designation on February 10, 2016 for the treatment of NMOSD.[512] Per the applicant, UPLIZNA® received FDA approval on June 11, 2020, for the treatment of NMOSD in adult patients who are AQP4 antibody positive (BLA #761142). The applicant stated that UPLIZNA® became commercially available on July 9, 2020, following FDA approval. According to the applicant, UPLIZNA® is administered as an intravenous infusion, and titrated to completion, over approximately 90 minutes under the close supervision of an experienced healthcare professional. The applicant stated that the recommended initial dose is a 300 mg intravenous infusion followed 2 weeks later by a second 300 mg intravenous infusion. The applicant also stated that subsequent doses, starting 6 months from the first infusion, consist of a single 300 mg intravenous infusion every 6 months.

According to the applicant, there are currently no ICD–10–PCS procedure codes that uniquely identify the use of UPLIZNA®. However, the applicant stated that the following procedure codes may be used to identify administration of UPLIZNA® in the inpatient setting, though they are not specific to UPLIZNA®: 3E033GC (Introduction of other therapeutic substance into the peripheral vein, percutaneous approach) or 3E043GC (Introduction of other therapeutic substance into central vein, percutaneous approach). The applicant submitted a request for approval of a unique ICD–10–PCS procedure code to identify use of the technology beginning in FY 2023. As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments. According to the applicant, the only approved treatments for NMOSD are UPLIZNA®, Soliris® (eculizumab), and ENSPRYNG™ (satralizumab). We note that ENSPRYNG™ and Soliris® previously submitted applications for new technology add-on payments. Please see discussion of ENSPRYNG™ in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45019 through 45028) and Soliris® in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58684 through 58689).

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant stated that UPLIZNA® is the only treatment for NMOSD that targets B-cells and causes B-cell depletion. The applicant contrasted the mechanism of action of UPLIZNA® with those of Soliris® and ENSPRYNG™. Per the applicant, the mechanism of action of Soliris® is the inhibition of aquaporin-4-antibody induced terminal complement C5b-9 deposition.[513] The applicant explained that Soliris® specifically binds to complement protein C5, inhibiting its cleavage to C5a and C5b and preventing the generation of C5b-9. The applicant also stated that ENSPRYNG™ is a recombinant humanized anti-human interleukin-6 (IL–6) receptor monoclonal antibody. Per the applicant, the mechanism of action of ENSPRYNG™ involves the inhibition of IL–6-mediated signaling through binding to soluble and membrane-bound IL–6 receptors.[514] Thus, the applicant asserted that each of the three FDA approved treatments for NMOSD—UPLIZNA®, Soliris®, and ENSPRYNG™—bind to a different molecular target and have different mechanisms of action.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG when compared to an existing technology, the applicant stated that cases representing patients who may be eligible for treatment with UPLIZNA® map to MS–DRGs 058, 059, or 060 (Multiple Sclerosis and Cerebellar Ataxia with

[510] Wingerchuck, D. (2009, November 15). Neuromyelitis optica: Effect of gender. Journal of the Neurological Sciences. Retrieved October 6, 2021, from *https://pubmed.ncbi.nlm.nih.gov/19740485/*.

[511] Flanagan, E.P. et al. (2016, April 4). Epidemiology of aquaporin-4 autoimmunity and Neuromyelitis Optica Spectrum. Wiley Online Library. Retrieved October 6, 2021, from *https://onlinelibrary.wiley.com/doi/10.1002/ana.24617*.

[512] U.S. Food and Drug Administration website: *https://www.accessdata.fda.gov/scripts/opdlisting/oopd/listResult.cfm*.

[513] U.S. Food and Drug Administration. (2019, June). Soliris Prescribing Information. Retrieved October 6, 2021, from *https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125166s431lbl.pdf*.

[514] Genentech. (2020, August). ENSPRYNG Factsheet. Retrieved October 6, 2021, from *https://www.gene.com/download/pdf/genentech_enspryng_factsheet.pdf*.

MCC, with CC, or without CC/MCC, respectively), which are the same MS–DRGs to which existing technologies may also be assigned.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant asserted that, while UPLIZNA® treats a patient population with the same type of disease (NMOSD) as Soliris® or ENSPRYNG™, it offers a treatment option for a subset of this patient population, which differentiates it from existing technologies. Per the applicant, UPLIZNA® has not been shown to carry an increased risk of meningitis and may be used in patient populations who are unvaccinated with the meningococcal vaccine and/or are not able to use prophylactic antibiotics. The applicant noted that while patients with NMOSD who are unvaccinated with the meningococcal vaccine can still receive other approved treatments for NMOSD, such as Soliris® or ENSPRYNG™, they need to have a risk reduction protocol instituted at the time of treatment and, in some cases, may require two weeks of prophylactic antibacterial treatment first.[515] [516]

In summary, the applicant maintained that UPLIZNA® is not substantially similar to other currently available therapies and/or technologies because it uses a new mechanism of action and treats a different subset of the patient population with NMOSD compared to an existing technology.

We note that the applicant asserts that UPLIZNA® treats a different subset of the patient population with NMOSD compared to existing technologies, specifically patients who are unvaccinated with the meningococcal vaccine. However, we question whether this subset is considered a new patient population since, as previously discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45021), ENSPRYNG™ is also not contraindicated in patients with unresolved serious *Neisseria meningitidis* infections, and therefore, may be a treatment option for patients with meningococcal disease as well as UPLIZNA®. Furthermore, as we previously stated in the FY 2022 IPPS/LTCH PPS final rule, individuals that are not vaccinated against *Neisseria mengitidis* are not considered a separate patient population because eligibility can be easily attained via a widely available vaccine (86 FR 45027). Additionally, we question whether the additional requirements for patients taking Soliris®—namely participation in a risk reduction protocol related to the associated risk of meningococcal infections, and prophylactic antibiotic treatment that may result in a 2-week delay for treatment—constitute a new patient population for technologies without those requirements.

We are inviting public comments on whether UPLIZNA® is substantially similar to existing technologies and whether UPLIZNA® meets the newness criterion.

With respect to the cost criterion, the applicant presented the following analysis. The applicant searched the FY 2019 Medicare Provider Analysis and Review (MedPAR) Hospital Limited Data Set (LDS) for cases with ICD–10–CM diagnosis code G36.0 for Neuromyelitis optica [Devic] (NMOSD) coded in the first diagnosis position. The applicant determined that cases representing patients who may be eligible for treatment with UPLIZNA® would map to MS–DRGs 058, 059, or 060 (Multiple Sclerosis and Cerebellar Ataxia with MCC, with CC, or without CC/MCC, respectively).

The applicant determined a case count of 257 after imputing a value of 11 for MS–DRGs with a case volume under 11. The applicant then removed 100% of the drug charges to estimate the potential decrease in costs due to the use of UPLIZNA®. The applicant noted that, although use of UPLIZNA® would replace current drug charges for therapies such as azathioprine, methotrexate, and rituximab, it is not possible to differentiate between drug costs on MedPAR claims, and so it removed all drug charges to be conservative. The applicant then standardized the charges and applied a 4-year inflation factor of 1.281834, or 28.1834%, based on the inflation factor used to update the outlier threshold in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542). The applicant added charges for the new technology by dividing the estimated cost of UPLIZNA® by the national average CCR for drugs which is 0.187, from the FY 2022 IPPS/LTCH PPS final rule (86 FR 44966).

The applicant calculated a final inflated average case-weighted standardized charge per case of $764,547, which exceeded the average case-weighted threshold amount of $48,165. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that UPLIZNA® meets the cost criterion.

We are inviting public comments on whether UPLIZNA® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant made two assertions. First, the applicant asserted that UPLIZNA® offers a treatment option for a patient population that is ineligible for currently available treatments. Specifically, the applicant asserted that UPLIZNA® is a new treatment option for patients who carry an increased risk of meningitis, patients following treatments with more frequent and burdensome dosing schedules, and patient populations more likely to be impacted by health disparities. Finally, the applicant asserted that UPLIZNA® significantly improves clinical outcomes relative to currently available technologies because it reduced the risk of NMOSD attacks and disability progression among patients with NMOSD when compared to placebo in the N–MOmentum trial, which the applicant asserted is the largest NMOSD study conducted.[517]

With respect to the applicant's assertion that UPLIZNA® is a substantial clinical improvement over existing technologies because it represents a new treatment option for a patient population ineligible for currently available treatments, the applicant stated that UPLIZNA® may be used in patient populations who are unvaccinated with the meningococcal vaccine and/or are not able to use prophylactic antibiotics because UPLIZNA® has not been shown to carry an increased risk of meningitis, as compared with Soliris®.

To support this claim, the applicant cited an article from the CDC explaining that patients taking complement inhibitors, such as Soliris®, are at an increased risk for meningococcal disease [518] and referenced the CDC's recommendation that patients receive the meningococcal vaccination prior to initiating treatment with a complement inhibitor. The applicant also cited a

[515] Soliris® prescribing details: *https://solirispro.com/pdf/Soliris_USPI.pdf.*

[516] ENSPRYNG™ prescribing information: *https://www.gene.com/download/pdf/enspryng_prescribing.pdf.*

[517] Marignier, R. et al., (2021, March 26). Disability Outcomes in the N–MOmentum Trial of Inebilizumab in Neuromyelitis Optica Spectrum Disorder. Neurology® neuroimmunology & neuroinflammation. Retrieved October 6, 2021, from *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8054974/.*

[518] Centers for Disease Control and Prevention. (2019, May 31). *Taking complement inhibitors increases risk for meningococcal disease*/CDC. Centers for Disease Control and Prevention. Retrieved October 1, 2021, from *https://www.cdc.gov/meningococcal/about/soliris-patients.html.*

study by McNamara et al.[519] that identified 16 cases in the U.S. between 2008 and 2016 of patients who were taking Soliris® who had meningococcal disease despite having received at least 1 dose of meningococcal vaccine before disease onset. Referring to the same article by McNamara et al., the applicant stated that some healthcare providers recommend prophylactic antibiotics even for vaccinated patients during treatment with Soliris®, exposing them to long-term antibiotic use, which carries the risk of developing antimicrobial resistance.

Furthermore, the applicant claimed that UPLIZNA® represents a new treatment option for patients following treatments with more frequent and burdensome dosing schedules than UPLIZNA®. Per the applicant, the dosing schedule for UPLIZNA® consists of 2 initial doses delivered 2 weeks apart, followed by 1 dose every 6 months after that.[520] In comparison, based on the FDA prescribing information for Soliris®, the applicant asserted that UPLIZNA®'s 6-month dosing regimen is less frequent than that of Soliris®, and, therefore, is less burdensome to follow.[521] The applicant asserted the dosing schedule for UPLIZNA® is more amenable to NMOSD patients for whom more frequent intravenous infusions may be burdensome and stated that its characteristics as a treatment regimen, compared to Soliris™, may help to improve medication adherence and decrease likelihood of relapse and hospitalization relative to placebo. To further demonstrate that UPLIZNA® may help to improve long-term patient adherence, compared to Soliris™, the applicant provided a review by Vlasnik et al.[522] noting that medication regimen complexity is one factor that can negatively affect adherence. The applicant emphasized that, for NMOSD, medication adherence to maintain immune suppression is essential for reducing the risk of attacks, which can lead to hospitalization, vision loss and paralysis. Finally, the applicant stated that UPLIZNA® poses less of a barrier for patient access, as it does not require patients or providers to participate in FDA's Risk Evaluation and Mitigation Strategy (REMS) program, or receive additional counselling regarding the program, as required by Soliris®.[523]

To support its claim that UPLIZNA® is a new treatment option for populations that are more likely to be impacted by health disparities, the applicant noted UPLIZNA®'s durable efficacy and favorable safety profile among African Americans with NMOSD. To support this claim, the applicant cited the safety results published by Cree et al.[524] from both a randomized control period (RCP) and an open label period (OLP) of the N–MOmentum trial. The RCP phase of N-Momentum was a multicenter, double-blind, ⅔ study conducted at 99 outpatient specialty clinics or hospitals in 25 countries that lasted up to 197 days. The primary endpoint was time to onset of an NMOSD attack, as determined by the investigator and adjudication committee. Eligible participants were randomized in a 3:1 ratio to receive either 300 mg intravenous UPLIZNA® (n=174) or a saline placebo (n=56) on days 1 and 15. Participants continued through the RCP for up to 28 weeks unless they had a confirmed NMOSD attack, at which point they could choose to continue in the OLP phase of the trial. The OLP included eligible adult participants (n=230) who had had at least 1 NMOSD attack in the year before screening or at least 2 attacks requiring rescue therapy in the 2 years before screening. During the OLP, all patients received UPLIZNA® for at least 2 years. As recommended by an independent committee, enrollment in the RCP phase stopped prior to study completion due to the early findings where 21 of 174 participants (12%) receiving UPLIZNA® had an attack as compared with 22 of the 56 placebo recipients (39%). Marignier et al. (2021) assessed treatment effects in N–MOmentum by measuring score worsening of the Expanded Disability Status Scale (EDSS) and modified Rankin Scale (mRS) scores.[525] EDSS scores were measured at baseline, then at RCP study weeks 12 and 28, and every 3 months during the OLP, and within 5 days of a potential attack. mRS scores were measured at baseline, and at weeks 4, 8, 12, 16, 22, and 28 of the RCP. The Marignier results from the N–MOmentum study found the annualized attack rate for African Americans was lower at 0.06 compared to an annualized attack rate of 0.09 in the overall group exposed to UPLIZNA®. The applicant stated that among the 19 African American participants who received UPLIZNA® or placebo during the RCP and/or OLP of the N–MOmentum trial, three had attacks 18, 29, and 104 days after their first UPLIZNA® dose. The summary of baseline demographics and characteristics of the intent-to-treat population notes that there were 14 African American participants who received UPLIZNA® and 5 who received the placebo.[526]

With respect to its claim that UPLIZNA® significantly improves clinical outcomes relative to previously available treatment options, the applicant stated that patients taking UPLIZNA® had a reduced risk of NMOSD attacks and disability progression when compared to placebo in the N–MOmentum trial. The applicant again referenced the results of the N–MOmentum trial reported by Cree et al., where 21 (12%) of the 174 participants receiving UPLIZNA® had an attack by the time enrollment ended versus 22 (39%) of the 56 participants receiving placebo (hazard ratio (HR) 0·272 [95% CI 0·150–0·496]; p<0·0001). The applicant also referred to the N–MOmentum results from the OLP and asserted that they show long-term treatment with UPLIZNA® provided a sustained reduction in NMOSD attack risk, MRI lesions, and NMOSD-related hospitalizations regardless of treatment provided during the RCP. The applicant

[519] McNamara, L. et al. (2017, July 7). High Risk for Invasive Meningococcal Disease Among Patients Receiving Eculizumab (Soliris) Despite Receipt of Meningococcal Vaccine Retrieved October 6, 2021, from *https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6627e1.pdf*.

[520] U.S. Food and Drug Administration. (2007, March). Highlights of prescribing information administration. Retrieved October 6, 2021, from *https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/125166lbl.pdf*.

[521] U.S. Food and Drug Administration. Alexion briefing information for the November 18, 2014, meeting of the Drug Safety and Risk Management Advisory Committee. *https://www.fda.gov/advisory-committees/human-drug-advisory-committees/drug-safety-and-risk-management-advisory-committee*.

[522] Vlasnik, J.J., Aliotta, S.L., & DeLor, B. (2005, April 7). Medication adherence: Factors influencing compliance with prescribed medication plans. The Case Manager. Retrieved October 6, 2021, from *https://www.sciencedirect.com/science/article/abs/pii/S1061925905000263?via%3Dihub*.

[523] Alexion Pharmaceutical, Inc. (2020). Soliris REMS. Retrieved October 6, 2021, from *https://solirisrems.com/*.

[524] Cree BAC, Bennett J.L., Kim H.J., Weinshenker B.G., Pittock S.J., Wingerchuk D.M., Fujihara K., Paul F., Cutter G.R., Marignier R., Green A.J., Aktas O., Hartung H.P., Lublin F.D., Drappa J., Barron G., Madani S., Ratchford J.N., She D., Cimbora D., Katz E.; N–MOmentum study investigators. Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N–MOmentum): a double-blind, randomised placebo-controlled phase ⅔ trial. Lancet. 2019 Oct 12;394(10206):1352–1363. doi: 10.1016/S0140–6736(19)31817–3. Epub 2019 Sep 5. PMID: 31495497.

[525] Marignier R., Bennett J.L., Kim H.J., Weinshenker B.G., Pittock S.J., Wingerchuk D., Fujihara K., Paul F., Cutter G.R., Green A.J., Aktas O., Hartung H.P., Lublin F.D., Williams I.M., Drappa J., She D., Cimbora D., Rees W., Smith M., Ratchford J.N., Katz E., Cree BAC; N–MOmentum Study Investigators. Disability Outcomes in the N–MOmentum Trial of Inebilizumab in Neuromyelitis Optica Spectrum Disorder. Neurol Neuroimmunol Neuroinflamm. 2021 Mar 26;8(3):e978. doi: 10.1212/NXI.0000000000000978. PMID: 33771837; PMCID: PMC8054974.

[526] Ibid.

referenced the disability data published by Marignier et al.[527] from the results of the N–MOmentum trial on the use of UPLIZNA® and asserted that they showed favorable results among patients with NMOSD when compared to placebo. Specifically, Marignier et al. assessed the treatment effects of UPLIZNA® in comparison with placebo by using a worsening score of the Expanded Disability Status Scale (EDSS) to measure confirmed disability progression (CDP). The applicant asserted that the results show UPLIZNA® reduced the risk of 3-month CDP compared with placebo (HR: 0.375; 95% CI: 0.148–0.952; p = 0.0390). The applicant also stated that UPLIZNA® showed a significantly lower risk of relapse among patients with NMOSD when compared to placebo. The applicant cited results from Pittock et al.,[528] a randomized, double-blind, time-to-event trial in which 143 adult subjects were randomly assigned to receive either UPLIZNA® or placebo weekly and continued use of an immunosuppressive therapy, as needed. The primary endpoint was the first adjudicated relapse, while secondary endpoints included the adjudicated annualized relapse rate. Pittock et al. reported that adjudicated relapses occurred in 3 of 96 patients (3%) in the UPLIZNA® group and 20 of 47 (43%) in the placebo group (hazard ratio 0.06; 95% confidence interval [CI], 0.02 to 0.20; P<0.001). The adjudicated annualized relapse rate was 0.02 in the eculizumab group and 0.35 in the placebo group (rate ratio, 0.04; 95% CI, 0.01 to 0.15; P<0.001). Referring to the results from the Pittock et al. study, the applicant asserted that UPLIZNA® showed a consistent effect in reducing the risk of attack compared to placebo, regardless of baseline disability status, attack history, or disease duration.[529]

After review of the information provided by the applicant, we have the following concerns regarding whether UPLIZNA® meets the substantial clinical improvement criterion. First, we note that while the applicant provided data comparing UPLIZNA® to placebo, we did not receive any data to demonstrate improved outcomes over existing FDA approved treatments. Additional information comparing outcomes such as relapse rate, risk of relapse, and disability progression for patients receiving UPLIZNA® versus other currently available treatments would help inform our assessment of whether UPLIZNA® demonstrates a substantial clinical improvement over existing technologies. Second, while the applicant asserted that UPLIZNA® represents a new treatment option for patients who are unvaccinated with the meningococcal vaccine, similar to the discussion in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45021) in response to a similar assertion with respect to ENSPRYNG™, we note that ENSPRYNG® is also not contraindicated in patients with unresolved serious *Neisseria meningitidis* infection and therefore may also be a treatment option for patients with meningococcal disease. We further note that the use of ENSPRYNG™ to treat patients with NMOSD also does not require a meningococcal vaccination. We note that the applicant sought to support its claim that UPLIZNA® represents a new treatment option for patients who are unvaccinated against *Neisseria meningitidis* through the inference that Soliris® has a high risk of causing meningitis; however, we have concerns about the applicant's claim because *Neisseria meningitidis* may easily be mitigated through the use of a common vaccine or antimicrobials. As discussed in the FY 2022 IPPS/LTCH PPS final rule in response to similar claims with respect to ENSPRYNG®, and as noted previously, individuals that are not vaccinated against *Neisseria mengitidis* are not considered a separate patient population because eligibility can be easily attained via a widely available vaccine and are also able to receive treatment with UPLIZNA® which does not require a vaccine (86 FR 45027).

With regard to the applicant's claim that UPLIZNA® is a new treatment option for patients following treatments with more frequent dosing schedules, we are unsure whether these patients may be considered as a separate patient population ineligible for currently available treatments. For example, although the applicant compared the UPLIZNA® dosing regimen against Soliris®, it did not provide a similar comparison against ENSPRYNG™, which—similar to UPLIZNA®—does not require frequent intravenous infusions or participation in the FDA REMS program (see 86 FR 45020). Therefore, it is unclear whether UPLIZNA® provides a treatment option for a separate patient population that is ineligible for currently available treatments, when there are other available treatments, like ENSPRYNG™, without the limitations that the applicant described with respect to Soliris®. In addition, while the applicant stated that UPLIZNA®'s dosing regimen may help to improve long-term patient medication adherence and decrease the likelihood of relapse and hospitalization, we question the strength of the correlation between UPLIZNA's® dosing regimen and these outcomes. We are also interested in additional information on the efficacy results of UPLIZNA® among African Americans with NMOSD, as cited by the applicant, as we understand that NMOSD disproportionately affects African American and Asian populations at rates approximately 2- to 3-fold higher than their Caucasian counterparts.[530] Specifically, we question whether the retrospective analysis of the results from the N–MOmentum trial on the annualized attack rate for African Americans (0.06 compared with 0.09 in the overall group) is generalizable to larger populations because the study included low numbers of participants. Of the 20 African American participants randomized in N-Momentum, 19 were AQP4 antibody positive and 1 was AQP4 antibody negative. As a result, of the 19 participants, 14 received UPLIZNA®, and only 5 received placebo.[531] [532] We further note that the applicant did not provide comparative data on the efficacy of UPLIZNA®, Soliris®, and ENSPRYNG™ in these populations.

We are inviting public comments on whether UPLIZNA® meets the

[527] Marignier R., Bennett J.L., Kim H.J., Weinshenker B.G., Pittock S.J., Wingerchuk D., Fujihara K., Paul F., Cutter G.R., Green A.J., Aktas O., Hartung H.P., Lublin F.D., Williams I.M., Drappa J., She D., Cimbora D., Rees W., Smith M., Ratchford J.N., Katz E., Cree BAC; N–MOmentum Study Investigators. Disability Outcomes in the N–MOmentum Trial of Inebilizumab in Neuromyelitis Optica Spectrum Disorder. Neurol Neuroimmunol Neuroinflamm. 2021 Mar 26;8(3): e978. doi: 10.1212/NXI.0000000000000978. PMID: 33771837; PMCID: PMC8054974.

[528] Pittock S.J., Berthele A., Fujihara K., Kim H.J., Levy M., Palace J., Nakashima I., Terzi M., Totolyan N., Viswanathan S., Wang K.C., Pace A., Fujita K.P., Armstrong R., Wingerchuk D.M. Eculizumab in Aquaporin-4-Positive Neuromyelitis Optica Spectrum Disorder. N Engl J Med. 2019 Aug 15;381(7):614–625. doi: 10.1056/NEJMoa1900866. Epub 2019 May 3. PMID: 31050279.

[529] Ibid.

[530] Flanagan, E.P. et al. (2016, April 4). Epidemiology of aquaporin-4 autoimmunity and Neuromyelitis Optica Spectrum. Wiley Online Library. Retrieved October 6, 2021, from *https://onlinelibrary.wiley.com/doi/10.1002/ana.24617*.

[531] Bernitsas, E., Cimbora, D., Dinh, Q., She, D., Katz, E. Safety and Efficacy of Inebilizumab in African Americans with Neuromyelitis Optica Spectrum Disorder. Poster presentation at the 15th World Congress on Controversies in Neurology (CONy Virtual). September 23–26, 2021.

[532] Cree BAC, Bennett JL, Kim HJ, Weinshenker BG, Pittock SJ, Wingerchuk DM, Fujihara K, Paul F, Cutter GR, Marignier R, Green AJ, Aktas O, Hartung HP, Lublin FD, Drappa J, Barron G, Madani S, Ratchford JN, She D, Cimbora D, Katz E; N–MOmentum study investigators. Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N–MOmentum): A double-blind, randomised placebo-controlled phase ⅔ trial. Lancet. 2019 Oct 12;394(10206):1352–1363. doi: 10.1016/S0140–6736(19)31817–3. Epub 2019 Sep 5. PMID: 31495497.

substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for UPLIZNA®.

m. XENOVIEW (hyperpolarized Xenon-129 [HP ^{129}Xe] gas for inhalation)

Polarean, Inc. and The Institute for Quality Resource Management (collectively referred to as ''applicant'') submitted an application for new technology add-on payments for XENOVIEW for FY 2023. Per the applicant, XENOVIEW is a gas blend used in chest magnetic resonance imaging (MRI) that is processed to consist of 89% Helium, 10% Nitrogen, and 1% Xenon. The applicant stated that the 1% Xenon in the gas blend is hyperpolarized (HP) to create Xenon-129 (^{129}Xe) (that is, 80% purity of ^{129}Xe isotope), which allows for high resolution 3-dimensional (3–D) images of the lungs and assessment of the lungs' functional status when inhaled by a patient during a pulmonary MRI scan. The applicant stated that XENOVIEW rapidly and directly quantifies regional lung function without ionizing radiation or compromising patient comfort and aids clinical decision-making by directly quantifying gas exchange across three compartments (airspace and ventilation, interstitial barrier tissues, and transfer to red blood cells (RBCs)) to provide a complete picture of lung function. The applicant stated that this makes it well-suited for longitudinal therapeutic evaluation and assessment of disease progression.[533]

The applicant stated that hyperpolarization of ^{129}Xe gas is generated by using the combination hyperpolarization system consisting of the ^{129}Xe gas cylinder, Hyperpolarizer, Measurement Station, and Dose Delivery Bag. The applicant noted that hospital trained clinical personnel use this drug system to activate the XENOVIEW from the initial gas blend cylinder, and to make HP ^{129}Xenon immediately prior to patient administration. The applicant explained that collectively, these components hyperpolarize (using the Xenon Hyperpolarizer) and measure the hyperpolarization of ^{129}Xe gas (using the Polarization Measurement Station), and then the clinician administers the XENOVIEW Dose Equivalent (DE) to the patient using the Polarean DE Dose Delivery Bag during a pulmonary MRI scan.

According to the applicant, XENOVIEW MRIs can be used to spatially characterize disease burden across a range of pulmonary disorders and lung abnormalities, including asthma, cystic fibrosis (CF), bronchiolitis obliterans, interstitial lung disease, patients recommended for surgical lung resection, post-lung transplant patients, and people diagnosed with chronic obstructive pulmonary disease (COPD). The applicant noted specifically that defects in all three compartments of lung function are commonly seen in COPD, and that XENOVIEW has been used to assess regional lung function in patients recommended for surgical lung resection as well as in post-lung transplant patients to sooner diagnose a failing transplant (where corrective action is needed to save the lung). Per the applicant, the estimated patient prevalence of these conditions is over 40 million diagnoses in the United States.

With respect to the newness criterion, the applicant stated it is pursuing an NDA from FDA for XENOVIEW as a drug combination for the evaluation of pulmonary function and imaging of the lungs using MRI. The applicant reported that on October 5, 2021, it received a complete response letter from FDA. The applicant stated that it intends to address FDA's concerns and resubmit the NDA, with FDA approval anticipated by July 1, 2022. The applicant anticipates commercial availability for XENOVIEW after FDA approval. Per the applicant, the recommended dosage for XENOVIEW is 75 mL Dose Equivalent (DE, where DE = total volume Xe gas × ^{129}Xe isotopic enrichment × polarized%) of HP ^{129}Xe (250–750 mL total Xe) mixed with nitrogen NF (99.999% purity) as an inert buffer to ensure that the total volume of gas contained in the XENOVIEW Dose Delivery Bag is 1L.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify cases involving the use of XENOVIEW. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for XENOVIEW beginning in FY 2023.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant explained that HP ^{129}Xe identifies regional function in the entire lung, facilitating more informed treatment decisions while reducing the patient's risk of receiving more invasive procedures, such as a right heart catherization. The applicant stated that the hyperpolarization and isotopic properties used by XENOVIEW are different from traditional MRI imaging, which is based on imaging of the hydrogen nucleus. Further, the applicant stated that XENOVIEW provides a completely new image requiring novel hardware, pulse sequence programming, post-processing interpretation software, and physician training for evaluation of lung function. Per the applicant, alternatives to XENOVIEW include nuclear scintigraphy methods using ^{133}Xe ventilation and/or Technetium (99mTc) perfusion (ventilation/perfusion [V/Q] scan) or spirometry measurements, which, according to the applicant, do not provide regional information and pose added ionizing radiation to the patient. The applicant stated that experimental computed tomography (CT) imaging using parametric modeling has also been used to infer function from structural imaging; however, unlike XENOVIEW, it does not directly measure function.

With respect to the second criterion, whether a product is assigned to the same or different MS–DRG when compared to an existing technology, the applicant stated that XENOVIEW has not been assigned to an MS–DRG and cannot be compared to an existing technology, nor is there data reflecting the cost of XENOVIEW in the MS–DRGs as it has not yet been billed to Medicare. However, the applicant noted that XENOVIEW is intended to aid diagnoses for patients with pulmonary disease frequently assigned to MS–DRGs 190–192 and 202–203, provided in the table.

[533] Wang Z, Rankine L, Bier EA, Mummy D, Lu J, et al. Using hyperpolarized ^{129}Xe gas exchange MRI to model the regional airspace, membrane and capillary contributions to diffusing capacity. J Appl Physiology 130: 1398–1409, 2021.

MS-DRG	DESCRIPTION
190	Chronic Obstructive Pulmonary Disease with MCC
191	Chronic Obstructive Pulmonary Disease with CC
192	Chronic Obstructive Pulmonary Disease without CC/MCC
202	Bronchitis and Asthma with CC/MCC
203	Bronchitis and Asthma without CC/MCC

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant asserted that XENOVIEW is available to a new population of patients whose underlying morbidities cannot safely tolerate standard lung imaging. The applicant noted that only 13% of patients within MS–DRGs 190–192 and 202–203 are without a complication or major complication, and that subjecting these patients to additional radiation exposure—such as that through single-photon emission computed tomography (SPECT)/CT, high-resolution CT, or nephrotoxicity from MRI—is not appropriate. The applicant further stated that an analysis of imaging ICD–10–PCS codes within these MS–DRGs indicates that less than 8% of these patients receive inpatient imaging. The applicant stated that XENOVIEW enables patients with comorbidities to have safe and effective MRIs to monitor their disease response to treatment or to identify loss of lung function. The applicant stated that XENOVIEW addresses an unmet medical need for a diagnostic agent that evaluates pulmonary function using more modern and precise imaging techniques (for example, MRI) without requiring patients to be exposed to radiation or nephrotoxicity.

In summary, the applicant stated that XENOVIEW is not substantially similar to other currently available therapies and/or technologies because it has a unique mechanism of action compared to existing lung imaging modalities, has not been assigned to an MS–DRG, and treats a new patient population. Therefore, the applicant asserted that XENOVIEW meets the ''newness'' criterion.

We note that although the applicant states that XENOVIEW has not been assigned to an MS–DRG and cannot be compared to an existing technology, we believe that based on its proposed FDA indication, cases involving the use of XENOVIEW would be assigned to the same MS–DRGs as cases involving the use of other MRIs and imaging modalities for pulmonary function and imaging of the lungs. We also believe that XENOVIEW may use the same or similar mechanism of action as other inhaled gases (^{133}Xe) and oxygen-enhanced pulmonary imaging, and we invite public comments on whether XENOVIEW's mechanism of action for the diagnosis and assessment of certain lung abnormalities is different than existing technologies. Further, we also invite public comments on whether XENOVIEW's safety profile allows patients with certain underlying morbidities access to previously contraindicated pulmonary testing and whether those patients with previous contraindication to current pulmonary imaging techniques should be considered a new patient population. We note that the proposed FDA indication for this technology is the evaluation of pulmonary function and imaging of the lungs using MRI, which is not unique to XENOVIEW, and does not mention the subset of patients with comorbidities that the applicant asserts is a new patient population.

We are inviting public comments on whether XENOVIEW is substantially similar to existing technologies and whether XENOVIEW meets the newness criterion.

With respect to the cost criterion, the applicant presented three analyses which varied the charges added for the new technology. For all three analyses, the applicant determined that cases representing patients potentially eligible for treatment with XENOVIEW (that is, patients with lung disease, exacerbations of lung disease, or those who require an inpatient admission to better monitor their response to or the side effects of pharmacologic therapy) mapped to five MS–DRGs, listed in the table.

MS-DRG	DESCRIPTION
190	Chronic Obstructive Pulmonary Disease with MCC
191	Chronic Obstructive Pulmonary Disease with CC
192	Chronic Obstructive Pulmonary Disease without CC/MCC
202	Bronchitis and Asthma with CC/MCC
203	Bronchitis and Asthma without CC/MCC

The applicant explained that it initially identified 255,651 cases as reported for the MS–DRGs in the preceding table in the FY 2019 MedPAR data. However, the applicant stated that because the cases it identified were 96% of total FY 2019 MS–DRG discharges reported in the FY 2023 threshold table, it decided to use the case counts from the FY 2023 Threshold Table, which resulted in a total of 267,158 cases. The applicant stated that it did not remove charges for prior drugs. The applicant then standardized the charges and applied a 4-year inflation factor of 1.281834 or 28.1834% based on the inflation factor used in the FY 2022 IPPS/LTCH PPS final rule and correction notice to calculate outlier threshold charges (86 FR 45542).

The applicant then added charges for the new technology by dividing the cost of XENOVIEW by the national average CCR for: (1) Drugs and radiology; (2) drugs alone; and (3) radiology alone. The applicant used the national average CCRs published in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44966).

In the first analysis, the applicant applied the national average CCR for

drugs, which is 0.187, to costs associated with the gas blend preparation, and the national average CCR for radiology, which is 0.136, for preparation of the hyperpolarized dose equivalent. Under this analysis, the applicant calculated a final inflated average case-weighted standardized charge per case of $51,418 which exceeded the average case-weighted threshold amount of $42,424.

In the second analysis, the applicant added charges for the new technology by dividing the cost of XENOVIEW by the national average CCR for drugs, which is 0.187, for costs associated with the gas blend preparation as well as costs associated with preparation of the hyperpolarized dose equivalent. Under this analysis, the applicant calculated a final inflated average case-weighted standardized charge per case of $49,012 which exceeded the average case-weighted threshold amount of $42,424.

In the third analysis, the applicant added charges for the new technology by dividing the total cost of XENOVIEW by the national average CCR for radiology, which is 0.136. Under this analysis, the applicant calculated a final inflated average case-weighted standardized charge per case of $52,622 which exceeded the average case-weighted threshold amount of $42,424.

Analysis	Average Case-Weighted Threshold	Final Inflated Average Case-Weighted Standardized Charge
CCR for drugs and radiology	$42,424	$51,418
CCR for drugs	$42,424	$49,012
CCR for radiology	$42,424	$52,622

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in each analysis, the applicant asserted that XENOVIEW meets the cost criterion.

We are inviting public comments on whether XENOVIEW meets the cost criterion, including whether it is appropriate to assume that no charges should be removed for the prior technology or the technologies being replaced for the cases assigned to the identified MS–DRGs, particularly as the applicant noted 13% of patients within MS–DRGs 190–192 and 202–203 are without a complication or major complication, and therefore might be able to handle additional radiation exposure such as that through SPECT/CT or high-resolution CT, or nephrotoxicity from MRI. For this reason, we invite comment on whether any charges should be removed within the specified MS–DRGs to account for prior technology XENOVIEW would be replacing.

With regard to the substantial clinical improvement criterion, the applicant asserted that XENOVIEW offers: (1) A new service or treatment option for patients with early symptoms of breathing difficulty, including those with an uncertain diagnosis that are unresponsive to, or ineligible for, currently available treatments; (2) the ability to diagnose a medical condition in a patient population where the medical condition is currently undetectable; (3) the ability to diagnose a medical condition earlier than currently available methods; (4) improved outcomes such as novel actionable information to inform treatment decisions; and (5) the ability to safely monitor unexplained dyspnea.

In support of its first assertion that XENOVIEW can help patients with early symptoms of breathing difficulty, the applicant noted that these patients—which include those with suspected COPD, asthma, or those living with idiopathic pulmonary fibrosis or inflammatory pulmonary disease—can benefit from XENOVIEW's safety profile as it allows them to receive medically necessary diagnostic treatment to aid their treatment decisions. The applicant stated that these patients are particularly vulnerable to gadolinium contrast enhanced MRI, lung SPECT, or thoracic CT imaging. According to the applicant, XENOVIEW can aid in treatment management and would be able to be used for clinical decision making to reduce a COPD exacerbation, preempt asthma exacerbation, and support therapies for interstitial lung disease.

The applicant also asserted that XENOVIEW can help identify the ventilation defect percentage (VDP) in patients with early symptoms, including patients in early phase COPD or asthma, and can provide diagnostic information with lesser risk than other pulmonary function tests (PFTs) and lung imaging methods. The applicant cited an opinion paper by Usmani et al.,[534] which discusses small airways disease in the context of asthma and COPD, as background to highlight gaps in current knowledge that impede earlier identification of obstructive lung disease and the development and standardization of novel small airways-specific end points for use in clinical trials. The applicant stated that because XENOVIEW is intended to help assess small airways, it could help address the gaps in current knowledge discussed in the opinion paper.

The applicant asserted that detailed imaging through the 23 branches of the lung that can be provided by XENOVIEW is an ideal way to preemptively manage the patients with lung disease. In support of this claim, the applicant cited a narrative review by Crisafulli et al.[535] as background on AECOPD and the current treatment options. In this narrative, the authors conducted a review of 160 citations, based on a search of Medline completed in the month of May 2018, to update the scientific evidence about the in-hospital pharmacological (inhaled bronchodilators, steroids, antibiotics) and non-pharmacological treatments (oxygen, high flow nasal cannulae (HFNC) oxygen, non-invasive mechanical ventilation (NIMV), pulmonary rehabilitation (PR)) used in the management of a severe COPD exacerbation as well as studies about non-conventional drugs for severe AECOPD. The applicant asserted that HP ^{129}Xe MRI has been shown to identify signs of COPD earlier than conventional techniques and can therefore enable earlier rehabilitation for the patient, which was identified in the

[534] Usmani OS, Han MK, Kaminsky DA, Hogg J, Hjobert J, et al. Seven pillars of small airway disease in Asthma and COPD. CHEST 2021; 160(1):114–134.

[535] Crisafulli, E., Barbeta, E., Ielpo, A., Torres, A. (2018) Management of severe acute exacerbations of COPD: An updated narrative review. *Multidiscip Respir Med* 13: 36.

study as one factor that could improve treatment of AECOPD.

In support of its claim that XENOVIEW offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, the applicant cited additional references. The applicant asserted that use of HP ^{129}Xe MRI correlates with asthma severity, health care utilization and oral corticosteroid use. The applicant referenced an article by Lin et al.[536] in which children with asthma have a higher VDP ($p = 0.002$) and a higher number of defects per image slice than children without asthma ($p = 0.0001$). The article noted that children with asthma who had higher defects per image slice had a higher rate of health care utilization correlation (r) ($r = 0.48$; $p = 0.03$) and oral corticosteroid use ($r = 0.43$, $p = 0.05$). Asthma severity can be difficult to assess in children and the authors postulate that HP ^{129}Xe MRI can be used to identify children at a higher risk for exacerbations and improve outcomes. The applicant stated that VDP detected by HP ^{129}Xe was significantly different between the healthy cohort (n = 16 subjects), mild/moderate asthma cohort (n = 8 subjects), and severe asthma cohort (n = 13 subjects) as well as between the healthy cohort and the combined asthma cohorts (all $p < 0.002$). The applicant also noted that the forced expiratory volume in 1 second (FEV_1) pulmonary function test did not detect significant differences between any of the cohorts ($p = 0.15$) whereas the FEV_1 to forced vital capacity (FVC) ratio did ($p = 0.009$).

The applicant also cited the opinion paper by Usmani et al.[537] discussed in its first claim regarding the importance of assessing small airways. The applicant again asserted that HP ^{129}XE offers the diagnostic ability needed to assess small airways, is minimally invasive, and does not require additional ionizing radiation. The applicant states that this combination is not found in any other existing diagnostic tool for pulmonary function.

The applicant also asserted that XENOVIEW has been demonstrated to detect early stages of lung disease in smokers before progression to COPD and could help diagnose patients more accurately than the use of FEV_1 and related pulmonary function tests, which the applicant asserted can impair spirometry results. In support of this claim, the applicant provided background from a study performed by Fortis et al.,[538] a retrospective cohort study to evaluate whether slow vital capacity (SVC) instead of FVC increased the sensitivity of spirometry to identify patients with early or mild obstructive lung disease. The study included 854 current and former smokers in the U.S. aged 40–80 years from the Sub-populations and Intermediate Outcome Measures in COPD Study cohort with a postbronchodilator $FEV_1/FVC \geq 0.7$ and FEV_1% predicted of ≥ 80% at enrollment. Characteristics, chest CT scan features, exacerbations, and progression to COPD (postbronchodilator $FEV_1/FVC, < 0.7$) were compared to the baseline during the follow-up period between 734 participants with postbronchodilator $FEV_1/SVC \geq 0.7$ and 120 with postbronchodilator $FEV_1/SVC < 0.7$ at the enrollment. The study included multivariate linear and logistic regression models and negative binomial and interval-censored proportion hazards regression models adjusted for demographics and smoking exposure to examine the association of $FEV_1/SVC < 0.7$ with those characteristics and outcomes.

Of the 854 current and former smokers with normal spirometry results at enrollment, 120 participants showed a post bronchodilator FEV_1/SVC less than 0.7, and 734 participants showed an FEV_1/SVC greater than or equal to 0.7. Participants with a postbronchodilator FEV_1/SVC of less than 0.7 experienced more emphysema, gas trapping and severe exacerbations and manifested more COPD symptoms relative to those patients with FEV_1/SVC greater than or equal to 0.7. They also found similar results in patients with a prebronchodilator FEV_1/SVC of less than 0.7 or FEV_1/SVC less than the lower limit of normal with chest CT scan features and progression to COPD. In conclusion, the authors believed that FEV_1/SVC less than 0.7 or the lower limit of normal may be used as a metric of early obstruction and may be a useful tool in identifying individuals at increased risk of COPD. The authors noted that the study had some limitations as the analysis was limited to a cohort of heavy smokers older than 40 years and cautioned that the study findings may not be generalizable. The authors also stated that they did not take into consideration other risk factors for obstructive lung disease such as occupational exposure. Fortis et al. also noted that because FEV_1/SVC ratios are not widely used, there are no widely accepted reference values so they used 0.7 as a cutoff for the FEV_1 to true vital capacity (VC) for the main analysis.[539] The applicant stated that FEV_1 and related pulmonary function tests can result in increased intrathoracic pressure, which could shorten exhalation time and impair accurate spirometry results, and that this issue is not prevalent with HP ^{129}Xe MRI.

The applicant stated that XENOVIEW can provide critical diagnostic information for patients that cannot perform spirometry or tolerate the risk of standard lung imaging, and/or require detailed information on ventilation differences. The applicant also asserted that the safety profile of XENOVIEW for MRI lung diagnostics is superior to alternative lung imaging options, including PFT, because XENOVIEW does not use any ionizing radiation or impart any ionizing radiation in the procedure, and it offers visualization of MRI images without nephrotoxicity (in contrast to CT images), which permits it to be used for longitudinal therapeutic evaluation and assessment of disease progression.

The applicant asserted that HP ^{129}Xe MRI is able to depict airway obstructions in mild to moderate asthma and significantly correlates with PFTs. In support of this claim, the applicant referenced a study by Ebner et al.,[540] which investigated ventilation in mild to moderate asthmatic patients and age-matched controls using HP ^{129}Xe MRI and correlated findings with PFTs. In this study, 30 subjects (10 young asthmatic patients, 26 ± 6 years; three males, seven females; 10 older asthmatic patients, 64 ± 6 years; three males, seven females; 10 healthy controls) were enrolled. After repeated PFTs 1 week apart, the subjects underwent two MRI scans within 10 minutes, inhaling 1-L volumes containing 0.5 to 1 L of HP ^{129}Xe. The applicant stated that HP ^{129}Xe MRI detected significant differences between young healthy subjects and young asthmatic subjects

[536] Lin NY, Roach DJ, Willmer MM, Walkup LL, Hossain M, et al. ^{129}Xe MRI as a measure of clinical disease severity for pediatric asthma. 2021; Journal of Allergy and Clinical Immunology 147(6): 2146–2153.

[537] Usmani OS, Han MK, Kaminsky DA, Hogg J, Hjobert J, et al. Seven pillars of small airway disease in Asthma and COPD. CHEST 2021; 160(1):114–134.

[538] Fortis, S., Comellas, A.P., Bhatt, S.P., Hoffman, E.A., Han, M.K., Bhakta, N.R., Barjaktarevic, I. (2021) Ratio of FEV1/slow vital capacity of < 0.7 is associated with clinical, functional, and radiologic features of obstructive lung disease in smokers with preserved lung function. CHEST 160(1): 94–103.

[539] Ibid.

[540] Ebner L., He M., Virgincar R.S., Heacock T., Kaushik S.S., et al. Hyperpolarized ^{129}xenon magnetic resonance imaging to quantify regional ventilation differences in mild to moderate asthma: A prospective comparison between semiautomated ventilation defect percentage calculation and pulmonary function tests. 2017; Investigative Radiology 52: 120–127.

(p = 0.03), between young asthmatic subjects and old asthmatic subjects (p = 0.02), and between young healthy subjects and old healthy subjects (p = 0.05), whereas FEV_1% only detected a significant difference between young healthy subjects and young asthmatic subjects (p = 0.01).

The applicant also asserted that in patients with COPD, the VDP obtained with HP ^{129}Xe is significantly greater than that with HP ^{3}He MRI, suggesting incomplete or delayed filling of lung regions that may be related to the different properties inherent to HP ^{129}Xe gas and physiologic and/or anatomic abnormalities in COPD. The applicant provided a peer-reviewed journal article by Kirby et al.[541] on HP ^{3}He and HP ^{129}Xe MRI imaging in healthy volunteers and patients with COPD. Kirby et al. quantitatively compared HP ^{3}He and HP ^{129}Xe MRI images in healthy volunteers and patients with COPD with measurements from spirometry and plethysmography. In the study, 8 healthy patients and 10 COPD patients underwent MRI (5 minutes between HP ^{3}He MRI and HP ^{129}Xe MRI), spirometry and plethysmography. VDPs were calculated in HP ^{3}He and HP ^{129}Xe MRIs. HP ^{129}Xe VDP was significantly greater than HP ^{3}He VDPs for patients with COPD (p < 0.0001) but not for healthy volunteers (p = 0.35).

The applicant asserted that functional alveolar wall thickness assessed by HP ^{129}Xe MRI allows discrimination between healthy subjects and healthy smokers and the applicant asserted its belief that HP ^{129}Xe could be a useful tool for detecting early-stage lung disease. The applicant referenced a prospective cohort study by Ruppert et al.[542] that hypothesized that the functional alveolar wall thickness as assessed by HP ^{129}Xe MR spectroscopy would be elevated in clinically healthy smokers before HP ^{129}Xe MR diffusion measurements would indicate emphysematous tissue destruction. The researchers used HP ^{129}Xe MR to measure the functional septal wall thickness and apparent diffusion coefficient of the gas phase in 16 subjects with smoking-related COPD, 9 clinically healthy current or former smokers, and 10 healthy never-smokers. The applicant stated that the study results reported that in healthy never-smokers, the septal wall thickness increased by 0.04 μm per year of age, while that the healthy smoker cohort exhibited normal PFT measures that did not significantly differ from the never-smoker cohort. The applicant stated that the study results noted that age-corrected septal wall thickness correlated well with diffusion capacity for carbon monoxide (R^2 = 0.56) and showed a statistically significant difference between healthy subjects and COPD patients (p < 0.001) but was the only measure that actually discriminated healthy subjects from healthy smokers (p < 0.006). The applicant stated that this suggests HP ^{129}Xe MRI can be used to detect early stages of lung disease, and that detecting early COPD could enable lifestyle changes and encourage patients to gain insight into their disease to aid their health.

According to the applicant, the unique properties of HP ^{129}Xe are well-suited to evaluate pulmonary function in patients with lung cancer and HP ^{129}Xe has a potential advantage over other imaging modalities such as a ventilation-perfusion (VQ) scan since both gaseous and dissolved phases can be measured to provide a more comprehensive 3–D evaluation of ventilation and interstitial thickening. In support of this claim, the applicant cited a case report by Song et al.[543] involving a 64-year-old male who presented with dyspnea. In the study, the patient's chest CT revealed a seven cm right lung mass with mediastinal invasion and compression of the right mainstem bronchus while bronchoscopy showed a 90% obstructing mass in the right mainstem bronchus. Pathology was consistent with adenocarcinoma. The mass was hypermetabolic on PET/CT with involvement of mediastinal lymph nodes. The patient was under concurrent radiation therapy (RT) and chemotherapy and subsequently enrolled in the HP ^{129}Xe study after institutional review board approval. The study design involved the evaluation of HP ^{129}Xe before and after RT. The patient's right lung was completely expanded at diagnosis, yet the patient displayed significant dyspnea. The applicant stated that HP ^{129}Xe MRI detected non-ventilation to the right lung despite the right lung appearing inflated in the CT scan, and that the increased FEV_1 values from pre- to post-treatment reflected re-ventilation induced by treatment resulting from detected non-ventilation by the HP ^{129}Xe MRI. The study authors noted that post-treatment HP ^{129}Xe MRI confirmed re-ventilation of the lung.

The applicant further asserted that emphysema index based on HP ^{3}He and HP ^{129}Xe diffusion MRI provides a repeatable measure of emphysema burden, independent of gas or *b* value, with similar diagnostic performance as quantitative CT or pulmonary function metrics. The applicant referenced an article from Tafti et al.,[544] a retrospective study that sought to introduce and test a quantitative framework with which to characterize emphysema burden based on HP ^{3}He and HP ^{129}Xe apparent diffusion coefficient (ADC) maps and compare its diagnostic performance with CT-based emphysema metrics and PFTs. The authors indicated that emphysema is a disease characterized by irreversible destruction of alveolar walls that causes loss of lung elastic recoil and impaired gas exchange. The study investigated 27 patients with mild, moderate, or severe COPD and 13 age-matched healthy control subjects participated in this retrospective study. Participants underwent CT and multiple *b* value diffusion-weighted HP ^{3}He and HP ^{129}Xe MRI examinations and standard PFTs between August 2014 and November 2017. The ADC-based emphysema index was computed separately for each gas and *b* value as the fraction of lung voxels with ADC values greater than in the healthy group 99th percentile. The resulting values were compared with quantitative CT results (relative lung area < − 950 HU) as the reference standard. Diagnostic performance metrics included area under the receiver operating characteristic curve (AUC). Spearman rank correlations and Wilcoxon rank sum tests were performed between ADC-, CT-, and PFT-based metrics, and intraclass correlation was performed between repeated measurements. The study concluded that an emphysema index based on HP ^{3}He and HP ^{129}Xe diffusion MRI provides a repeatable measure of emphysema burden, independent of gas or *b* value, with similar diagnostic performance as quantitative CT or pulmonary function metrics. The applicant stated that HP ^{129}Xe MRI offered higher sensitivity in detecting pulmonary obstruction, as

[541] Kirby M., Svenningsen S., Owrangi A., Wheatley A., Farag A., et al. Hyperpolarized ^{3}He and ^{129}Xe MR imaging in healthy volunteers and patients with chronic obstructive pulmonary disease. 2012;Radiology 265(2): 600–610.

[542] Ruppert K., Qing K., Patrie J.T., Altes T.A., Mugler J.P.. Using hyperpolarized xenon-129 MRI to quantify early-stage lung disease in smokers. Acad. Radiol. 2019 March; 26(3): 355–366. doi:10.1016/j.acra.2018.11.005.

[543] Song, E.J., Kelsey, C.R., Driehuys, B., Rankine, L. (2018) Functional airway obstruction observed with hyperpolarized ^{129}xenon-MRI. *J Med Imaging Radiat Oncol* 62: 91–98.

[544] Tafti, S., Garrison, W.J., Mugler III, J.P., Shim, Y.M., Altes, T.A., Mata, J.F., de Lange, E.E., Cates, G.D., Ropp, A.M., Wang, C., Miller, G W. (2020) Emphysema index based on hyperpolarized ^{3}He or ^{129}Xe diffusion MRI: Performance and comparison with quantitative CT and pulmonary function tests. *Radiology* 297: 201–210.

19% of subjects with COPD appeared healthy based on CT scans, and emphysematous based on HP ^{3}He and HP ^{129}Xe MRI ADC, whereas no subjects with COPD appeared healthy based on HP ^{3}He and HP ^{129}Xe MRI ADC.

The applicant asserted that HP ^{129}Xe MRI could develop into a tool that can guide individualized patient care and the use of HP ^{129}Xe MRI may have a role as a tool for both patient selection and measuring treatment response in future COPD clinical trials. To support its claim that HP ^{129}Xe MRI provides a quantitative, reproducible measure of treatment effectiveness, the applicant cited a study by Mummy et al.,[545] a prospective study characterizing changes in HP ^{129}Xe gas transfer function following administration of an inhaled long-acting beta-agonist/long-acting muscarinic receptor antagonist (LABA/LAMA) bronchodilator. The study involved 17 COPD study participants with a GOLD II/III classification per Global Initiative for Chronic Obstructive Lung Disease criteria. The study participants were imaged before and after 2 weeks of LABA/LAMA therapy. According to the applicant, the study concluded that LABA/LAMA therapy tended to preferentially improve ventilation in those subjects with relatively preserved measures of HP ^{129}Xe barrier uptake and DL_{CO} (carbon monoxide) and noted that even in study participants with improved ventilation, newly ventilated lung regions often revealed persistent HP ^{129}Xe red blood cell (RBC) transfer defects, an aspect of LABA/LAMA therapy response that is opaque to spirometry. The study indicated that these results add to the body of knowledge regarding COPD phenotypes and indicate a possible role for HP ^{129}Xe gas transfer MRI as a tool for both patient selection and measuring treatment response in future COPD clinical trials. The study also concluded that as health care develops therapies that demonstrably improve not only ventilation but also RBC transfer, HP ^{129}Xe may develop into a tool that can guide individualized patient care.[546]

The applicant asserted HP ^{129}Xe is a useful imaging tool for conducting pulmonary assessments on a patient-specific scale and allows for a deeper examination of underlying pathologies and pulmonary function test results. In support, the applicant referenced an article by Wang et al.[547] that indicated that HP ^{129}Xe MRI has emerged as a novel means to evaluate pulmonary function via 3-D mapping of ventilation, interstitial barrier uptake, and RBC transfer, and the physiological interpretation of these measurements has yet to be firmly established. The authors proposed a model that uses the three components of HP ^{129}Xe MRI to estimate accessible alveolar volume (V_A), membrane conductance, and capillary blood volume contributions to carbon monoxide (DL_{CO}). The model was built on a cohort of 41 healthy subjects and 101 patients with pulmonary disorders. The study concluded that the ability to use HP ^{129}Xe MRI measures of ventilation, barrier uptake, and RBC transfer to estimate each of the underlying constituents of DL_{CO} clarifies the interpretation of these images while enabling their use to monitor these aspects of gas exchange independently and regionally. The applicant stated that HP ^{129}Xe MRI-derived DL_{CO} values and measured DL_{CO} values were significantly correlated ($p < 0.001$), while ventilated volume, barrier transfer, and red blood cell transfer were significantly different between the healthy cohort and the individual disease cohorts.

With respect to the applicant's assertion that XENOVIEW will provide novel actionable information that will lead to improved treatment decisions because it will provide clinicians with information beyond current lung imaging techniques, the applicant summarized a Song et al.[548] case study of a 64-year-old with dyspnea, discussed previously. The applicant asserted that HP ^{129}Xe identified the right lung to be unventilated despite a fairly normal CT appearance. The applicant stated that XENOVIEW can safely monitor unexplained dyspnea and that a prospective study is underway to validate the value HP ^{129}Xe MRI can add to evaluate pulmonary function in patients with lung cancer. The applicant asserted that this case report and prior studies consistently found that HP ^{129}Xe MRI has imaging capabilities above those of reporting VQ scans because both gaseous and dissolved phases can be measured to provide more comprehensive 3-D evaluation of ventilation and interstitial thickening. The applicant stated that further analysis of the benefit of established regional lung function and ventilation, when added to analysis of gaseous exchange, will enable better patient identification for surgical planning and RT and that dose-dependent functional changes of radiation could be evaluated allowing guided radiation administration to limit the RT to the most highly functional regions in the lung, reducing long-term effects of the therapy.

Based on the information provided by the applicant in support of the substantial clinical improvement criterion, we have the following concerns. With respect to the applicant's claim that XENOVIEW offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, we note that XENOVIEW is a diagnostic test and does not itself provide a treatment, but can be used in monitoring patients with pulmonary pathologies.

With respect to the applicant's claim that XENOVIEW is able to diagnose a medical condition in a patient population where the medical condition is currently undetectable and diagnose a medical condition earlier than currently available methods, we note that the studies do not appear to provide evidence showing that use of the technology to make a diagnosis affected the management of the patients, as under § 412.87(b)(1)(ii)(B). We also note that one of the studies cited utilized a pediatric cohort of patients, which is a patient population largely distinct from the Medicare population.[549] We note that, in other instances, the journal articles provided for review were for clinical studies with contributors outside the U.S. such as the Ebner et

[545] Mummy, D.G., Coleman, E.M., Wang, Z., Bier, E.A., Lu, J., Driehuys, B., Huang, Y.C. (2021) Regional gas exchange measured by ^{129}Xe magnetic resonance imaging before and after combination bronchodilators treatment in chronic obstructive pulmonary disease. *J Magn Reson Imaging* 54(3): 964–974. DOI: 10.1002/jmri.27662.

[546] Mummy, D.G., Coleman, E.M., Wang, Z., Bier, E.A., Lu, J., Driehuys, B., Huang, Y.C. (2021) Regional gas exchange measured by ^{129}Xe magnetic resonance imaging before and after combination bronchodilators treatment in chronic obstructive pulmonary disease. *J Magn Reson Imaging* 54(3): 964–974. DOI: 10.1002/jmri.27662.

[547] Wang Z., Rankine L., Bier E.A., Mummy D., Lu J., et al. Using hyperpolarized ^{129}Xe gas exchange MRI to model the regional airspace, membrane and capillary contributions to diffusing capacity. J Appl Physiol 130: 1398–1409, 2021. First published March 18, 2021; doi:10.1152/japplp.

[548] Song, E.J., Kelsey, C.R., Driehuys, B., Rankine, L. (2018) Functional airway obstruction observed with hyperpolarized ^{129}xenon-MRI. *J Med Imaging Radiat Oncol* 62: 91–98.

[549] Lin N.Y., Roach D.J., Willmer M.M., Walkup L.L., Hossain M., et al. ^{129}Xe MRI as a measure of clinical disease severity for pediatric asthma. 2021; Journal of Allergy and Clinical Immunology 147(6): 2146–2153.

al.[550] and Crisafulli et al.[551] articles, and that there may be differing standards of care that could affect the detection of these medical conditions as well as the subsequent management of the patients. We also note that the narrative review by Crisafulli et al. does not address the use of XENOVIEW, but rather discusses potential future improvements in the treatment of AECOPD. As the study does not measure the effect of XENOVIEW on actual treatment outcomes, we are uncertain if the technology will lead to improvement in clinical outcomes. We invite public comments as to whether the studies discussed previously can be generalized to the Medicare population.

With respect to the applicant's claim that XENOVIEW used in MRI will provide novel actionable information that will lead to improved treatment decisions, we question whether the results of a single case report, consisting of only one patient, are generalizable to the Medicare population as a whole. We also question whether XENOVIEW's use in Song et al.[552] was used to inform the patient treatment decision, as it appears from the case study that the treatment for the right lung collapse was radiation therapy for the adenocarcinoma, and that this radiation planning was informed via CT imaging. In addition, while the applicant asserts that XENOVIEW can provide actionable information by early detection of lung diseases such as asthma/COPD, we question whether this is relevant to patients in the inpatient setting. We also note that the studies provided by the applicant do not appear to assess the use of XENOVIEW to significantly improve clinical outcomes over existing technologies, as they are primarily feasibility/correlation studies,[553] [554] [555] [556] and that the studies assume but do not provide evidence that earlier diagnosis and potentially earlier treatment would result in better clinical outcomes. We also note that some studies appeared to describe the use of non-XENOVIEW HP ^{129}Xe (that is, xenon hyperpolarized using the XeBox–E10, which is manufactured by Xemed, LLC), and we question whether the results of these studies using non-XENOVIEW HP ^{129}Xe MRI can be extrapolated to the use of XENOVIEW HP ^{129}Xe MRI.[557] [558] We would also be interested in additional evidence that demonstrates how the use of XENOVIEW results in a change in patient disease management, improved clinical decisions, as well as improvement in clinical outcomes based on earlier diagnosis and/or enhanced imaging.

We are inviting public comments on whether XENOVIEW meets the substantial clinical improvement criterion.

In this section, we summarize and respond to written public comments received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for XENOVIEW.

Comment: The applicant submitted a public comment in response to three questions posed at the December 2021 New Technology Town Hall meeting and provided additional studies. First, the applicant was asked whether there are studies in the medical literature that have shown that early detection of disease using XENOVIEW and followed longitudinally have better outcomes than patients who are monitored with PFTs or other diagnostic tools. In response, the applicant stated that HP ^{129}Xe is currently under review by FDA as a drug used in MRI and that there are no published studies reporting early detection of disease using XENOVIEW and following longitudinally reported outcomes.

The applicant then cited the Mummy D.G., et al.[559] prospective study about 67 asthmatics comparing HP ^{3}He VDP and PFTs over 2 years to correlate VDP levels with outcomes. The Mummy et al. study found that HP ^{3}He at levels greater than 4.28% were associated with an exacerbation incidence ratio of 2.5 (95% CI 1.3–4.7) compared to VDP less than 4.28%. The applicant also stated that XENOVIEW VDP correlates well with HP ^{3}He VDP and is more sensitive than spirometry.[560] Further, the applicant stated that HP ^{129}Xe allows radiologists and pulmonologists to evaluate images within the patient's own thoracic cavity and contrasted HP ^{129}Xe with PFTs, which the applicant asserts requires comparisons to reference equations that depend on age, sex, height, and ethnicity.

Next, the applicant stated additional studies report HP ^{129}Xe MRI being correlated with the apparent diffusion coefficient-based emphysema index (ADC) obtained with quantitative computed tomography (CT).[561] [562] [563] According to the applicant VDP, FEV_1, FEV_1/FVC and ADC are measures relied upon by pulmonologists to follow a patient's response to treatment, to refine the patient's diagnosis and to aid patient compliance. The applicant stated that

[550] Ebner L., He M., Virgincar R.S., Heacock T., Kaushik S.S., et al. Hyperpolarized ^{129}xenon magnetic resonance imaging to quantify regional ventilation differences in mild to moderate asthma: A prospective comparison between semiautomated ventilation defect percentage calculation and pulmonary function tests. 2017; Investigative Radiology 52: 120–127.

[551] Crisafulli, E., Barbeta, E., Ielpo, A., Torres, A. (2018) Management of severe acute exacerbations of COPD: An updated narrative review. *Multidiscip Respir Med* 13: 36.

[552] Song, E.J., Kelsey, C.R., Driehuys, B., Rankine, L. (2018) Functional airway obstruction observed with hyperpolarized ^{129}xenon-MRI. *J Med Imaging Radiat Oncol* 62: 91–98.

[553] Ebner L., He M., Virgincar R.S., Heacock T., Kaushik S.S., et al. Hyperpolarized ^{129}Xenon magnetic resonance imaging to quantify regional ventilation differences in mild to moderate asthma: A prospective comparison between semiautomated ventilation defect percentage calculation and pulmonary function tests. 2017; Investigative Radiology 52: 120–127.

[554] Tafti, S., Garrison, W.J., Mugler III, J.P., Shim, Y.M., Altes, T.A., Mata, J.F., de Lange, E.E., Cates, G.D., Ropp, A.M., Wang, C., Miller, G.W. (2020) Emphysema index based on hyperpolarized ^{3}He or ^{129}Xe diffusion MRI: Performance and comparison with quantitative CT and pulmonary function tests. Radiology 297: 201–210.

[555] Kirby M., Svenningsen S., Owrangi A., Wheatley A., Farag A., Ourladov A., Santyr G.E., Etemad-Rezai R., Coxson H.O., McCormack D.G., Parraga G.. Hyperpolarized ^{3}He and ^{129}Xe MR imaging in healthy volunteers and patients with chronic obstructive pulmonary disease. Radiology. 2012;265(2):600–610.

[556] Wang Z., Rankine L., Bier E.A., Mummy D., Lu J., et al. Using hyperpolarized ^{129}Xe gas exchange MRI to model the regional airspace, membrane and capillary contributions to diffusing capacity. J Appl Physiol 130: 1398–1409, 2021. First published March 18, 2021; doi:10.1152/japplp.

[557] Ruppert K., Qing K., Patrie J.T., Altes T.A., Mugler III J.P. Using hyperpolarized xenon-129 MRI to quantify early-stage lung disease in smokers. Acad Radiol. 2019;26(3):355–366. doi: 10.1016/j.acra.2018.11.005

[558] Tafti, S., Garrison, W.J., Mugler III, J.P., Shim, Y.M., Altes, T.A., Mata, J.F., de Lange, E.E., Cates, G.D., Ropp, A.M., Wang, C., Miller, G.W. (2020) Emphysema index based on hyperpolarized ^{3}He or ^{129}Xe diffusion MRI: Performance and comparison with quantitative CT and pulmonary function tests. Radiology 297: 201–210.

[559] Mummy D.G., Carey K.J., Evans M.D., et al. Ventilation defects on hyperpolarized helium-3 MRI in asthma are predictive of 2-year exacerbation frequency [published online ahead of print March 13, 2020]. J Allergy Clin Immunol.

[560] Kirby M., Svenningsen S., Owrangi A., Wheatley A., Farag A., et al. Hyperpolarized ^{3}He and ^{129}Xe MR imaging in healthy volunteers and patients with chronic obstructive pulmonary disease. Radiology: Volume 265: Number 2—November 2012.

[561] Kirby M, Svenningsen S, Owrangi A, Wheatley A, Farag A, Ourladov A, Santyr GE, Etemad-Rezai R, Coxson HO, McCormack DG, Parraga G. Hyperpolarized ^{3}He and ^{129}Xe MR imaging in healthy volunteers and patients with chronic obstructive pulmonary disease. *Radiology*. 2012;265(2):600–610.

[562] Tafti S, Garrison WJ, Mugler III JP, Shim YM, Altes TA, Mata JF, de Lange EE, Cates GD, Ropp AM, Wang C, Miller GW. Emphysema index based on hyperpolarized ^{3}He or ^{129}Xe diffusion MRI: Performance and comparison with quantitative CT and pulmonary function tests. Radiology. 2020;297:201–210.

[563] Doganay O, Matin T, Chen M, Kim M, McIntyre A, McGowan DR, Bradley KM, Povey T, Gleeson FV. Time-series hyperpolarized xenon-129 MRI of lobar lung ventilation of COPD in comparison to V/Q–SPECT/CT and CT. *Eur Radiol*. 2019;29:4058–4067.

HP ^{129}Xe MRI provides these measures with a high degree of accuracy and correlates well to disease clinical signs and symptoms.

Next, the applicant provided a ''summary of evidence'' by first citing a Horn et al. study that measured HP ^{3}He MRI to determine its effectiveness at treatment response mapping (TRM) in response to respiratory therapeutic agents in the lungs.[564] According to the applicant, 20 patients with asthma were examined in this analysis using TRM to quantify regional physiologic response to a bronchodilator and provide regional quantitative information on changes in inhaled gas ventilation in response to therapy. The applicant stated that the study concluded that TRM has potential to aid treatment decisions for the assessment of regional lung interventions such as anti-inflammatory therapies or targeted therapies such as thermoplasty, endobronchial valve therapy, and lung volume reduction surgery. The applicant asserted the findings are applicable to measurements derived from HP ^{129}Xe and that HP ^{129}Xe can be used to provide regional insight into alterations of both the structure and function of the lungs, and that this is increasingly being used as an outcome measure in the early-phase evaluation of respiratory therapeutic agents. The applicant also noted that regionally specific therapies, such as bronchial thermoplasty, require regional information so the efficacy of the intervention can be assessed. The applicant also noted, but did not cite, that previous studies have used computed tomography (CT) and computational fluid dynamics-derived markers of airflow to assess functional changes after bronchodilator therapy.

The applicant also cited Rayment JH, et al. who performed a study measuring the VDP in 15 CF patients between the ages of 8–18 who underwent HP ^{129}Xe MRI, spirometry, plethysmography and multiple-breath nitrogen washout at the beginning and end of inpatient treatment of a pulmonary exacerbation. Per the applicant, VDP was calculated from HP ^{129}Xe MRI obtained during a static breath hold using semi-automated *k*-means clustering and linear binning approaches. The applicant stated that Rayment et al. reported that imaging, spirometric FEV_1, lung clearance index, plethysmographic, MBW, and symptom score outcomes improved with treatment. The applicant noted that the study reported that VDP showed the largest relative improvement compared to all outcome measures (−42.1%, 95% CI −52.1−−31.9%, p<0.0001). The applicant suggested that this technique can generate outcomes that are responsive to treatment regardless of the image analysis technique used, and that using HP Xe-129 MRI to measure VDP as a metric of outcome response is expected to aid understanding of the individual patient response to treatment.[565]

The applicant also cited an Altes et al.[566] blinded study on a population of CF patients >12 years of age with a G551D–CFTR mutation to measure the effect of short- and long-term ivacaftor treatment on HP ^{3}He MRI defined ventilation defects. According to the applicant, the study design included: Part A (single-blind) comprised 4 weeks of ivacaftor treatment; and Part B (open-label) comprised 48 weeks of treatment. The applicant noted that the study's primary outcome measure was the change from baseline in total ventilation defect (TVD; total defect volume: Total lung volume ratio). The applicant reported that the study findings revealed that the mean change in TVD ranged from −8.2% (p = 0.0547) to −12.8% (p = 0.0078) in Part A (n = 8) and −6.3% (p = 0.1953) to −9.0% (p = 0.0547) in Part B (n = 8) as assessed by human reader and computer algorithm, respectively. The applicant stated that the study concluded that TVD responded to ivacaftor therapy, and that HP ^{3}He MRI provided an individual quantification of disease burden that may be able to detect aspects of the disease missed by population-based spirometry metrics.

The applicant also re-submitted the New Technology Town Hall slide discussing the Thomen et al.[567] study in patients with mild CF to illustrate that HP ^{129}Xe MRI is a more sensitive measure than spirometry. The applicant also provided additional evidence of HP ^{129}Xe's quantitative measurement of pulmonary function from Doganay et al.[568] in which HP ^{129}Xe MRI was compared to PFT imaging standards relied upon by pulmonologists when following patients recommended for pharmacologic therapy. The applicant stated that in the study, 12 COPD subjects who were subjected to rapid time-series HP ^{129}Xe MRI imaging and compared to ventilation/perfusion single-photon emission computed tomography (V/Q–SPECT), high-resolution CT and PFTs for measuring lobar percentage ventilation. The applicant stated that the study concluded that lobar ventilation with HP ^{129}Xe MRI showed a strong correlation with lobar ventilation and perfusion measurements derived from SPECT/CT (r = 0.644; p < 0.001 for percentage ventilation SPECT and r = 0.767; p <0.001 for perfusion SPECT) and that the measured whole lung HP ^{129}Xe MRI percentage ventilation correlated with the PFT measurements (FEV_1 with r = −0.886, p < 0.001, and FEV_1/FVC with r = −0.861, p < 0.001) better than the emphysema score obtained from high resolution CT (FEV_1 with r = −0.635, p = 0.027; and FEV_1/FVC with r = −0.652, p = 0.021).

The applicant repeated an assertion that XENOVIEW's sensitivity of pulmonary regions that cannot be imaged by CT or SPECT/CT has been found to identify signs of COPD disease earlier and more accurately than conventional techniques,[569] which enables clinicians to identify patients at risk of readmission.[570]

Next, the applicant asserted that Kirby et al. validated HP ^{3}He VDP measurements to HP ^{129}Xe VDP measurements.[571] The applicant then stated HP ^{3}He was the most commonly studied MRI agent; however HP ^{129}Xe MRI has evolved into the ''favored'' inhaled gas for functional pulmonary MRI due to the lower cost and higher availability of HP ^{129}Xe as well as advances in hyperpolarization physics that have allowed for greater

[564] Horn FC, Marshall H, Collier GJ, Kay R, Siddiqui S, Brightling CE, Parra-Robles J, Wild JM. Regional Ventilation Changes in the Lung: Treatment Response Mapping by Using Hyperpolarized Gas MR Imaging as a Quantitative Biomarker. Radiology 2017;284(3):854–861.

[565] Rayment JH, Couch MJ, McDonald N, Kanhere N, Manson D, Santyr G, Ratjen F. Hyperpolarised ^{129}Xe magnetic resonance imaging to monitor treatment response in children with cystic fibrosis. Eur Respir J 2019;53(5).

[566] Altes TA, Johnson M, Fidler M, Botfield M, Tustison NJ, Leiva-Salinas C, de Lange EE, Froh D, Mugler JP. Use of hyperpolarized helium-3 MRI to assess response to ivacaftor treatment in patients with cystic fibrosis. J Cyst Fibros 2017;16(2):267–274.

[567] Thomen RP, Walkup LL, Roach DJ, Cleveland ZI, Clancy JP, Woods JC. Hyperpolarized ^{129}Xe for investigation of mild cystic fibrosis lung disease in pediatric patients. J Cyst Fibros 2017;16(2):275–282.

[568] Doganay O, Matin T, Chen M, Kim M, McIntyre A, McGowan DR, Bradley KM, Povey T, Gleeson FV. Time-series hyperpolarized xenon-129 MRI of lobar lung ventilation of COPD in comparison to V/Q–SPECT/CT and CT. *Eur Radiol.* 2019;29:4058–4067.

[569] Crisafulli E, Barbeta E, Ielpo A, Torres A. Management of severe acute exacerbations of COPD: An updated narrative review. *Multidiscip Respir Med.* 2018;13:36.

[570] Press VG, Konetzka RT, White SR. Insights about the economic impact of COPD readmissions post implementation of the Hospital Readmission Reduction Program. *Curr Opin Pulm Med.* 2018;24(2):138–146.

[571] Kirby M, Svenningsen S, Owrangi A, Wheatley A, Farag A, et al. Hyperpolarized ^{3}He and ^{129}Xe MR imaging in healthy volunteers and patients with chronic obstructive pulmonary disease. Radiology: Volume 265: Number 2—November 2012.

polarization efficiency of HP ^{129}Xe.[572] Next, the applicant stated that studies using HP ^{3}He MR images reporting treatment response correlate well to HP ^{129}Xe MR images. The applicant also referenced a table excerpted from Kirby et al., and reports that there are significant correlations between HP ^{3}He and HP ^{129}Xe MR imaging measurements of VDP with FEV_1.[573]

According to the applicant, VDP obtained from HP ^{3}He MRI was found to be a predictor of asthma severity and predict exacerbation in a population of asthma and COPD patients.[574] [575] [576] The applicant stated that HP ^{129}Xe VDP can be relied upon as quantitatively similar or better than HP ^{3}He VDP.[577] According to the applicant, HP ^{3}He and HP ^{129}Xe MR images were quantitatively compared to results from spirometry and those from plethysmography in a population of 8 healthy volunteers and 10 patients with COPD. According to the applicant, quantitative gold standard measurements included VDPs of HP ^{3}He and HP ^{129}Xe MR imaging, compared to measurements of FEV_1, FEV_1/FVC ratio, ADC, and CT emphysema score. The applicant stated that tables in Kirby et al. provided a comparison of the correlation of HP ^{129}Xe to gold standard PF measurements relied upon by pulmonologists.

The applicant asserted that the predictive power of VDP obtained from HP ^{3}He identified COPD patients with a higher likelihood of increased hospitalization due to exacerbation, therefore HP ^{129}Xe MRI VDP can be relied upon to be equally predictive. The applicant stated that Kirby et al. concluded that, in patients with COPD, the VDP obtained with HP ^{129}Xe MRI was ''significantly greater'' than that obtained with HP ^{3}He, and that this was likely due to HP ^{129}Xe's ability to fill lung spaces even in the presence of the physiologic and/or anatomic abnormalities in COPD patients.[578] The applicant stated that because HP ^{129}Xe is delivered and imaged in the same manner as HP ^{3}He, XENOVIEW likely shares that predictive power while also providing more extensive detail of alveolar gas-exchange compared to HP ^{3}He MRI.

Next, the applicant noted that numerous studies, including a Mummy et al.[579] study and a Svenningsen et al.,[580] study have suggested that HP ^{129}Xe is a useful resource to guide patient treatment decisions of COPD and asthma, respectively, based on the deeper understanding it provides of patient response to treatment (for example, bronchodilators).

In summary, the applicant stated in response to the first question asked at the New Technology Town Hall meeting that HP ^{129}Xe MRI provides pulmonologists with relied upon measurements of pulmonary function to inform treatment decisions. The applicant stated that lung CT can only image the first six airway branches. The applicant stated earlier disease and more subtle response to pharmacologic treatment has been quantified because XENOVIEW provides regional function and ventilation on 23 branches of the airway tree. Per the applicant, XENOVIEW MRIs enable identification of COPD or lung tissue abnormalities, leading to reduced elasticity earlier than spirometry or lung CT.[581]

The next two questions asked at the New Technology Town Hall meeting pertained to the ''gold standard'' for diagnosis when comparing sensitivity for HP ^{129}Xe and FEV_1, and a request to share ''receiver operator characteristics'' for the comparison of diagnostic accuracy. The applicant stated that the evidence for these answers was related and provided a combined response.

According to the applicant, pulmonary function is reported using FEV_1 measured by spirometry for FEV_1/FVC <0.7, yet lacks accuracy at the individual patient level.[582] Next, the applicant stated high resolution CT (HRCT) and in some cases SPECT/(CT) have been added to aid accuracy in diagnosis to inform treatment decisions. The applicant stated that these diagnostic tools are the gold standard(s) for measuring pulmonary function as a measure of diminished lung capacity.[583]

The applicant explained that due to the versatility of HP ^{129}Xe MRI, XENOVIEW can produce different measurements for PF related to disease with the accuracy reported by receiver operator characteristics (ROC). The applicant referenced Ebner, et al., a retrospective study that reported ROC data on the relationship of the ventilation defect scores (VDSs) derived from HP ^{129}Xe MRI identified with clinically relevant airway obstruction. The applicant stated that healthy volunteers (n=27) were compared to patients with asthma (n=20), and COPD (n=8), and that all the subjects underwent spirometry 1 day before MRI to establish the presence of airway obstruction (FEV_1/FVC <70%). The applicant stated that five blinded readers assessed the degree of ventilation impairment and assigned a VDS (range, 0–100%). According to the applicant, the study found that VDS measured with HP ^{129}Xe MRI correlated with the severity of airway obstruction and is significantly different between healthy control subjects and patients with mild to moderate airway obstruction. The applicant stated that while FEV_1/FVC is an imperfect gold standard, Ebner et al applied HP ^{129}Xe MRI, a less effort-dependent and reproducible test, to establish a threshold for clinically significant ventilation defects to enable informed treatment decisions.[584]

According to the applicant, Ruppert et al.[585] were able to detect early stages of

[572] Mugler JP, Altes TA. Hyperpolarized ^{129}Xe MRI of the human lung. J Magn Reson Imaging 2013; 37: 313–331.

[573] Kirby M, Svenningsen S, Owrangi A, Wheatley A, Farag A, et al. Hyperpolarized ^{3}He and ^{129}Xe MR imaging in healthy volunteers and patients with chronic obstructive pulmonary disease. Radiology: Volume 265: Number 2—November 2012.

[574] Mummy DG, Kruger SJ, Zha W, et al. Ventilation defect percent in helium-3 magnetic resonance imaging as a biomarker of severe outcomes in asthma. *J Allergy Clin Immunol.* 2018;141(3):1140–1141 e1144.

[575] Mummy DG, Carey KJ, Evans MD, et al. Ventilation defects on hyperpolarized helium-3 MRI in asthma are predictive of 2-year exacerbation frequency [published online ahead of print March 13, 2020]. *J Allergy Clin Immunol.*

[576] Kirby M, Pike D, Coxson HO, McCormack DG, Parraga G. Hyperpolarized (3)He ventilation defects used to predict pulmonary exacerbations in mild to moderate chronic obstructive pulmonary disease. Radiology 2014;273(3):887–896.

[577] Kirby M, Svenningsen S, Owrangi A, Wheatley A, Farag A, et al. Hyperpolarized ^{3}He and ^{129}Xe MR imaging in healthy volunteers and patients with chronic obstructive pulmonary disease. Radiology: Volume 265: Number 2—November 2012.

[578] Kirby M, Svenningsen S, Owrangi A, Wheatley A, Farag A, et al. Hyperpolarized ^{3}He and ^{129}Xe MR imaging in healthy volunteers and patients with chronic obstructive pulmonary disease. Radiology: Volume 265: Number 2—November 2012.

[579] Mummy DG, Coleman EM, Wang Z, Bier EA, Lu J, Driehuys B, Huang YC. Regional gas exchange measured by ^{129}Xe magnetic resonance imaging before and after combination bronchodilators treatment in chronic obstructive pulmonary disease. *J Magn Reson Imaging.* 2021;54(3):964–974. doi: 10.1002/jmri.27662.

[580] Svenningsen S, Eddy RL, Lim HF, Cox PG, Nair P, Parrage G. Sputum eosinophilia and magnetic resonance imaging ventilation heterogeneity in severe asthma. *Am J Respir Crit Care Med.* 2018;197(7):876–884. doi: 10.1164/rccm.201709–1948OC.

[581] Doganay O, Chen M, Matin T, Kim M, McIntyre A, et al. Magnetic resonance imaging of the time course of hyperpolarized. ^{129}Xe gas exchange in the human lungs and heart. *Eur Radiol.* 2019;29:2283–2292.

[582] Salzman SH. Which Pulmonary Function Tests Best Differentiate Between COPD Phenotypes? Respiratory Care. 2012;57:50–60.

[583] Mallallah F, Packham A, Lee E, Hind D. Is hyperpolarised gas magnetic resonance imaging a valid and reliable tool to detect lung health in cystic fibrosis patients? A COSMIN systematic review. 2021; Journal of Cystic Fibrosis online 14 January 2021.

[584] Ebner L, Virgincar R, He M, Choudhury KR, Robertson SH et al. Multi-Reader Determination of Clinically Significant Airway Obstruction using Hyperpolarized ^{129}Xe Ventilation MRI. AJR Am J Roentgenol. 2019 April; 212(4): 758–7.

[585] Ruppert K, Qing K, Patrie JT, Altes TA, Mugler III JP. Using hyperpolarized xenon-129 MRI to

Continued

lung disease in smokers before it progressed to COPD detected by spirometry. The applicant stated that in this study, the functional septal wall thickness and apparent diffusion coefficient of the gas phase was compared across 16 patients with smoking-related COPD, 9 clinically healthy current or former smokers, and 10 healthy never smokers. The applicant stated that a table from Ruppert et al. showed the ROC area under curve (AUC) provides evidence to aid in understanding HP ^{129}Xe MRI when considering the metrics of early-stage lung disease.[586] According to the applicant, HP ^{129}Xe MRI produced favorable metrics for determining early-stage lung disease compared to FEV_1. The applicant reported while the study had a small sample size, the ROC and AUC indicate HP ^{129}Xe MR imaging does detect patients with early lung disfunction.

The applicant stated that in a separate study by Tafti et al.,[587] a table reported that ADC yielded a much higher ROC AUC of ≥0.92 [0.83, 1.00] when used to determine emphysema. The applicant stated that the ADC emphysema index showed near-perfect sensitivity in a sample of 17 patients, all of whom were measured with both HP ^{3}He and HP ^{129}Xe (95% CI: 94%, 100%), but somewhat lower specificity (14 of 19 = 74% for HP ^{3}He [95% CI: 49%, 99%]; 13 of 19 = 68% for HP ^{129}Xe [95% CI: 42%, 94%]).

The applicant stated that Lin et al.[588] showed, in a population of children with asthma, a difference in HP ^{129}Xe compared to spirometry related to patient's clinical signs and symptoms. The applicant stated that in this study of 37 children with asthma, ^{129}Xe MRI was able to distinguish between control patients and patients with disease, whereas spirometry did not. The applicant stated Lin et al. demonstrated sensitivity, specificity and PPV values of HP ^{129}Xe to provide reliable prediction of asthma severity. The applicant stated that currently, there are no adequate predictive diagnostic tools to clearly measure clinical severity of pediatric asthma that concurrently provide information about regional ventilation differences.[589] The applicant stated that results from HP ^{129}Xe MRI are correlated with increased asthma severity, as well as increased healthcare utilization (HCU) and oral corticosteroid (OCS) use. According to the applicant, even with relatively modest cohort numbers, ROC analysis demonstrated that VDP and image scoring can predict increased asthma severity and HCU in a pediatric asthma cohort. The applicant stated that the improved predictive value, high safety profile, and short and tolerable imaging process allows for longitudinal follow-up in children. According to the applicant, the ROC curves from Lin et al. demonstrated that the number of defects (AUC, 0.83) is more predictive of healthcare utilization (HCU) than VDP (AUC, 0.73), and that the number of defects is more predictive of severe asthma (AUC, 0.86) than is VDP (AUC, 0.80).[590] The applicant stated that these findings are consistent with HP ^{129}Xe MRI (similar to HP ^{3}He) VDP in COPD patients as predictive of a higher likelihood of increased hospitalization.

Response: We thank the applicant for its comments and will take this information into consideration when deciding whether to approve new technology add-on payments for XENOVIEW. Regarding XENOVIEW, we note the applicant stated there are no published studies reporting early detection of disease using XENOVIEW that followed longitudinally reported outcomes. We also note that many of the articles submitted by the applicant were not about XENOVIEW, but rather described the usage of hyperpolarized 3-Helium (or HP ^{3}He) imaging and the correlation of measurements obtained through HP ^{3}He imaging with existing standard of care imaging modalities such as spirometry. We question whether results from studies that utilize HP ^{3}He MRI can be extrapolated to the use of HP ^{129}Xe MRI. We also note that several citations provided by the applicant are limited to pediatric populations, and we question whether the results would be generalizable to a Medicare population.

7. Proposed FY 2023 Applications for New Technology Add-On Payments (Alternative Pathways)

As discussed previously, beginning with applications for FY 2021, under the regulations at § 412.87(c), a medical device that is part of FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation may qualify for the new technology add-on payment under an alternative pathway. Additionally, beginning with FY 2021, under the regulations at § 412.87(d), a medical product that is designated by FDA as a QIDP and has received marketing authorization for the indication covered by the QIDP designation, and, beginning with FY 2022, a medical product that is a new medical product approved under FDA's LPAD and used for the indication approved under the LPAD pathway, may also qualify for the new technology add-on payment under an alternative pathway. Under an alternative pathway, a technology will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS and will not need to meet the requirement that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. These technologies must still be within the 2–3 year newness period to be considered ''new,'' and must also still meet the cost criterion.

We note, section 1886(d)(5)(K)(ii)(II) of the Act provides for the collection of data with respect to the costs of a new medical service or technology described in subclause (I) for a period of not less than 2 years and not more than 3 years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology. Our regulations in § 412.87(c)(2) for breakthrough devices and § 412.87(d)(2) for certain antimicrobial products state that a medical device/product that meets the condition in paragraph (c)(1) or (d)(1) of § 412.87 will be considered new for not less than 2 years and not more than 3 years after the point at which data begin to become available reflecting the inpatient hospital code (as defined in section 1886(d)(5)(K)(iii) of the Act) assigned to the new technology (depending on when a new code is assigned and data on the new technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical technology, the

quantify early-stage lung disease in smokers. *Acad Radiol.* 2019;26(3):355–366. doi: 10.1016/j.acra.2018.11.005.

[586] Ruppert K, Qing K, Patrie JT, Altes TA, Mugler III JP. Using hyperpolarized xenon-129 MRI to quantify early-stage lung disease in smokers. *Acad Radiol.* 2019;26(3):355–366. doi: 10.1016/j.acra.2018.11.005.

[587] Tafti S, Garrison WJ, Mugler III JP, Shim YM, Altes TA, Mata JF, de Lange EE, Cates GD, Ropp AM, Wang C, Miller GW. Emphysema index based on hyperpolarized ^{3}He or ^{129}Xe diffusion MRI: Performance and comparison with quantitative CT and pulmonary function tests. *Radiology.* 2020;297:201–210.

[588] Lin NY, Roach DJ, Willmer MM, Walkup LL, Hossain M, et al. ^{129}Xe MRI as a measure of clinical disease severity for pediatric asthma. 2021; Journal of Allergy and Clinical Immunology 147(6): 2146–2153.

[589] Teague WG, Tustison NJ, Altes TA. Ventilation heterogeneity in asthma. J Asthma 2014;51:677–84.

[590] Lin NY, Roach DJ, Willmer MM, Walkup LL, Hossain M, et al. ^{129}Xe MRI as a measure of clinical disease severity for pediatric asthma. 2021; Journal of Allergy and Clinical Immunology 147(6): 2146–2153.

medical technology will no longer be considered ''new'' under the criterion of this section.

We received 19 applications for new technology add-on payments for FY 2023 under the new technology add-on payment alternative pathways. Six applicants withdrew applications prior to the issuance of this proposed rule. Of the remaining 13 applications, 11 of the technologies received a Breakthrough Device designation from FDA, 1 has a pending Breakthrough Device designation from FDA, and the remaining application was designated as a QIDP by FDA and is also requesting approval under the LPAD pathway from FDA.

In accordance with the regulations under § 412.87(e)(2), applicants for new technology add-on payments, including Breakthrough Devices, must have FDA marketing authorization by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Under the policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58742), we revised the regulations at § 412.87(e) by adding a new paragraph (e)(3) which provides for conditional approval for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products (QIDPs and LPADs) at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for a complete discussion of this policy (85 FR 58737 through 58742).

As we did in the FY 2022 IPPS/LTCH PPS proposed rule, for applications under the alternative new technology add-on payment pathway, in this proposed rule we are making a proposal to approve or disapprove each of these 13 applications for FY 2023 new technology add-on payments. Therefore, in this section of the preamble of this proposed rule, we provide background information on each alternative pathway application and propose whether or not each technology would be eligible for the new technology add-on payment for FY 2023. We refer readers to section II.H.8. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58715 through 58733) for further discussion of the alternative new technology add-on payment pathways for these technologies.

a. Alternative Pathway for Breakthrough Devices

(1) CERAMENT® G

BONESUPPORT AB submitted an application for new technology-add on payments for CERAMENT® G for FY 2023. Per the applicant, CERAMENT® G is an injectable bone-void filler made of calcium sulfate, hydroxyapatite, and gentamicin sulfate indicated for the surgical treatment of osteomyelitis. Per the applicant, this bone graft substitute fills gaps resulting from debridement of infected bone and prevents colonization of sensitive bacteria, promoting bone healing in two ways. The applicant stated that the primary mode of action is for CERAMENT® G to act as a resorbable ceramic bone-void filler intended to fill gaps and voids in the skeleton system created when infected bone is debrided. The applicant also stated that the secondary mode of action is to prevent the colonization of gentamicin-sensitive microorganisms in order to protect bone healing. Per the applicant, CERAMENT® G may eliminate the need to harvest autologous bone, avoiding pain and infection at the donor site. We note that BONESUPPORT Inc. previously submitted an application for new technology add-on payments for CERAMENT® G for FY 2022, as summarized in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25368 through 25373) but the technology did not meet the deadline of July 1, 2021, for FDA approval or clearance of the technology and, therefore, was not eligible for consideration for new technology add-on payments for FY 2022 (86 FR 45126 through 45127).

According to the applicant, CERAMENT® G is designated as a Breakthrough Device for use as a bone-void filler as an adjunct to systemic antibiotic therapy and surgical debridement as part of the surgical treatment of osteomyelitis. The applicant indicated that it anticipates FDA will grant its De Novo classification request in the second quarter of calendar year 2022. The applicant applied for and received a unique ICD–10–PCS procedure code to identify cases involving the administration of CERAMENT® G in 2021. Effective October 1, 2021, CERAMENT® G administration can be identified by ICD–10–PCS procedure code XWOV0P7 (Introduction of antibiotic eluting bone void filler into bones, open approach, new technology group 7), which is unique to CERAMENT® G administration. The applicant stated that the following existing ICD–10–CM codes for osteomyelitis appropriately describe the proposed indication for which the device received Breakthrough Device designation (''Breakthrough Device Indication''):

BILLING CODE 4120–01–P

ICD-10-CM Code Range	Description of Code Range
M86.00 - M86.09	Acute hematogenous osteomyelitis
M86.10 - M86.19	Other acute osteomyelitis
M86.20 - M86.29	Subacute osteomyelitis
M86.30 - M86.39	Chronic multifocal osteomyelitis
M86.40 - M86.49	Chronic osteomyelitis with draining sinus
M86.50 - M86.59	Other chronic hematogenous osteomyelitis
M86.60 - M86.69	Other chronic osteomyelitis
M86.8X0 - M86.8X9	Other osteomyelitis
M86.9	Osteomyelitis, unspecified

With respect to the cost criterion, the applicant identified candidate cases using ICD–10–PCS procedure and ICD–10–CM diagnosis codes, which are detailed in the tables in this section. With these codes identified, the

applicant then went through the Grouper logic in the MS–DRG v39.0 Definitions Manual and located where cases with these codes would be assigned in the MS–DRG system. This process yielded 13 MS–DRGs which the applicant used for their analysis. The applicant also submitted an additional subanalysis using only cases from the applicant's top three identified MS–DRGs (464, 493, and 504), to demonstrate that the technology meets the cost criterion.

Under the first analysis, the applicant searched claims in the FY 2019 MedPAR final rule dataset within the 13 identified MS–DRGs that reported one of the M86 ICD–10–CM diagnosis codes listed previously in combination with the ICD–10–PCS procedure codes listed in the following table, which identify procedures that could involve the use of CERAMENT® G as an adjunct to systemic antibiotic therapy and surgical debridement where there is a need for supplemental bone void filler material.

ICD-10-PCS Code	Description
0PBK0ZZ	Excision of right ulna, open approach
0PBL0ZZ	Excision of left ulna, open approach
0PDK0ZZ	Extraction of right ulna, open approach
0PDL0ZZ	Extraction of left ulna, open approach
0PBC0ZZ	Excision of right humeral head, open approach
0PBD0ZZ	Excision of left humeral head, open approach
0PBF0ZZ	Excision of right humeral shaft, open approach
0PBG0ZZ	Excision of left humeral shaft, open approach
0PDF0ZZ	Extraction of right humeral shaft, open approach
0PDG0ZZ	Extraction of left humeral shaft, open approach
0PTC0ZZ	Resection of right humeral head, open approach
0PTD0ZZ	Resection of left humeral head, open approach
0PTF0ZZ	Resection of right humeral shaft, open approach
0PTG0ZZ	Extraction of left humeral shaft, open approach
0PCC0ZZ	Extirpation of matter from right humeral head, open approach
0PCF0ZZ	Extirpation of matter from right humeral shaft, open approach
0PCG0ZZ	Extirpation of matter from left humeral shaft, open approach
0PDC0ZZ	Extraction of right humeral head, open approach
0PDD0ZZ	Extraction of left humeral head, open approach
0PDF0ZZ	Extraction of right humeral shaft, open approach
0PDG0ZZ	Extraction of left humeral shaft, open approach
0QBG0ZZ	Excision of right tibia, open approach
0QBH0ZZ	Excision of left tibia, open approach
0QBJ0ZZ	Excision of right fibula, open approach
0QBK0ZZ	Excision of left fibula, open approach
0QCG0ZZ	Extirpation of matter from right tibia, open approach
0QCH0ZZ	Extirpation of matter from left tibia, open approach
0QCJ0ZZ	Extirpation of matter from right fibula, open approach
0QCK0ZZ	Extirpation of matter from left fibula, open approach
0QDG0ZZ	Extraction of right tibia, open approach
0QDH0ZZ	Extraction of left tibia, open approach
0QDJ0ZZ	Extraction of right fibula, open approach

ICD-10-PCS Code	Description
0QDK0ZZ	Extraction of left fibula, open approach
0PCD0ZZ	Extirpation of matter from left humeral head, open approach
0MR507Z	Replace of r wrist bursa/lig with autol sub, open approach
0MR50JZ	Replace of r wrist bursa/lig with synth sub, open approach
0MR50KZ	Replace of r wrist bursa/lig with nonautol sub, open approach
0P9H00Z	Drainage of right radius, open approach
0P9J00Z	Drainage of left radius, open approach
0P9K00Z	Drainage of right ulna, open approach
0P9L00Z	Drainage of left ulna, open approach
0PCH0ZZ	Extirpation of matter from right radius, open approach
0PCJ0ZZ	Extirpation of matter from left radius, open approach
0PCK0ZZ	Extirpation of matter from right ulna, open approach
0PCL0ZZ	Extirpation of matter from left ulna, open approach
0PCM0ZZ	Extirpation of matter from right carpal, open approach
0PCN0ZZ	Extirpation of matter from left carpal, open approach
0Q9200Z	Drainage of right pelvic bone, open approach
0Q9300Z	Drainage of right pelvic bone with drain dev, perc approach
0Q9400Z	Drainage of r pelvic bone with drain dev, perc endo approach
0Q9500Z	Drainage of left acetabulum, open approach
0QC20ZZ	Extirpation of matter from right pelvic bone, open approach
0QC30ZZ	Extirpation of matter from left pelvic bone, open approach
0QC40ZZ	Extirpation of matter from right acetabulum, open approach
0QC50ZZ	Extirpation of matter from left acetabulum, open approach
0PC9C0ZZ	Drainage of right humeral head, open approach
0P9D00Z	Drainage of left humeral head, open approach
0P9F00Z	Drainage of right humeral shaft, open approach
0P9G00Z	Drainage of left humeral shaft, open approach
0Q9G00Z	Drainage of right tibia, open approach
0Q9H00Z	Drainage of left tibia, open approach
0Q9J00Z	Drainage of right fibula, open approach
0Q9K00Z	Drainage of left fibula, open approach
0QCG0ZZ	Extirpation of matter from right tibia, open approach
0QCJ0ZZ	Extirpation of matter from right fibula, open approach
0S9F00Z	Drainage of right ankle joint, open approach
0S9G00Z	Drainage of left ankle joint, open approach
0P9700Z	Drainage of r glenoid cav with drain dev, open approach
0P9800Z	Drainage of l glenoid cav with drain dev, open approach
0P9C00Z	Drainage of right humeral head with drain dev, open approach
0P9D00Z	Drainage of left humeral head with drain dev, open approach
0P5H0ZZ	Destruction of right radius, open approach
0P5J0ZZ	Destruction of left radius, open approach
0PBH0ZZ	Excision of right radius, open approach
0PBJ0ZZ	Excision of left radius, open approach
0Q9600Z	Drainage of right upper femur, open approach
0Q9700Z	Drainage of left upper femur, open approach
0Q9800Z	Drainage of right femoral shaft, open approach
0Q9900Z	Drainage of left femoral shaft, open approach

ICD-10-PCS Code	Description
0Q9B00Z	Drainage of right lower femur, open approach
0Q9C00Z	Drainage of left lower femur, open approach
0Q9D00Z	Drainage of right patella, open approach
0Q9F00Z	Drainage of left patella, open approach
0QB80ZZ	Excision of right femoral shaft, open approach
0QB90ZZ	Excision of left femoral shaft, open approach
0QBB0ZZ	Excision of right lower femur, open approach
0QBC0ZZ	Excision of left lower femur, open approach
0QBG0ZZ	Excision of right tibia, open approach
0QBH0ZZ	Excision of left tibia, open approach
0QBJ0ZZ	Excision of right fibula, open approach
0QBK0ZZ	Excision of left fibula, open approach
0QB60ZZ	Excision of right upper femur, open approach
0QD80ZZ	Extraction of right femoral shaft, open approach
0QD90ZZ	Extraction of left femoral shaft, open approach
0QDBOZZ	Extraction of right lower femur, open approach
0QDC0ZZ	Extraction of left lower femur, open approach
0QDG0ZZ	Extraction of right tibia, open approach
0QDH0ZZ	Extraction of left tibia, open approach
0QDJ0ZZ	Extraction of right fibula, open approach
0QDK0ZZ	Extraction of left fibula, open approach
0Q560ZZ	Destruction of right upper femur, open approach
0Q570ZZ	Destruction of left upper femur, open approach
0QB60ZZ	Excision of right upper femur, open approach
0QB70ZZ	Excision of left upper femur, open approach
0QC70ZZ	Extirpation of matter from left upper femur, open approach
0QD20ZZ	Extraction of right pelvic bone, open approach
0QD30ZZ	Extraction of left pelvic bone, open approach
0QD60ZZ	Extraction of right upper femur, open approach
0QD70ZZ	Extraction of left upper femur, open approach
0QC60ZZ	Extirpation of matter from right upper femur, open approach
0QT60ZZ	Resection of right upper femur, open approach
0QT70ZZ	Resection of left upper femur, open approach
0QBM0ZZ	Excision of left tarsal, open approach
0QDL0ZZ	Extraction of right tarsal, open approach
0QDM0ZZ	Extraction of left tarsal, open approach
0Q9N00Z	Drainage of right metatarsal, open approach
0Q9P00Z	Drainage of left metatarsal, open approach
0QBP0ZZ	Excision of left metatarsal, open approach
0QDN0ZZ	Extraction of right metatarsal, open approach
0QDP0ZZ	Extraction of left metatarsal, open approach
0P5K0ZZ	Destruction of right ulna, open approach
0P5L0ZZ	Destruction of left ulna, open approach
0PBK0ZZ	Excision of right ulna, open approach
0PBL0ZZ	Excision of left ulna, open approach
0PDK0ZZ	Extraction of right ulna, open approach
0PDL0ZZ	Extraction of left ulna, open approach

ICD-10-PCS Code	Description
0PBH0ZZ	Excision of right radius, open approach
0PBJ0ZZ	Excision of left radius, open approach
0PDH0ZZ	Extraction of right radius, open approach
0PDJ0ZZ	Extraction of left radius, open approach
0PCH0ZZ	Extirpation of matter from right radius, open approach
0PCJ0ZZ	Extirpation of matter from left radius, open approach
0PCK0ZZ	Extirpation of matter from right ulna, open approach
0PCL0ZZ	Extirpation of matter from left ulna, open approach
0PC90ZZ	Extirpation of matter from right clavicle, open approach
0PCB0ZZ	Extirpation of matter from left clavicle, open approach
0PD90ZZ	Extraction of right clavicle, open approach
0PDB0ZZ	Extraction of left clavicle, open approach
0PB90ZZ	Excision of right clavicle, open approach
0PBB0ZZ	Excision of left clavicle, open approach
0PC50ZZ	Extirpation of matter from right scapula, open approach
0PC60ZZ	Extirpation of matter from left scapula, open approach
0PD50ZZ	Extraction of right scapula, open approach
0PD60ZZ	Extraction of left scapula, open approach
0PB50ZZ	Excision of right scapula, open approach
0PB60ZZ	Excision of left scapula, open approach
0PB73ZZ	Excision of right glenoid cavity, percutaneous approach
0PB74ZZ	Excision of right glenoid cavity, perc endo approach
0PB83ZZ	Excision of left glenoid cavity, percutaneous approach
0PB84ZZ	Excision of left glenoid cavity, perc endo approach
0QBQ0ZZ	Excision of right toe phalanx, open approach
0QBR0ZZ	Excision of left toe phalanx, open approach
0QDQ0ZZ	Extraction of right toe phalanx, open approach
0QDR0ZZ	Extraction of left toe phalanx, open approach

The applicant identified 11,620 cases across 13 MS–DRGs as identified in the table that follows.

MS-DRG	Description
463	Wound Debridement and Skin Graft Except Hand for Musculoskeletal System and Connective Tissue Disorders with MCC
464	Wound Debridement and Skin Graft Except Hand for Musculoskeletal System and Connective Tissue Disorders with CC
492	Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with MCC
493	Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with CC
495	Local Excision and Removal of Internal Fixation Devices Except Hip and Femur with MCC
496	Local Excision and Removal of Internal Fixation Devices Except Hip and Femur with CC
498	Local Excision and Removal Internal Fixation Devices of Hip and Femur with CC/MCC
503	Foot Procedures with MCC
504	Foot Procedures with CC
510	Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures with MCC
511	Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures with CC
515	Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC
516	Other Musculoskeletal System and Connective Tissue O.R. Procedures with CC

BILLING CODE 4120–01–C

The applicant noted that candidate cases for CERAMENT® G with osteomyelitis would qualify for the CC/MCC MS–DRGs because osteomyelitis is listed in the Grouper as a CC condition. Therefore, the applicant concluded that cases with osteomyelitis would not be grouped in the uncomplicated MS–DRGs (for example, 465, 494, etc.). The applicant stated that because osteomyelitis is never assigned to uncomplicated surgical MS–DRGs, it excluded uncomplicated MS–DRGs from its analysis.

The applicant then removed charges for the prior technology that may be replaced by CERAMENT® G. The applicant conducted a market analysis that identified 3 types of prior technology devices: Poly(methyl methacrylate) (PMMA) manually mixed with antibiotics, PMMA pre-loaded with antibiotics, and calcium sulfate (CaS) mixed with antibiotics. The applicant researched the average sales price (ASP) for major competitors for 5cc and 10cc of each device type and calculated a weighted average cost of $444 per 5cc and $727 per 10 cc.[591] Then the applicant converted costs to charges by dividing costs by the Supplies & Equipment CCR of 0.297 (86 FR 44966). Using this CCR, $444 per 5cc and $727 per 10cc yielded an estimated hospital charge of prior technologies of $1,495 per 5cc and $2,449 per 10cc. The applicant explained that the total amount of antibiotics depends on the amount of product required for different sized bones. The applicant then standardized the charges and applied a 4-year inflation factor of 1.281834 based on the inflation factor used to update the outlier threshold in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542).

The applicant added estimated charges for the new technology by dividing the estimated, expected hospital list price for the device (based on expected 5/10/15 cc costs for CERAMENT® G, by MS–DRG), by the aforementioned Supplies & Equipment CCR of 0.297.

The applicant calculated a final inflated case-weighted average standardized charge per case of $135,258 and an average case-weighted threshold of $86,603. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

The applicant also provided an alternate cost analysis using the applicant's top three identified MS–DRGs (464, 493, and 504), which together constituted more than half of the applicant's identified cases. Using the same methodology and data sources above, the applicant calculated a final inflated case-weighted average standardized charge per case of $112,316 and an average case-weighted threshold of $77,375. The applicant maintained that CERAMENT® G meets the cost criterion under this alternate analysis.

We agree with the applicant that CERAMENT® G meets the cost criterion and therefore, subject to the technology receiving FDA marketing authorization for use as a bone-void filler as an adjunct to systemic antibiotic therapy and surgical debridement as part of the surgical treatment of osteomyelitis by July 1, 2022, we are proposing to approve CERAMENT® G for new technology add-on payments for FY 2023.

Based on preliminary information from the applicant at the time of this proposed rule, the total cost of CERAMENT® G for a typical patient is $7,567 per procedure. Per the applicant, the amount of CERAMENT® G used per patient depends on the complexity of the patient's injury, subsequent comorbidities, as well as the location and size of the bone void. The applicant expects that an average patient will require ~10cc per procedure, based on the case weighted volume of expected utilization across the MS–DRGs. From this weighted average, the applicant derived the average, weighted cost of $7,567 per patient. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the product CERAMENT® G would be $4,918.55 for FY 2022 (that is, 65% of the average cost of the technology).

We are inviting public comments on whether CERAMENT® G meets the cost criterion and our proposal to approve new technology add-on payments for CERAMENT® G for FY 2023, subject to CERAMENT® G receiving FDA marketing authorization for use as a bone-void filler as an adjunct to systemic antibiotic therapy and surgical debridement as part of the surgical treatment of osteomyelitis by July 1, 2022.

(2) GORE® TAG® Thoracic BranchEndoprosthesis (TBE Device)

W.L. Gore and Associates, Inc., submitted an application for new technology add-on payments for the GORE® TAG® Thoracic Branch Endoprosthesis (TBE) device for FY 2023. According to the applicant, the GORE® TAG® TBE device is a modular device consisting of three components, an Aortic Component, a Side Branch Component, and an optional Aortic Extender Component, each of which is pre-mounted on a catheter delivery system for treatment of thoracic aortic aneurysms, traumatic aortic transection, and aortic dissection.

According to the applicant, the GORE® TAG® TBE device was granted designation under the Expedited Access Pathway (EAP) by FDA (and is therefore considered part of the Breakthrough Devices Program by FDA) on July 17, 2015, for endovascular repair of descending thoracic aortic and aortic arch for patients who have appropriate anatomy. The applicant indicated that it anticipates receiving premarket approval of the GORE® TAG® TBE device as a Class III device from FDA in Spring 2022 with a proposed indication for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery, in patients who have adequate iliac/femoral access, and eligible proximal aorta, left subclavian, or distal landing zones (isolated lesion patients only). Since the indication for which the applicant anticipates receiving premarket approval is included within the scope of the EAP designation, it appears that the proposed PMA indication is appropriate for new technology add-on payment under the alternative pathway criteria.

The applicant noted that a combination of two existing ICD–10–PCS procedure codes can be used to uniquely identify the GORE® TAG® TBE: 02VW4EZ (Restriction of thoracic aorta, descending with branched or fenestrated intraluminal device, one or two arteries, percutaneous endoscopic approach), in combination with 02VX4EZ (Restriction of thoracic aorta, ascending/arch with branched or fenestrated intraluminal device, one or two arteries, percutaneous endoscopic approach). Per the applicant, the GORE® TAG® TBE device is placed such that it

[591] The applicant's analysis was informed by 2019 and 2020 data for Osteoset, Stimulan, and Calcigen S (calcium sulfates mixed with antibiotics), Palacos, Cobalt (PMMA manually mixed with antibiotics), Cobalt G, Biomet Bone Cement R, and Refobacin Bone Cement R (PMMA pre-loaded with antibiotics) from three sources: an iData Market Research 2019 Sku Data Report, Global Data US Hospital Bone Grafts and Substitutes Q3 2019 Report, and feedback from sales representatives in the field.

straddles two anatomic regions, the descending thoracic aorta and thoracic aortic arch, thereby necessitating the use of both ICD–10–PCS procedure codes to accurately describe the use of the device.

With regard to the cost criterion, the applicant searched the FY 2019 MedPAR dataset from the FY 2022 IPPS proposed rule for cases reporting a combination of a thoracic endovascular repair (TEVAR) procedure and a bypass procedure. The applicant listed the following ICD–10–PCS codes for TEVAR procedures and bypass procedures, which the applicant used to identify potential cases that may be eligible for treatment with the GORE® TAG® TBE device. Per the applicant, cases with at least one ICD–10–PCS procedure code from each category were included in the analysis.

ICD-10-PCS	Description
Codes Identifying TEVAR Procedure	
02VW3DZ	Restriction of thoracic aorta, descending with intraluminal device, percutaneous approach
02VW4DZ	Restriction of thoracic aorta, descending with intraluminal device, percutaneous endoscopic approach
Codes Identifying Bypass Procedure	
03140JK	Bypass left subclavian artery to left extracranial artery with synthetic substitute, open approach
03140KK	Bypass left subclavian artery to left extracranial artery with an autologous tissue substitute, open approach
03140ZK	Bypass left subclavian artery to left extracranial artery, open approach
03150J1	Bypass right axillary artery to left upper arm artery with synthetic substitute, open approach
03160JK	Bypass left axillary artery to left extracranial artery with synthetic substitute, open approach
031J0JK	Bypass left common carotid artery to left extracranial artery with synthetic substitute, open approach
031J0JY	Bypass left common carotid artery to upper artery with synthetic substitute, open approach
03S40ZZ	Reposition left subclavian artery, open approach
03S43ZZ	Reposition left subclavian artery, percutaneous approach
03SQ0ZZ	Reposition left vertebral artery, open approach
03SQ3ZZ	Reposition left vertebral artery, percutaneous approach

MS-DRG	Description	%Cases
220	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC	41.0%
219	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC	36.7%
221	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC	11.9%
003	ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures	5.2%
216	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC	5.2%

The applicant identified 210 cases mapping to five MS–DRGs. The applicant then removed charges for the technology being replaced. The applicant stated that the use of TAG® Conformable devices in cases that also use the GORE® TAG® TBE device is entirely dependent on the patient's anatomy. The applicant explained that the average case utilizing the GORE® TAG® TBE device uses 0.6 TAG® Conformable devices, compared to an average of 1.4 TAG® Conformable devices per procedure for current TEVAR cases, resulting in a difference of 0.8 TAG® Conformable devices which will no longer be used in cases utilizing the GORE® TAG® TBE device. Accordingly, 80% of all device implant charges were removed from the claims to be conservative, per the applicant. The applicant then removed other charges related to the prior technology. According to the applicant, a research study [592] that compared 24 patients treated with TBE to 31 patients treated with the traditional method at one facility found that TBE device cases have a 19% reduction in operating room (OR) time compared to the OR time for the combined procedures (TEVAR with a bypass procedure), and a 48% reduction in length of stay. Accordingly, the applicant removed 19% of OR charges (revenue code 0360), removed 48% of routine charges (revenue code 01XX) when a claim showed routine charges, and removed 48% of intensive care unit (ICU) charges if a claim included no routine charges. The applicant then standardized the charges and applied a 4-year inflation factor of 1.2818 based on the inflation factor used in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45538), to update the charges from FY 2019 to FY 2023. The applicant then added charges for the new technology by dividing the average per patient cost of the GORE® TAG® TBE device by the national CCR for implantable devices (0.293) from the FY 2022 IPPS/LTCH PPS final rule (86 FR 44966). The applicant calculated a final inflated case-weighted average standardized charge per case of $400,515 and an average case-weighted threshold of $217,182. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold

[592] Shultze W, Baxter R, Gable C, et al. Comparison Of Surgical Debranching Versus Branched Endografts In Zone 2 TEVAR. Oral presentation at the Society for Vascular Surgery Meeting; March 2021, Miami FL. *https://symposium.scvs.org/abstracts/2021/M76.cgi.*

amount, the applicant asserted that the technology meets the cost criterion.

We note that the charges removed for prior technology are based on length of stay in a small study conducted at a single institution. Specifically, the study involved 24 patients who received the TBE device during elective procedures and 31 who had the procedures with bypass. Three of these procedures were emergent and only 14 and 17, respectively, were procedures in Zone 2 where the GORE® TAG® TBE would be indicated. Given the small percentage of procedures that directly relate to the proposed GORE® TAG® TBE indication, we question the extent to which these results are generalizable to the cost analysis performed above and the greater Medicare population. Additionally, the applicant did not specify the revenue codes used to identify and remove intensive care unit charges. We note the applicant listed two ICD–10–PCS codes (03S43ZZ and 03SQ3ZZ) in their analysis which are percutaneous procedures and question whether the inclusion of these codes is appropriate as the devices currently used to repair the aortic arch require the creation of a bypass performed in an open surgery. We also question whether the cases that the applicant identified are appropriately representative of cases eligible for treatment with GORE® TAG® TBE and request additional information to clarify this issue.

Subject to the applicant adequately addressing these concerns, we would agree that the technology meets the cost criterion and therefore are proposing to approve the GORE® TAG® TBE device for new technology add-on payments for FY 2023, subject to the technology receiving FDA marketing authorization for the proposed indication by July 1, 2022.

Based on preliminary information from the applicant at the time of this proposed rule, the per-patient anticipated hospital cost of the GORE® TAG® TBE device is $42,780. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. In the event we receive supplemental information from the applicant to adequately address our concerns regarding the cost criterion, and we were to approve new technology add-on payments for the GORE® TAG® TBE device in the final rule, the maximum new technology add-on payment for a case involving the use of the GORE® TAG® TBE device would be $27,807 for FY 2023 (that is, 65% of the average cost of the technology).

We are inviting public comments on whether the GORE® TAG® TBE device meets the cost criterion and our proposal to approve new technology add-on payments for the GORE® TAG® TBE device for FY 2023, subject to the technology receiving FDA marketing authorization for the proposed indication that corresponds to the EAP designation by July 1, 2022.

(3) iFuse Bedrock Granite Implant System

SI–BONE, Inc., submitted an application for new technology add-on payments for the iFuse Bedrock Granite Implant System for FY 2023. According to the applicant, the iFuse Bedrock Granite Implant System is a sterile, single-use permanent implant intended to provide sacropelvic fusion of the sacroiliac joint and fixation to the pelvis when used in conjunction with commercially available pedicle screw fixation systems as a foundational element for segmental spinal fusion. The applicant states that the joint fusion occurs as a result of the device's porous surface and interstices, and fixation occurs through the device's helical threaded design and traditional posterior fixation rod connection. Per the applicant, the iFuse Bedrock Granite Implant System can be placed into the pelvis in two trajectories: Sacroalar-iliac (SAI) trajectory (that is, into the sacrum, across the SI joint and into the ilium) or directly into the ilium, and joint fusion occurs only when the SAI trajectory is used.

According to the applicant, the iFuse Bedrock Granite Implant System received FDA Breakthrough Device designation on November 23, 2021 for sacropelvic fixation and as an adjunct for sacroiliac joint fusion (when used with commercially available sacroiliac joint fusion promoting devices) in conjunction with commercially available posterior pedicle screw systems for the treatment of the acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine; degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies; severe spondylolisthesis (Grades 3 and 4) of the L5–S1 vertebra in skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion; spondylolisthesis; trauma (that is, fracture or dislocation); spinal stenosis; deformities or curvatures (that is, scoliosis, kyphosis, and/or lordosis); spinal tumor; pseudarthrosis; and/or failed previous fusion. The applicant is seeking 510(k) clearance from FDA for the same indication.

The applicant stated that ICD–10–PCS codes that may be utilized to describe the placement of an internal fixation device into the pelvic bone or acetabulum, listed in the following table, do not distinctly identify the iFuse Bedrock Granite Implant System. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a unique code for FY 2023 to identify the technology.

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ICD-10-PCS	Description
0QH204Z	Insertion of internal fixation device into right pelvic bone, open approach
0QH304Z	Insertion of internal fixation device into left pelvic bone, open approach
0SG734Z	Fusion of right sacroiliac joint with internal fixation device, percutaneous approach
0SG834Z	Fusion of left sacroiliac joint with internal fixation device, percutaneous approach
0SG804Z	Fusion of left sacroiliac joint with internal fixation device, open approach
0SG704Z	Fusion of right sacroiliac joint with internal fixation device, open approach

With regard to the cost criterion, the applicant conducted two analyses based on 100% of identified claims and 78% of identified claims. To identify potential cases where the iFuse Bedrock Granite Implant System could be

utilized, the applicant searched the FY 2019 MedPAR final rule file for claims reporting a combination of at least one of the ICD–10–PCS procedure codes for the placement of an internal fixation device into the pelvic bone or acetabulum, noted previously, and at least one of the following ICD–10–CM diagnosis codes used to describe the indication under the Breakthrough Device designation.

ICD-10-CM	Description
M40.00	Postural kyphosis, site unspecified
M40.04	Postural kyphosis, thoracic region
M40.05	Postural kyphosis, thoracolumbar region
M40.10	Other secondary kyphosis, site unspecified
M40.13	Other secondary kyphosis, cervicothoracic region
M40.14	Other secondary kyphosis, thoracic region
M40.15	Other secondary kyphosis, thoracolumbar region
M40.204	Unspecified kyphosis, thoracic region
M40.205	Unspecified kyphosis, thoracolumbar region
M40.209	Unspecified kyphosis, site unspecified
M40.294	Other kyphosis, thoracic region
M40.295	Other kyphosis, thoracolumbar region
M40.35	Flatback syndrome, thoracolumbar region
M40.36	Flatback syndrome, lumbar region
M40.37	Flatback syndrome, lumbosacral region
M40.40	Postural lordosis, site unspecified
M40.45	Postural lordosis, thoracolumbar region
M40.46	Postural lordosis, lumbar region
M40.47	Postural lordosis, lumbosacral region
M40.55	Lordosis, unspecified, thoracolumbar region
M40.56	Lordosis, unspecified, lumbar region
M40.57	Lordosis, unspecified, lumbosacral region
M41.124	Adolescent idiopathic scoliosis, thoracic region
M41.125	Adolescent idiopathic scoliosis, thoracolumbar region
M41.126	Adolescent idiopathic scoliosis, lumbar region
M41.127	Adolescent idiopathic scoliosis, lumbosacral region
M41.129	Adolescent idiopathic scoliosis, site unspecified
M41.20	Other idiopathic scoliosis, site unspecified
M41.24	Other idiopathic scoliosis, thoracic region
M41.25	Other idiopathic scoliosis, thoracolumbar region
M41.26	Other idiopathic scoliosis, lumbar region
M41.27	Other idiopathic scoliosis, lumbosacral region
M41.30	Thoracogenic scoliosis, site unspecified
M41.34	Thoracogenic scoliosis, thoracic region
M41.35	Thoracogenic scoliosis, thoracolumbar region
M41.40	Neuromuscular scoliosis, site unspecified
M41.45	Neuromuscular scoliosis, thoracolumbar region
M41.46	Neuromuscular scoliosis, lumbar region
M41.47	Neuromuscular scoliosis, lumbosacral region
M41.50	Other secondary scoliosis, site unspecified
M41.54	Other secondary scoliosis, thoracic region

For the analysis using 100% of cases, the applicant identified 2,165 cases mapping to the following 26 MS–DRGs:

ICD-10-CM	Description
M41.55	Other secondary scoliosis, thoracolumbar region
M41.56	Other secondary scoliosis, lumbar region
M41.57	Other secondary scoliosis, lumbosacral region
M41.84	Other forms of scoliosis, thoracic region
M41.85	Other forms of scoliosis, thoracolumbar region
M41.86	Other forms of scoliosis, lumbar region
M41.87	Other forms of scoliosis, lumbosacral region
M42.10	Adult osteochondrosis of spine, site unspecified
M42.14	Adult osteochondrosis of spine, thoracic region
M42.15	Adult osteochondrosis of spine, thoracolumbar region
M42.16	Adult osteochondrosis of spine, lumbar region
M42.17	Adult osteochondrosis of spine, lumbosacral region
M42.18	Adult osteochondrosis of spine, sacral and sacrococcygeal region
M42.19	Adult osteochondrosis of spine, multiple sites in spine
M43.15	Spondylolisthesis, thoracolumbar region
M43.16	Spondylolisthesis, lumbar region
M43.17	Spondylolisthesis, lumbosacral region
M43.18	Spondylolisthesis, sacral and sacrococcygeal region
M43.19	Spondylolisthesis, multiple sites in spine
M43.8X5	Other specified deforming dorsopathies, thoracolumbar region
M43.8X6	Other specified deforming dorsopathies, lumbar region
M43.8X7	Other specified deforming dorsopathies, lumbosacral region
M43.8X8	Other specified deforming dorsopathies, sacral and sacrococcygeal region
M43.8X9	Other specified deforming dorsopathies, site unspecified
M43.9	Deforming dorsopathy, unspecified
M48.26	Kissing spine, lumbar region
M48.27	Kissing spine, lumbosacral region
M48.36	Traumatic spondylopathy, lumbar region
M48.37	Traumatic spondylopathy, lumbosacral region
M53.2X6	Spinal instabilities, lumbar region
M53.2X7	Spinal instabilities, lumbosacral region
M53.2X8	Spinal instabilities, sacral and sacrococcygeal region
M53.3	Sacrococcygeal disorders, not elsewhere classified

MS-DRG	Description
028	Spinal Procedures with MCC
029	Spinal Procedures with CC or Spinal Neurostimulators
252	Other Vascular Procedures with MCC
453	Combined Anterior and Posterior Spinal Fusion with MCC
454	Combined Anterior and Posterior Spinal Fusion with CC
455	Combined Anterior and Posterior Spinal Fusion without CC/MCC
456	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC
457	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with CC
458	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions without CC/MCC
459	Spinal Fusion Except Cervical with MCC
460	Spinal Fusion Except Cervical without MCC
496	Local Excision and Removal of Internal Fixation Devices Except Hip and Femur with CC
515	Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC
516	Other Musculoskeletal System and Connective Tissue O.R. Procedures with CC
517	Other Musculoskeletal System and Connective Tissue O.R. Procedures without CC/MCC
518	Back and Neck Procedures Except Spinal Fusion with Mcc or Disc Device or Neurostimulator
519	Back and Neck Procedures Except Spinal Fusion with CC
628	Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC
853	Infectious and Parasitic Diseases with O.R. Procedures with MCC
854	Infectious and Parasitic Diseases with O.R. Procedures with CC
856	Postoperative or Post-Traumatic Infections with O.R. Procedures with MCC
907	Other O.R. Procedures for Injuries with MCC
908	Other O.R. Procedures for Injuries with CC
957	Other O.R. Procedures for Multiple Significant Trauma with MCC
981	Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC
982	Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC

BILLING CODE 4120–01–C

The applicant then removed 50% of the charges associated with medical supplies and implantable devices (revenue centers 027x and 0624). The applicant stated that the removal of 50% of the charges associated with medical supplies and implantable devices reflects a conservative estimate as the iFuse Bedrock Granite Implant System is used in conjunction with commercially available pedicle screw fixation systems as a foundational element for segmental spinal fusion. The applicant then standardized the charges and applied the three-year inflation factor of 20.4% used to update the outlier threshold in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542) to update the charges from FY 2019 to FY 2022. The applicant then added charges for the new technology by dividing the per-patient anticipated hospital cost of the iFuse Bedrock Granite Implant System by the national average cost-to-charge ratio for implantable devices (0.239) from the FY 2022 IPPS/LTCH PPS final rule. Under the analysis based on 100% of identified claims, the applicant calculated a final inflated case-weighted average standardized charge per case of $254,264 and an average case-weighted threshold of $159,841.

For the analysis using 78% of cases, the applicant identified 1,682 cases mapping to 4 MS–DRGs. The applicant conducted the same analysis noted previously and determined a final inflated case-weighted average standardized charge per case of $253,333 and an average case-weighted threshold of $164,561. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount under both analyses, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that iFuse Bedrock Granite Implant System meets the cost criterion and therefore are proposing to approve the iFuse Bedrock Granite Implant System for new technology add-on payments for FY 2023, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by July 1, 2022.

Based on preliminary information from the applicant at the time of this proposed rule, the per-patient anticipated hospital cost of the iFuse Bedrock Granite Implant System is $15,120. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the iFuse Bedrock Granite Implant System would be $9,828 for FY 2023 (that is, 65% of the average cost of the technology).

We are inviting public comments on whether the iFuse Bedrock Granite Implant System meets the cost criterion and our proposal to approve new technology add-on payments for the iFuse Bedrock Granite Implant System for FY 2023, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by July 1, 2022.

(4) LigaPASS 2.0 PJK Prevention System

Medtronic submitted an application for new technology add-on payments for the LigaPASS 2.0 PJK Prevention System for FY 2023. Per the applicant, the LigaPASS 2.0 PJK Prevention System is intended to mitigate the risk of post-operative proximal junctional kyphosis (PJK) and proximal junctional failure (PJF) in patients with spinal

deformities. The applicant states that the LigaPASS 2.0 PJK Prevention System is designed to restore balance and stability as a complement to a posterior thoracolumbar fixation system, and provides surgeons the ability to mimic anatomical muscle and ligament functionality and stabilization between vertebrae adjacent to fused levels in a spine surgery. According to the applicant, the LigaPASS 2.0 PJK Prevention System consists of a polyester (PET) band and titanium alloy medial open connector with two set screws. The applicant indicates the LigaPASS 2.0 PJK Prevention System bands are laced around the vertebra independently of the vertebra anatomy and then connected to a LigaPASS 2.0 PJK Prevention System connector to make the rod-bone connection, allowing the surgeon to create a posterior vertebra anchorage without the use of a pedicle screw or hook.

According to the applicant, the LigaPASS 2.0 PJK Prevention System was granted Breakthrough Device designation on September 2, 2021, for spinal trauma surgery, used in sublaminar or facet wiring techniques; spinal reconstructive surgery, incorporated into construct for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis and kyphosis; spinal degenerative surgery as an adjunct to spinal fusions; intended for use at the non-fused level(s) adjacent to a posterior spinal instrumentation construct when ligament augmentation is considered appropriate to mitigate the risk of post-operative PJK and PJF. The applicant noted that a 510(k) has been submitted to FDA for the same indication (K213659). The applicant stated that the LigaPASS 2.0 PJK Prevention System includes components from two predicate devices: The LigaPASS 2.0 connector (K172021), previously cleared to provide temporary stabilization as a bone anchor during the development of solid bony fusion, and the LigaPASS 2.0 band (K173506), previously cleared to aid in the repair of bone fractures. According to the applicant, there are no technological differences between the subject device and its predicates; the only difference would be the added PJK/PJF indication covered by the Breakthrough Device designation. The applicant indicated that it is seeking new technology add-on payment only for the LigaPASS 2.0 PJK Prevention System's proposed new PJK and PJF indication for which the device has been designated as a Breakthrough Device by FDA. According to the applicant, there are no ICD–10–PCS codes that uniquely identify procedures involving the use of the LigaPASS 2.0 PJK Prevention System. The applicant also noted there are no unique ICD–10–CM diagnosis codes that describe the indication for prophylactic use of the LigaPASS 2.0 PJK Prevention System for PJK/PJF prevention covered by the Breakthrough Device designation. The applicant has submitted a request for a unique ICD–10–CM diagnosis code and a unique ICD–10–PCS code that can be used together to uniquely identify cases involving use of the technology for the Breakthrough Device designation for the technology.

With regard to the cost criterion, the applicant provided the following cost analysis to demonstrate that the LigaPASS 2.0 PJK Prevention System meets the cost criterion. The applicant searched the FY 2019 MedPAR dataset for cases representing patients who may be eligible for LigaPASS 2.0 PJK Prevention System. The applicant stated they conducted a thorough review of ICD–10–PCS codes for procedures in which the LigaPASS 2.0 PJK Prevention System might be placed into the spine to prevent PJK/PJF in an adult patient who is diagnosed with spinal deformity. The applicant provided the following ICD–10–PCS procedure codes and ICD–10–CM diagnosis codes used to identify cases representing patients who may be eligible for the LigaPASS 2.0 PJK Prevention System.

BILLING CODE 4120–01–P

ICD-10-PCS	Description
0PH404Z	Insertion of internal fixation device into thoracic vertebra, open approach
0PH434Z	Insertion of internal fixation device into thoracic vertebra, percutaneous approach
0PH444Z	Insertion of internal fixation device into thoracic vertebra, percutaneous endoscopic approach
0QH004Z	Insertion of internal fixation device into lumbar vertebra, open approach
0QH034Z	Insertion of internal fixation device into lumbar vertebra, percutaneous approach
0QH044Z	Insertion of internal fixation device into lumbar vertebra, percutaneous endoscopic approach
0QS004Z	Reposition lumbar vertebra with internal fixation device, open approach
0QS034Z	Reposition lumbar vertebra with internal fixation device, percutaneous approach
0QS044Z	Reposition lumbar vertebra with internal fixation device, percutaneous endoscopic approach
0RG4070	Fusion of cervicothoracic vertebral joint with autologous tissue substitute, anterior approach, anterior column, open approach
0RG4071	Fusion of cervicothoracic vertebral joint with autologous tissue substitute, posterior approach, posterior column, open approach
0RG407J	Fusion of cervicothoracic vertebral joint with autologous tissue substitute, posterior approach, anterior column, open approach
0RG40A0	Fusion of cervicothoracic vertebral joint with interbody fusion device, anterior approach, anterior column, open approach
0RG40AJ	Fusion of cervicothoracic vertebral joint with interbody fusion device, posterior approach, anterior column, open approach
0RG40J0	Fusion of cervicothoracic vertebral joint with synthetic substitute, anterior approach, anterior column, open approach
0RG40J1	Fusion of cervicothoracic vertebral joint with synthetic substitute, posterior approach, posterior column, open approach

ICD-10-PCS	Description
0RG40JJ	Fusion of cervicothoracic vertebral joint with synthetic substitute, posterior approach, anterior column, open approach
0RG40K0	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, anterior approach, anterior column, open approach
0RG40K1	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, posterior approach, posterior column, open approach
0RG40KJ	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, posterior approach, anterior column, open approach
0RG4370	Fusion of cervicothoracic vertebral joint with autologous tissue substitute, anterior approach, anterior column, percutaneous approach
0RG4371	Fusion of cervicothoracic vertebral joint with autologous tissue substitute, posterior approach, posterior column, percutaneous approach
0RG437J	Fusion of cervicothoracic vertebral joint with autologous tissue substitute, posterior approach, anterior column, percutaneous approach
0RG43A0	Fusion of cervicothoracic vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0RG43AJ	Fusion of cervicothoracic vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0RG43J0	Fusion of cervicothoracic vertebral joint with synthetic substitute, anterior approach, anterior column, percutaneous approach
0RG43J1	Fusion of cervicothoracic vertebral joint with synthetic substitute, posterior approach, posterior column, percutaneous approach
0RG43JJ	Fusion of cervicothoracic vertebral joint with synthetic substitute, posterior approach, anterior column, percutaneous approach
0RG43K0	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, anterior approach, anterior column, percutaneous approach
0RG43K1	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, posterior approach, posterior column, percutaneous approach
0RG43KJ	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, posterior approach, anterior column, percutaneous approach
0RG4470	Fusion of cervicothoracic vertebral joint with autologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RG4471	Fusion of cervicothoracic vertebral joint with autologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RG447J	Fusion of cervicothoracic vertebral joint with autologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0RG44A0	Fusion of cervicothoracic vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0RG44AJ	Fusion of cervicothoracic vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0RG44J0	Fusion of cervicothoracic vertebral joint with synthetic substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RG44J1	Fusion of cervicothoracic vertebral joint with synthetic substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RG44JJ	Fusion of cervicothoracic vertebral joint with synthetic substitute, posterior approach, anterior column, percutaneous endoscopic approach
0RG44K0	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RG44K1	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RG44KJ	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0RG40J1	Fusion of cervicothoracic vertebral joint with synthetic substitute, posterior approach, posterior column, open approach
0RG40JJ	Fusion of cervicothoracic vertebral joint with synthetic substitute, posterior approach, anterior column, open approach
0RG40K0	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, anterior approach, anterior column, open approach

ICD-10-PCS	Description
0RG40K1	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, posterior approach, posterior column, open approach
0RG40KJ	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, posterior approach, anterior column, open approach
0RG4370	Fusion of cervicothoracic vertebral joint with autologous tissue substitute, anterior approach, anterior column, percutaneous approach
0RG4371	Fusion of cervicothoracic vertebral joint with autologous tissue substitute, posterior approach, posterior column, percutaneous approach
0RG437J	Fusion of cervicothoracic vertebral joint with autologous tissue substitute, posterior approach, anterior column, percutaneous approach
0RG43A0	Fusion of cervicothoracic vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0RG43AJ	Fusion of cervicothoracic vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0RG43J0	Fusion of cervicothoracic vertebral joint with synthetic substitute, anterior approach, anterior column, percutaneous approach
0RG43J1	Fusion of cervicothoracic vertebral joint with synthetic substitute, posterior approach, posterior column, percutaneous approach
0RG43JJ	Fusion of cervicothoracic vertebral joint with synthetic substitute, posterior approach, anterior column, percutaneous approach
0RG43K0	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, anterior approach, anterior column, percutaneous approach
0RG43K1	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, posterior approach, posterior column, percutaneous approach
0RG43KJ	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, posterior approach, anterior column, percutaneous approach
0RG4470	Fusion of cervicothoracic vertebral joint with autologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RG4471	Fusion of cervicothoracic vertebral joint with autologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RG447J	Fusion of cervicothoracic vertebral joint with autologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0RG44A0	Fusion of cervicothoracic vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0RG44AJ	Fusion of cervicothoracic vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0RG44J0	Fusion of cervicothoracic vertebral joint with synthetic substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RG44J1	Fusion of cervicothoracic vertebral joint with synthetic substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RG44JJ	Fusion of cervicothoracic vertebral joint with synthetic substitute, posterior approach, anterior column, percutaneous endoscopic approach
0RG44K0	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RG44K1	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RG44KJ	Fusion of cervicothoracic vertebral joint with nonautologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0RG6070	Fusion of thoracic vertebral joint with autologous tissue substitute, anterior approach, anterior column, open approach
0RG6071	Fusion of thoracic vertebral joint with autologous tissue substitute, posterior approach, posterior column, open approach
0RG607J	Fusion of thoracic vertebral joint with autologous tissue substitute, posterior approach, anterior column, open approach
0RG60A0	Fusion of thoracic vertebral joint with interbody fusion device, anterior approach, anterior column, open approach
0RG60AJ	Fusion of thoracic vertebral joint with interbody fusion device, posterior approach, anterior column, open approach

ICD-10-PCS	Description
0RG60J0	Fusion of thoracic vertebral joint with synthetic substitute, anterior approach, anterior column, open approach
0RG60J1	Fusion of thoracic vertebral joint with synthetic substitute, posterior approach, posterior column, open approach
0RG60JJ	Fusion of thoracic vertebral joint with synthetic substitute, posterior approach, anterior column, open approach
0RG60K0	Fusion of thoracic vertebral joint with nonautologous tissue substitute, anterior approach, anterior column, open approach
0RG60K1	Fusion of thoracic vertebral joint with nonautologous tissue substitute, posterior approach, posterior column, open approach
0RG60KJ	Fusion of thoracic vertebral joint with nonautologous tissue substitute, posterior approach, anterior column, open approach
0RG6370	Fusion of thoracic vertebral joint with autologous tissue substitute, anterior approach, anterior column, percutaneous approach
0RG6371	Fusion of thoracic vertebral joint with autologous tissue substitute, posterior approach, posterior column, percutaneous approach
0RG637J	Fusion of thoracic vertebral joint with autologous tissue substitute, posterior approach, anterior column, percutaneous approach
0RG63A0	Fusion of thoracic vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0RG63AJ	Fusion of thoracic vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0RG63J0	Fusion of thoracic vertebral joint with synthetic substitute, anterior approach, anterior column, percutaneous approach
0RG63J1	Fusion of thoracic vertebral joint with synthetic substitute, posterior approach, posterior column, percutaneous approach
0RG63JJ	Fusion of thoracic vertebral joint with synthetic substitute, posterior approach, anterior column, percutaneous approach
0RG63K0	Fusion of thoracic vertebral joint with nonautologous tissue substitute, anterior approach, anterior column, percutaneous approach
0RG63K1	Fusion of thoracic vertebral joint with nonautologous tissue substitute, posterior approach, posterior column, percutaneous approach
0RG63KJ	Fusion of thoracic vertebral joint with nonautologous tissue substitute, posterior approach, anterior column, percutaneous approach
0RG6470	Fusion of thoracic vertebral joint with autologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RG6471	Fusion of thoracic vertebral joint with autologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RG647J	Fusion of thoracic vertebral joint with autologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0RG64A0	Fusion of thoracic vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0RG64AJ	Fusion of thoracic vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0RG64J0	Fusion of thoracic vertebral joint with synthetic substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RG64J1	Fusion of thoracic vertebral joint with synthetic substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RG64JJ	Fusion of thoracic vertebral joint with synthetic substitute, posterior approach, anterior column, percutaneous endoscopic approach
0RG64K0	Fusion of thoracic vertebral joint with nonautologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RG64K1	Fusion of thoracic vertebral joint with nonautologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RG64KJ	Fusion of thoracic vertebral joint with nonautologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0RG7070	Fusion of 2 to 7 thoracic vertebral joints with autologous tissue substitute, anterior approach, anterior column, open approach

ICD-10-PCS	Description
0RG7071	Fusion of 2 to 7 thoracic vertebral joints with autologous tissue substitute, posterior approach, posterior column, open approach
0RG707J	Fusion of 2 to 7 thoracic vertebral joints with autologous tissue substitute, posterior approach, anterior column, open approach
0RG70A0	Fusion of 2 to 7 thoracic vertebral joints with interbody fusion device, anterior approach, anterior column, open approach
0RG70AJ	Fusion of 2 to 7 thoracic vertebral joints with interbody fusion device, posterior approach, anterior column, open approach
0RG70J0	Fusion of 2 to 7 thoracic vertebral joints with synthetic substitute, anterior approach, anterior column, open approach
0RG70J1	Fusion of 2 to 7 thoracic vertebral joints with synthetic substitute, posterior approach, posterior column, open approach
0RG70JJ	Fusion of 2 to 7 thoracic vertebral joints with synthetic substitute, posterior approach, anterior column, open approach
0RG70K0	Fusion of 2 to 7 thoracic vertebral joints with nonautologous tissue substitute, anterior approach, anterior column, open approach
0RG70K1	Fusion of 2 to 7 thoracic vertebral joints with nonautologous tissue substitute, posterior approach, posterior column, open approach
0RG70KJ	Fusion of 2 to 7 thoracic vertebral joints with nonautologous tissue substitute, posterior approach, anterior column, open approach
0RG7370	Fusion of 2 to 7 thoracic vertebral joints with autologous tissue substitute, anterior approach, anterior column, percutaneous approach
0RG7371	Fusion of 2 to 7 thoracic vertebral joints with autologous tissue substitute, posterior approach, posterior column, percutaneous approach
0RG737J	Fusion of 2 to 7 thoracic vertebral joints with autologous tissue substitute, posterior approach, anterior column, percutaneous approach
0RG73A0	Fusion of 2 to 7 thoracic vertebral joints with interbody fusion device, anterior approach, anterior column, percutaneous approach
0RG73AJ	Fusion of 2 to 7 thoracic vertebral joints with interbody fusion device, posterior approach, anterior column, percutaneous approach
0RG73J0	Fusion of 2 to 7 thoracic vertebral joints with synthetic substitute, anterior approach, anterior column, percutaneous approach
0RG73J1	Fusion of 2 to 7 thoracic vertebral joints with synthetic substitute, posterior approach, posterior column, percutaneous approach
0RG73JJ	Fusion of 2 to 7 thoracic vertebral joints with synthetic substitute, posterior approach, anterior column, percutaneous approach
0RG73K0	Fusion of 2 to 7 thoracic vertebral joints with nonautologous tissue substitute, anterior approach, anterior column, percutaneous approach
0RG73K1	Fusion of 2 to 7 thoracic vertebral joints with nonautologous tissue substitute, posterior approach, posterior column, percutaneous approach
0RG73KJ	Fusion of 2 to 7 thoracic vertebral joints with nonautologous tissue substitute, posterior approach, anterior column, percutaneous approach
0RG7470	Fusion of 2 to 7 thoracic vertebral joints with autologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RG7471	Fusion of 2 to 7 thoracic vertebral joints with autologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RG747J	Fusion of 2 to 7 thoracic vertebral joints with autologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0RG74A0	Fusion of 2 to 7 thoracic vertebral joints with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0RG74AJ	Fusion of 2 to 7 thoracic vertebral joints with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0RG74J0	Fusion of 2 to 7 thoracic vertebral joints with synthetic substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RG74J1	Fusion of 2 to 7 thoracic vertebral joints with synthetic substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RG74JJ	Fusion of 2 to 7 thoracic vertebral joints with synthetic substitute, posterior approach, anterior column, percutaneous endoscopic approach

ICD-10-PCS	Description
0RG74K0	Fusion of 2 to 7 thoracic vertebral joints with nonautologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RG74K1	Fusion of 2 to 7 thoracic vertebral joints with nonautologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RG74KJ	Fusion of 2 to 7 thoracic vertebral joints with nonautologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0RG8070	Fusion of 8 or more thoracic vertebral joints with autologous tissue substitute, anterior approach, anterior column, open approach
0RG8071	Fusion of 8 or more thoracic vertebral joints with autologous tissue substitute, posterior approach, posterior column, open approach
0RG807J	Fusion of 8 or more thoracic vertebral joints with autologous tissue substitute, posterior approach, anterior column, open approach
0RG80A0	Fusion of 8 or more thoracic vertebral joints with interbody fusion device, anterior approach, anterior column, open approach
0RG80AJ	Fusion of 8 or more thoracic vertebral joints with interbody fusion device, posterior approach, anterior column, open approach
0RG80J0	Fusion of 8 or more thoracic vertebral joints with synthetic substitute, anterior approach, anterior column, open approach
0RG80J1	Fusion of 8 or more thoracic vertebral joints with synthetic substitute, posterior approach, posterior column, open approach
0RG80JJ	Fusion of 8 or more thoracic vertebral joints with synthetic substitute, posterior approach, anterior column, open approach
0RG80K0	Fusion of 8 or more thoracic vertebral joints with nonautologous tissue substitute, anterior approach, anterior column, open approach
0RG80K1	Fusion of 8 or more thoracic vertebral joints with nonautologous tissue substitute, posterior approach, posterior column, open approach
0RG80KJ	Fusion of 8 or more thoracic vertebral joints with nonautologous tissue substitute, posterior approach, anterior column, open approach
0RG8370	Fusion of 8 or more thoracic vertebral joints with autologous tissue substitute, anterior approach, anterior column, percutaneous approach
0RG8371	Fusion of 8 or more thoracic vertebral joints with autologous tissue substitute, posterior approach, posterior column, percutaneous approach
0RG837J	Fusion of 8 or more thoracic vertebral joints with autologous tissue substitute, posterior approach, anterior column, percutaneous approach
0RG83A0	Fusion of 8 or more thoracic vertebral joints with interbody fusion device, anterior approach, anterior column, percutaneous approach
0RG83AJ	Fusion of 8 or more thoracic vertebral joints with interbody fusion device, posterior approach, anterior column, percutaneous approach
0RG83J0	Fusion of 8 or more thoracic vertebral joints with synthetic substitute, anterior approach, anterior column, percutaneous approach
0RG83J1	Fusion of 8 or more thoracic vertebral joints with synthetic substitute, posterior approach, posterior column, percutaneous approach
0RG83JJ	Fusion of 8 or more thoracic vertebral joints with synthetic substitute, posterior approach, anterior column, percutaneous approach
0RG83K0	Fusion of 8 or more thoracic vertebral joints with nonautologous tissue substitute, anterior approach, anterior column, percutaneous approach
0RG83K1	Fusion of 8 or more thoracic vertebral joints with nonautologous tissue substitute, posterior approach, posterior column, percutaneous approach
0RG83KJ	Fusion of 8 or more thoracic vertebral joints with nonautologous tissue substitute, posterior approach, anterior column, percutaneous approach
0RG8470	Fusion of 8 or more thoracic vertebral joints with autologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RG8471	Fusion of 8 or more thoracic vertebral joints with autologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RG847J	Fusion of 8 or more thoracic vertebral joints with autologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0RG84A0	Fusion of 8 or more thoracic vertebral joints with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach

ICD-10-PCS	Description
0RG84AJ	Fusion of 8 or more thoracic vertebral joints with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0RG84J0	Fusion of 8 or more thoracic vertebral joints with synthetic substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RG84J1	Fusion of 8 or more thoracic vertebral joints with synthetic substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RG84JJ	Fusion of 8 or more thoracic vertebral joints with synthetic substitute, posterior approach, anterior column, percutaneous endoscopic approach
0RG84K0	Fusion of 8 or more thoracic vertebral joints with nonautologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RG84K1	Fusion of 8 or more thoracic vertebral joints with nonautologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RG84KJ	Fusion of 8 or more thoracic vertebral joints with nonautologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0RGA070	Fusion of thoracolumbar vertebral joint with autologous tissue substitute, anterior approach, anterior column, open approach
0RGA071	Fusion of thoracolumbar vertebral joint with autologous tissue substitute, posterior approach, posterior column, open approach
0RGA07J	Fusion of thoracolumbar vertebral joint with autologous tissue substitute, posterior approach, anterior column, open approach
0RGA0A0	Fusion of thoracolumbar vertebral joint with interbody fusion device, anterior approach, anterior column, open approach
0RGA0AJ	Fusion of thoracolumbar vertebral joint with interbody fusion device, posterior approach, anterior column, open approach
0RGA0J0	Fusion of thoracolumbar vertebral joint with synthetic substitute, anterior approach, anterior column, open approach
0RGA0J1	Fusion of thoracolumbar vertebral joint with synthetic substitute, posterior approach, posterior column, open approach
0RGA0JJ	Fusion of thoracolumbar vertebral joint with synthetic substitute, posterior approach, anterior column, open approach
0RGA0K0	Fusion of thoracolumbar vertebral joint with nonautologous tissue substitute, anterior approach, anterior column, open approach
0RGA0K1	Fusion of thoracolumbar vertebral joint with nonautologous tissue substitute, posterior approach, posterior column, open approach
0RGA0KJ	Fusion of thoracolumbar vertebral joint with nonautologous tissue substitute, posterior approach, anterior column, open approach
0RGA370	Fusion of thoracolumbar vertebral joint with autologous tissue substitute, anterior approach, anterior column, percutaneous approach
0RGA371	Fusion of thoracolumbar vertebral joint with autologous tissue substitute, posterior approach, posterior column, percutaneous approach
0RGA37J	Fusion of thoracolumbar vertebral joint with autologous tissue substitute, posterior approach, anterior column, percutaneous approach
0RGA3A0	Fusion of thoracolumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0RGA3AJ	Fusion of thoracolumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0RGA3J0	Fusion of thoracolumbar vertebral joint with synthetic substitute, anterior approach, anterior column, percutaneous approach
0RGA3J1	Fusion of thoracolumbar vertebral joint with synthetic substitute, posterior approach, posterior column, percutaneous approach
0RGA3JJ	Fusion of thoracolumbar vertebral joint with synthetic substitute, posterior approach, anterior column, percutaneous approach
0RGA3K0	Fusion of thoracolumbar vertebral joint with nonautologous tissue substitute, anterior approach, anterior column, percutaneous approach
0RGA3K1	Fusion of thoracolumbar vertebral joint with nonautologous tissue substitute, posterior approach, posterior column, percutaneous approach
0RGA3KJ	Fusion of thoracolumbar vertebral joint with nonautologous tissue substitute, posterior approach, anterior column, percutaneous approach

ICD-10-PCS	Description
0RGA470	Fusion of thoracolumbar vertebral joint with autologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RGA471	Fusion of thoracolumbar vertebral joint with autologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RGA47J	Fusion of thoracolumbar vertebral joint with autologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0RGA4A0	Fusion of thoracolumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0RGA4AJ	Fusion of thoracolumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0RGA4J0	Fusion of thoracolumbar vertebral joint with synthetic substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RGA4J1	Fusion of thoracolumbar vertebral joint with synthetic substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RGA4JJ	Fusion of thoracolumbar vertebral joint with synthetic substitute, posterior approach, anterior column, percutaneous endoscopic approach
0RGA4K0	Fusion of thoracolumbar vertebral joint with nonautologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0RGA4K1	Fusion of thoracolumbar vertebral joint with nonautologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0RGA4KJ	Fusion of thoracolumbar vertebral joint with nonautologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0SG0070	Fusion of lumbar vertebral joint with autologous tissue substitute, anterior approach, anterior column, open approach
0SG0071	Fusion of lumbar vertebral joint with autologous tissue substitute, posterior approach, posterior column, open approach
0SG007J	Fusion of lumbar vertebral joint with autologous tissue substitute, posterior approach, anterior column, open approach
0SG00A0	Fusion of lumbar vertebral joint with interbody fusion device, anterior approach, anterior column, open approach
0SG00AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG00J0	Fusion of lumbar vertebral joint with synthetic substitute, anterior approach, anterior column, open approach
0SG00J1	Fusion of lumbar vertebral joint with synthetic substitute, posterior approach, posterior column, open approach
0SG00JJ	Fusion of lumbar vertebral joint with synthetic substitute, posterior approach, anterior column, open approach
0SG00K0	Fusion of lumbar vertebral joint with nonautologous tissue substitute, anterior approach, anterior column, open approach
0SG00K1	Fusion of lumbar vertebral joint with nonautologous tissue substitute, posterior approach, posterior column, open approach
0SG00KJ	Fusion of lumbar vertebral joint with nonautologous tissue substitute, posterior approach, anterior column, open approach
0SG0370	Fusion of lumbar vertebral joint with autologous tissue substitute, anterior approach, anterior column, percutaneous approach
0SG0371	Fusion of lumbar vertebral joint with autologous tissue substitute, posterior approach, posterior column, percutaneous approach
0SG037J	Fusion of lumbar vertebral joint with autologous tissue substitute, posterior approach, anterior column, percutaneous approach
0SG03A0	Fusion of lumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG03AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG03J0	Fusion of lumbar vertebral joint with synthetic substitute, anterior approach, anterior column, percutaneous approach
0SG03J1	Fusion of lumbar vertebral joint with synthetic substitute, posterior approach, posterior column, percutaneous approach

ICD-10-PCS	Description
0SG03JJ	Fusion of lumbar vertebral joint with synthetic substitute, posterior approach, anterior column, percutaneous approach
0SG03K0	Fusion of lumbar vertebral joint with nonautologous tissue substitute, anterior approach, anterior column, percutaneous approach
0SG03K1	Fusion of lumbar vertebral joint with nonautologous tissue substitute, posterior approach, posterior column, percutaneous approach
0SG03KJ	Fusion of lumbar vertebral joint with nonautologous tissue substitute, posterior approach, anterior column, percutaneous approach
0SG0470	Fusion of lumbar vertebral joint with autologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0SG0471	Fusion of lumbar vertebral joint with autologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0SG047J	Fusion of lumbar vertebral joint with autologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0SG04A0	Fusion of lumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0SG04AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG04J0	Fusion of lumbar vertebral joint with synthetic substitute, anterior approach, anterior column, percutaneous endoscopic approach
0SG04J1	Fusion of lumbar vertebral joint with synthetic substitute, posterior approach, posterior column, percutaneous endoscopic approach
0SG04JJ	Fusion of lumbar vertebral joint with synthetic substitute, posterior approach, anterior column, percutaneous endoscopic approach
0SG04K0	Fusion of lumbar vertebral joint with nonautologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0SG04K1	Fusion of lumbar vertebral joint with nonautologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0SG04KJ	Fusion of lumbar vertebral joint with nonautologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0SG1070	Fusion of 2 or more lumbar vertebral joints with autologous tissue substitute, anterior approach, anterior column, open approach
0SG1071	Fusion of 2 or more lumbar vertebral joints with autologous tissue substitute, posterior approach, posterior column, open approach
0SG107J	Fusion of 2 or more lumbar vertebral joints with autologous tissue substitute, posterior approach, anterior column, open approach
0SG10A0	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, anterior approach, anterior column, open approach
0SG10AJ	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, anterior column, open approach
0SG10J0	Fusion of 2 or more lumbar vertebral joints with synthetic substitute, anterior approach, anterior column, open approach
0SG10J1	Fusion of 2 or more lumbar vertebral joints with synthetic substitute, posterior approach, posterior column, open approach
0SG10JJ	Fusion of 2 or more lumbar vertebral joints with synthetic substitute, posterior approach, anterior column, open approach
0SG10K0	Fusion of 2 or more lumbar vertebral joints with nonautologous tissue substitute, anterior approach, anterior column, open approach
0SG10K1	Fusion of 2 or more lumbar vertebral joints with nonautologous tissue substitute, posterior approach, posterior column, open approach
0SG10KJ	Fusion of 2 or more lumbar vertebral joints with nonautologous tissue substitute, posterior approach, anterior column, open approach
0SG1370	Fusion of 2 or more lumbar vertebral joints with autologous tissue substitute, anterior approach, anterior column, percutaneous approach
0SG1371	Fusion of 2 or more lumbar vertebral joints with autologous tissue substitute, posterior approach, posterior column, percutaneous approach
0SG137J	Fusion of 2 or more lumbar vertebral joints with autologous tissue substitute, posterior approach, anterior column, percutaneous approach

ICD-10-PCS	Description
0SG13A0	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG13AJ	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG13J0	Fusion of 2 or more lumbar vertebral joints with synthetic substitute, anterior approach, anterior column, percutaneous approach
0SG13J1	Fusion of 2 or more lumbar vertebral joints with synthetic substitute, posterior approach, posterior column, percutaneous approach
0SG13JJ	Fusion of 2 or more lumbar vertebral joints with synthetic substitute, posterior approach, anterior column, percutaneous approach
0SG13K0	Fusion of 2 or more lumbar vertebral joints with nonautologous tissue substitute, anterior approach, anterior column, percutaneous approach
0SG13K1	Fusion of 2 or more lumbar vertebral joints with nonautologous tissue substitute, posterior approach, posterior column, percutaneous approach
0SG13KJ	Fusion of 2 or more lumbar vertebral joints with nonautologous tissue substitute, posterior approach, anterior column, percutaneous approach
0SG1470	Fusion of 2 or more lumbar vertebral joints with autologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0SG1471	Fusion of 2 or more lumbar vertebral joints with autologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0SG147J	Fusion of 2 or more lumbar vertebral joints with autologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0SG14A0	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0SG14AJ	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG14J0	Fusion of 2 or more lumbar vertebral joints with synthetic substitute, anterior approach, anterior column, percutaneous endoscopic approach
0SG14J1	Fusion of 2 or more lumbar vertebral joints with synthetic substitute, posterior approach, posterior column, percutaneous endoscopic approach
0SG14JJ	Fusion of 2 or more lumbar vertebral joints with synthetic substitute, posterior approach, anterior column, percutaneous endoscopic approach
0SG14K0	Fusion of 2 or more lumbar vertebral joints with nonautologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0SG14K1	Fusion of 2 or more lumbar vertebral joints with nonautologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0SG14KJ	Fusion of 2 or more lumbar vertebral joints with nonautologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0SG3070	Fusion of lumbosacral joint with autologous tissue substitute, anterior approach, anterior column, open approach
0SG3071	Fusion of lumbosacral joint with autologous tissue substitute, posterior approach, posterior column, open approach
0SG307J	Fusion of lumbosacral joint with autologous tissue substitute, posterior approach, anterior column, open approach
0SG30A0	Fusion of lumbosacral joint with interbody fusion device, anterior approach, anterior column, open approach
0SG30AJ	Fusion of lumbosacral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG30J0	Fusion of lumbosacral joint with synthetic substitute, anterior approach, anterior column, open approach
0SG30J1	Fusion of lumbosacral joint with synthetic substitute, posterior approach, posterior column, open approach
0SG30JJ	Fusion of lumbosacral joint with synthetic substitute, posterior approach, anterior column, open approach
0SG30K0	Fusion of lumbosacral joint with nonautologous tissue substitute, anterior approach, anterior column, open approach
0SG30K1	Fusion of lumbosacral joint with nonautologous tissue substitute, posterior approach, posterior column, open approach

ICD-10-PCS	Description
0SG30KJ	Fusion of lumbosacral joint with nonautologous tissue substitute, posterior approach, anterior column, open approach
0SG3370	Fusion of lumbosacral joint with autologous tissue substitute, anterior approach, anterior column, percutaneous approach
0SG3371	Fusion of lumbosacral joint with autologous tissue substitute, posterior approach, posterior column, percutaneous approach
0SG337J	Fusion of lumbosacral joint with autologous tissue substitute, posterior approach, anterior column, percutaneous approach
0SG33A0	Fusion of lumbosacral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG33AJ	Fusion of lumbosacral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG33J0	Fusion of lumbosacral joint with synthetic substitute, anterior approach, anterior column, percutaneous approach
0SG33J1	Fusion of lumbosacral joint with synthetic substitute, posterior approach, posterior column, percutaneous approach
0SG33JJ	Fusion of lumbosacral joint with synthetic substitute, posterior approach, anterior column, percutaneous approach
0SG33K0	Fusion of lumbosacral joint with nonautologous tissue substitute, anterior approach, anterior column, percutaneous approach
0SG33K1	Fusion of lumbosacral joint with nonautologous tissue substitute, posterior approach, posterior column, percutaneous approach
0SG33KJ	Fusion of lumbosacral joint with nonautologous tissue substitute, posterior approach, anterior column, percutaneous approach
0SG3470	Fusion of lumbosacral joint with autologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0SG3471	Fusion of lumbosacral joint with autologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0SG347J	Fusion of lumbosacral joint with autologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach
0SG34A0	Fusion of lumbosacral joint with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0SG34AJ	Fusion of lumbosacral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG34J0	Fusion of lumbosacral joint with synthetic substitute, anterior approach, anterior column, percutaneous endoscopic approach
0SG34J1	Fusion of lumbosacral joint with synthetic substitute, posterior approach, posterior column, percutaneous endoscopic approach
0SG34JJ	Fusion of lumbosacral joint with synthetic substitute, posterior approach, anterior column, percutaneous endoscopic approach
0SG34K0	Fusion of lumbosacral joint with nonautologous tissue substitute, anterior approach, anterior column, percutaneous endoscopic approach
0SG34K1	Fusion of lumbosacral joint with nonautologous tissue substitute, posterior approach, posterior column, percutaneous endoscopic approach
0SG34KJ	Fusion of lumbosacral joint with nonautologous tissue substitute, posterior approach, anterior column, percutaneous endoscopic approach

ICD-10-CM	Description
M41.2	Other idiopathic scoliosis
M41.3	Thoracogenic scoliosis
M41.4	Neuromuscular scoliosis
M41.5	Other secondary scoliosis
M41.8	Other forms of scoliosis

The applicant identified 433,845 cases using the combination of ICD–10–PCS and ICD–10–CM codes which mapped to the following 11 MS–DRGs:

MS-DRG	Description
028	Spinal Procedures with MCC
029	Spinal Procedures with CC or Spinal Neurostimulators
030	Spinal Procedures without CC/ MCC
453	Combined Anterior and Posterior Spinal Fusion with MCC
454	Combined Anterior and Posterior Spinal Fusion with CC
455	Combined Anterior and Posterior Spinal Fusion without CC/MCC
456	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC
457	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with CC
458	Spinal Fusion Except Cervical With Spinal Curvature, Malignancy, Infection or Extensive Fusions without CC/MCC
459	Spinal Fusion Except Cervical with MCC
460	Spinal Fusion Except Cervical without MCC

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The applicant did not remove charges for prior technology. The applicant standardized the charges and applied a 4-year inflation factor of 1.281834 based on the inflation factor used to update the outlier threshold in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542), to update the charges from FY 2019 to FY 2023. The applicant then added charges for the new technology by dividing the per-patient anticipated hospital cost of the LigaPASS 2.0 PJK Prevention System by the national average cost-to-charge ratio for implantable devices (0.239) from the FY 2022 IPPS/LTCH PPS final rule (86 FR 44966). The applicant also added related charges for the new technology, estimated by the cost of 15 additional minutes of operating room time and 15 additional minutes of nursing time divided by the national average cost-to-charge ratios for Operating Room (0.167) and Other Services (0.344), respectively, from the FY 2022 IPPS/LTCH PPS final rule (86 FR 44966). The applicant calculated a final inflated case-weighted average standardized charge per case of $386,183 and an average case-weighted threshold of $165,473. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that the LigaPASS 2.0 PJK Prevention System meets the cost criterion and therefore are proposing to approve the LigaPASS 2.0 PJK Prevention System for new technology add-on payments for FY 2023, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by July 1, 2022.

Based on the preliminary information from the applicant at the time of this proposed rule, the cost per case of the LigaPASS 2.0 PJK Prevention System is $17,392, which includes $10,458 for 2 bands and $6,934 for 2 connectors per surgery. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the LigaPASS 2.0 PJK Prevention System would be $11,305 for FY 2023 (that is, 65% of the average cost of the technology).

We are inviting public comments on whether the LigaPASS 2.0 PJK Prevention System meets the cost criterion and our proposal to approve new technology add-on payments for LigaPASS 2.0 PJK Prevention System for FY 2023, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by July 1, 2022.

(5) Magnus Neuromodulation System With SAINT Technology

Magnus Medical, Inc. submitted an application for new technology add-on payments for Magnus Neuromodulation System (MNS) with Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT) technology for FY 2023. Per the applicant, the Magnus Neuromodulation System with SAINT technology is a transcranial magnetic stimulation (TMS) device with intermittent theta burst (iTBS) capability and includes a neuronavigation system to direct neurostimulation to individualized targets, and has target identification software that identifies individualized targets in the brain for stimulation using structural and functional MRI outputs. According to the applicant, the Magnus Neuromodulation System with SAINT technology utilizes magnetic pulses delivered to the prefrontal cortex in order to treat major depressive disorder (MDD), and has redesigned aspects of TMS to personalize the treatment and optimize individual patient response. These aspects include the identification of a target for stimulation, the dose or amount of stimulation, and the stimulation pattern.

The applicant stated that on July 2, 2021, the FDA designated the Magnus Transcranial Magnetic Stimulation (TMS) System with MINT (Magnus Intelligent Neuromodulation Therapy) as a Breakthrough Device for the treatment of major depressive disorder (MDD) in adult patients who have failed to receive satisfactory improvement

from prior antidepressant medication in the current episode. According to the applicant, the Magnus Neuromodulation System with SAINT technology is the same system that received the Breakthrough Device designation, but with a revised name. Per the applicant, Magnus Neuromodulation System with SAINT technology is a Class II device. The applicant stated that it is seeking FDA 510(k) clearance for the same indication, which the applicant expects to receive by June 1, 2022.

According to the applicant, there are currently no ICD–10–PCS codes to distinctly identify the Magnus Neuromodulation System with SAINT technology. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for Magnus Neuromodulation System with SAINT technology beginning in FY 2023. The applicant stated that the following ICD–10–CM diagnosis codes may be used to identify cases corresponding to the proposed Breakthrough Device indication for use of Magnus Neuromodulation System with SAINT technology: F32.2 (Major depressive affective disorder, single episode, severe, without mention of psychotic behavior) and F33.3 (Major depressive affective disorder, recurrent episode, severe, without mention of psychotic behavior).

With respect to the cost criterion, the applicant completed an analysis, as well as an additional subanalysis including only cases containing the ICD–10–CM diagnosis codes that correspond to their Breakthrough Device indication, to demonstrate that the Magnus Neuromodulation System with SAINT technology meets the cost criterion.

Under the main analysis, after determining that cases representing patients who may be eligible for treatment with Magnus Neuromodulation System with SAINT technology would map to MS–DRG 885 (Psychoses), the applicant determined a case count of 68,602 based on the number of cases reported for MS–DRG 885 in the FY 2023 New Technology Thresholds data file published with the FY 2022 IPPS/LTCH PPS final rule. The applicant then searched the FY 2020 Inpatient Standard Analytic File (IPSAF) for claims incurred during FY 2020 with an MS–DRG of 885. The applicant aggregated the charges at the facility level and calculated a weighted average of covered charges across all facilities.

The applicant stated that it declined to remove charges for prior technology, as the applicant determined that analogous technologies are currently used almost exclusively on an outpatient basis. The applicant then standardized the charges using inputs from the FY 2022 Standardizing File and the geographic adjustment factor (GAF) from the IPPS FY 2022 final rule impact file. The applicant applied the 3-year inflation factor used in the FY 2022 IPPS/LTCH PPS final rule and correction notice to calculate outlier threshold charges, which the applicant stated as 1.204686 (86 FR 45542). The applicant then added charges for the new technology by dividing the cost of Magnus Neuromodulation System with SAINT technology by the national average CCR for the Other Services, which is 0.334 (86 FR 44966), and inflating the charges using the same three year-inflation factor. The applicant added costs using the Outpatient Standard Analytic File (OPSAF) for FY 2020 data to populate estimated charges related to the technology and specifically included the following charges related to procedures from the OSPAF 2020:

- Brain Stimulation Consultation (completed on day 1 or 2 of the admission): Average weighted charges for CPT codes 99253–99255 ($481.91).
- Neuro Navigation (completed on day 1 or 2 of the admission): Average weighted charges for CPT code 61782 ($3,871.77). This procedure is performed every day before stimulation treatment and the day of the fMRI (Functional MRI) (6 instances on separate days).
- Functional MRI (fMRI) (completed on day 1 or day 2 of the admission): Average charges for CPT code 70554 ($3,333.89).
- Motor Threshold Determination (completed on the first day of the brain stimulation sessions): Average charges for CPT code 90867 within revenue code 900 ($639.05).
- Brain Stimulation Sessions (10 sessions a day across 5 treatment days, that is 50 sessions): Average charges for CPT code 90868 within revenue code 900 ($502.63).

The applicant calculated a final inflated average case-weighted standardized charge per case of $120,840 which exceeded the average case-weighted threshold amount of $34,073. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that Magnus Neuromodulation System with SAINT technology meets the cost criterion.

Under the subanalysis, the applicant included only cases within MS–DRG 885 reporting an ICD–10–CM diagnosis code of F32.2 or F33.3, as these two diagnosis codes match their Breakthrough Device indication. The applicant identified 2,787 cases containing either of these two ICD–10–CM diagnosis codes within MS–DRG 885. The applicant then applied the same methodology for calculations as in the main analysis. The calculations in this sub-analysis resulted in a case-weighted average standardized charge per case of $29,882 and a final inflated average case weight standardized charge per case of $125,152. The final inflated average case-weighted standardized charge per case under this subanalysis also exceeded the average case-weighted threshold amount of $34,073.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the Magnus Neuromodulation System with SAINT technology to the hospital to be a $12,500 fee per patient. The applicant stated that the cost of the technology consists of the three individual components of the Magnus Neuromodulation System with SAINT technology: The neurostimulation hardware, the neuronavigation hardware, and the target identification software. The applicant also noted that none of these were operating costs. Because section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for payment of the operating costs of inpatient hospital services, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (86 FR 45145). Based on the information from the applicant, it appears that the costs of the Magnus Neuromodulation System with SAINT technology only include capital costs. Therefore, even if the technology meets the cost criterion, it appears that the Magnus Neuromodulation System with SAINT technology is not eligible for new technology add-on payment because, as discussed in prior rulemaking and noted previously, we only make new technology add-on payments for operating costs (72 FR 47307 through 47308). However, we are inviting public comments on whether the Magnus Neuromodulation System with SAINT technology has any operating costs, and if it meets the cost criterion. If the Magnus Neuromodulation System with SAINT technology does have operating costs, since it appears to meet the cost criterion, we are proposing to approve

new technology add-on payments for only the operating costs of the Magnus Neuromodulation System with SAINT technology for FY 2023, subject to the technology receiving FDA marketing authorization for the treatment of MDD in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode, by July 1, 2022.

(6) Nelli® Seizure Monitoring System

Neuro Event Labs, Inc. submitted an application for new technology add-on payments for the Nelli® Seizure Monitoring System for FY 2023. Per the applicant, the Nelli® Seizure Monitoring System is software designed to automate the analysis of audio and video data to identify seizure events with a positive motor component as an adjunct to seizure monitoring in a hospital inpatient or home setting for adults and children 6 years of age and older. The applicant stated that data is collected while the patient is 'observed' using the Nelli® Seizure Monitoring System hardware (Personal Recording Unit [PRU]), which temporarily stores and pre-processes raw media data to extract only periods likely to contain clinically relevant activity. The applicant then stated that data is transmitted via a secure internet connection to the Nelli® Seizure Monitoring System software running on a remote server where it is processed using analysis algorithms which create and categorize media samples that may be indicative of epileptic seizure events. Per the applicant, the software provides objective summaries of semiological components of identified events (including velocity and acceleration of movements, seizure frequency, seizure duration, heart rate, and respiratory rate) to enable the detection and classification of epileptic events using pretrained artificial intelligence (AI).

According to the applicant, the Nelli® Seizure Monitoring System received Breakthrough Device designation from FDA on October 9, 2020 for the automated analysis of audio and video data to identify seizure events with a positive motor component in children and adults as well as to characterize seizures and peri-ictal events. The applicant stated that the Nelli® Seizure Monitoring System is not yet commercially available as it is awaiting 510(k) clearance of the device from the FDA for the same indication, which the applicant submitted on August 17, 2021.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the Nelli® Seizure Monitoring System. The applicant stated that the inpatient population for which the Nelli® Seizure Monitoring System is indicated would undergo standard video EEG monitoring, which is described by the ICD–10–PCS code 4A10X4Z (Monitoring of central nervous electrical activity, external approach). The applicant has submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a unique code for FY 2023 to identify the technology.

With respect to the cost criterion, the applicant conducted two analyses to demonstrate that the Nelli® Seizure Monitoring System meets the cost criterion, one based on 100% of identified claims, and second based on 91.1% of identified claims.

Under the first scenario, which included 100% of claims, the applicant searched the FY 2020 MedPAR database for cases representing patients who may be eligible for the Nelli® Seizure Monitoring System. The applicant extracted all inpatient claims for which ICD–10–PCS code 4A10X4Z (Monitoring of central nervous electrical activity, external approach) appeared in conjunction with any of the ICD–10–CM codes listed in the table below. The applicant stated this approach to identifying cases is based on the methodology used in a recent paper, which assessed the ability of using code-based queries to identify inpatient epilepsy monitoring unit (EMU) admissions from billing records in a large academic medical center over a 4-year period, 2016–2019.[593]

ICD-10-CM Codes and Ranges	Description of Codes and Ranges
G40.XXX	Epilepsy
G40.0XX, G40.1XX, G40.2XX G40.3XX, G40.4XX G40.5XX G40.AXX, G40.BXX G40.8XX, G40.9XX	Focal epilepsy Generalized epilepsy Epilepsy related to external causes Absence and juvenile myoclonic epilepsy Other epilepsy, unspecified
R56.01	Post-traumatic seizures
R56.9	Unspecified convulsions / seizure-like activity
F44.5 F44.9	Conversion disorder with psychogenic non-epileptic seizures Dissociative and conversion disorder, unspecified
R25.0-R25.9	Abnormal involuntary movements
R40.4	Transient alteration of awareness
R41.0	Disorientation, unspecified
R41.82	Altered mental status, unspecified
R55	Syncope and collapse
R94.01	Abnormal EEG

[593] Kamitaki B.K., Rishty S., Mani R., et al. Using ICD–10 codes to identify elective epilepsy monitoring unit admissions from administrative billing data: A validation study. Epilepsy Behav. 2020;111:107194.

After imputing a case count of 11 for those MS–DRGs with fewer than 11 cases, the applicant identified 9,506 claims mapping to the following 11 MS–DRGs, with over 90% of cases mapping to MS–DRGs 100 (Seizures with MCC) and 101 (Seizures without MCC):

MS-DRG	Description
056	Degenerative Nervous System Disorders with MCC
064	Intracranial Hemorrhage or Cerebral Infarction with MCC
070	Nonspecific Cerebrovascular Disorders with MCC
071	Nonspecific Cerebrovascular Disorders with CC
092	Other Disorders of Nervous System with CC
100	Seizures with MCC
101	Seizures without MCC
312	Syncope and Collapse
689	Kidney and Urinary Tract Infections with MCC
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC
880	Acute Adjustment Reaction and Psychosocial Dysfunction

The applicant did not remove charges for prior technology as it asserted there is no technology being replaced when the Nelli® Seizure Monitoring System is used in a hospital inpatient setting. The applicant then standardized the charges by applying the 3-year inflation factor of 1.204686 used in the FY 2022 IPPS/LTCH PPS final rule and correction notice to calculate outlier threshold charges (86 FR 45542). The applicant then added charges for the new technology by dividing the cost of the Nelli® Seizure Monitoring System by the national average CCR for ''Other Services,'' which is 0.344 as published in the FY 2022 IPPS/LTCH IPPS final rule (86 FR 44966).

The applicant calculated a case-weighted average standardized charge per case of $56,770 and a final inflated average case-weighted standardized charge per case of $71,297, both of which exceeded the average case-weighted threshold amount of $48,474.

Under the second scenario, the applicant included only cases mapping to MS–DRGs 100 and 101 (seizures with and without MCC, respectively) as these two MS–DRGs represented 91.1% of patients undergoing video EEG, which the applicant identified using the ICD–10–PCS code 4A10X4Z (Monitoring of central nervous electrical activity, external approach). Per the applicant, 30.2% of the procedures mapped to MS–DRG 100 and 60.9% of the procedures mapped to MS–DRG 101. The applicant asserted that these patients more likely represent the inpatient EMU population for which the Nelli® Seizure Monitoring System would be especially applicable. The applicant identified 6,182 cases mapping to these 2 MS–DRGs. The applicant then applied the same methodology for calculations as in the first analysis. The calculations in this sub-analysis resulted in a case-weighted average standardized charge per case of $55,524 and a final inflated average case weight standardized charge per case of $69,796. Both of these amounts exceed the case-weighted threshold amount of $48,404.

Because the final inflated case-weighted average standardized charge per case for each scenario exceeded the average case-weighted threshold amount for all scenarios, the applicant asserted that the Nelli® Seizure Monitoring System meets the cost criterion.

We agree that the Nelli® Seizure Monitoring System meets the cost criterion and therefore are proposing to approve the Nelli® Seizure Monitoring System for new technology add on payments for FY 2023, subject to the technology receiving FDA marketing authorization for the automated analysis of audio and video data to identify seizure events with a positive motor component in children and adults by July 1, 2022.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the non-capital cost of the Nelli® Seizure Monitoring System to the hospital to be $1,000 per patient for the semiological report and seizure detection notification produced following patient assessment. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. The applicant based the cost per case of its technology on two pricing models that it currently uses in Europe. The first pricing model consists of an approximately $350 per day charge for the technology. The applicant stated that this results in a typical cost to the hospital of around $1,000 USD (excluding capital costs) for an average patient stay of 3–4 days in an EMU. The applicant stated that the second pricing model is a single 1000 € per-patient fee for measurement of readings and producing the report, regardless of the number of days the system is used. Therefore, based on the information provided by the applicant, it appears that the average cost per case for the use of the Nelli® Seizure Monitoring System is $1000 USD. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the Nelli® Seizure Monitoring System would be $650 for FY 2023 (that is 65% of the average cost of the technology).

We are inviting public comments on whether the Nelli® Seizure Monitoring System meets the cost criterion and our proposal to approve new technology add-on payments for the Nelli® Seizure Monitoring System for FY 2023, subject to the technology receiving FDA marketing authorization for the automated analysis of audio and video data to identify seizure events with a positive motor component in children and adults by July 1, 2022.

(7) Phagenyx® System

Phagenesis Ltd. submitted an application for new technology-add on payments for the Phagenyx® System for

FY 2023. The Phagenyx® System (Phagenyx®) is a neurostimulation device for the treatment of neurogenic dysphagia, which is often seen after stroke, traumatic brain injury, or prolonged mechanical ventilation. Per the applicant, the system is comprised of a sterile single-use per patient catheter (the PNX–1000 catheter), introduced nasally and extending as far as the patient's stomach; and the (reusable) EPSB3 Base Station, described as a touch screen user interface that facilitates the optimization of stimulation levels and stores patient and treatment information. Per the applicant, treatment involves the use of electric pulses to stimulate sensory nerves in the oropharynx. The applicant is requesting new technology add-on payments for the PNX–1000 catheter only. We note that Phagenesis Ltd. previously submitted an application for new technology add-on payments for the Phagenyx® System for FY 2022, as summarized in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25382 through 25384) but the technology did not meet the deadline of July 1, 2021, for FDA approval or clearance of the technology and, therefore, was not eligible for consideration for new technology add-on payments for FY 2022 (86 FR 45126 through 45127).

Per the applicant, Phagenyx® received Breakthrough Device designation on December 4, 2019 for use in treating neurogenic dysphagia in adult tracheotomized patients weaned from ventilation. The Breakthrough Device designation was revised on January 29, 2021 to include the treatment of nonprogressive neurogenic dysphagia in adult patients, for which the applicant indicated that it anticipates FDA will grant a De Novo classification request in the second quarter of calendar year 2022.

The applicant applied for and received a unique ICD–10–PCS procedure code to identify cases involving the administration of Phagenyx® effective for FY 2022. Phagenyx® administration can now be identified by the ICD–10–PCS procedure code XWHD7Q7 (Insertion of neurostimulator lead into mouth and pharynx, via natural or artificial opening, new technology group 7), which is unique to Phagenyx® administration.

With respect to the cost criterion, the applicant provided an analysis, as well as an additional subanalysis containing only MS–DRGs having at least 1% of the entire sample volume, to demonstrate that the technology meets the cost criterion. Under the first analysis, the applicant first identified discharges from the 2019 MedPAR final rule dataset reporting one of the following ICD–10–CM codes for dysphagia:

ICD-10-CM	Description
R13.10	Unspecified
R13.12	Oropharyngeal phase
R13.13	Pharyngeal phase
R13.14	Pharyngoesophageal phase
R13.19	Other dysphagia

The applicant then removed all discharges reporting one of the following ICD–10–CM codes for a progressive neurodegenerative disease or condition:

ICD-10-CM Code Range	Description of Code Range
G10.x	Huntington's disease
G11.1x	Friedreich's ataxia
G12.x	Spinal muscular atrophy and related syndromes
G20.x	Parkinson's disease
G30xx	Alzheimer's disease
G31.83x	Lewy body disease
G35xx	Multiple sclerosis

The applicant included only inpatient fee-for-service discharges (claim type ''60'') and excluded Medicare Advantage discharges.

After imputing a value of 11 cases for any MS–DRG with a discharge count under 11, the applicant identified 391,136 cases spanning 722 MS–DRGs. The applicant explained that it did not remove charges for prior technology as Phagenyx® does not replace any existing therapy for treating neurogenic dysphagia. The applicant then standardized the charges using the FY 2019 final rule and correction notice impact file and excluded any discharges without a standardized charge. The applicant applied a 4-year inflation factor of 1.281834 to update the charges from FY 2019 to FY 2023, based on the inflation factor used to update the outlier threshold in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542). The applicant then added charges for the new technology by dividing the estimated cost of Phagenyx® by the national cost-to-charge ratio for supplies and equipment of .297 from the FY 2022 IPPS/LTCH PPS final rule (86 FR 44966). The applicant determined a final inflated case weighted average standardized charge per case of $115,910, which exceeded the case weighted threshold of $68,761. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

The applicant submitted an additional analysis containing only cases mapping to MS–DRGs with at least 1% of the

entire sample volume. This secondary analysis contained 19 MS–DRGs (vs. 722 MS–DRGs in the original analysis). Using the same methodology above, the applicant determined a final inflated case weighted standardized charge per case of $102,682 and a case-weighted threshold of $60,674. Because the final inflated case weighted standardized charge per case exceeded the case-weighted threshold under this second analysis, the applicant maintained that the technology meets the cost criterion.

We agree with the applicant that Phagenyx® meets the cost criterion and are therefore proposing to approve Phagenyx® for new technology add-on payments for FY 2023, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by July 1, 2022.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of Phagenyx® is $5,000 per catheter, which is the subject of this application. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of Phagenyx® would be $3,250 for FY 2023 (that is, 65% of the average cost of the technology).

We are inviting public comments on whether Phagenyx® meets the cost criterion and our proposal to approve new technology add-on payments for Phagenyx® for FY 2023 for the indication corresponding to the updated Breakthrough Device designation, subject to Phagenyx® receiving FDA marketing authorization for that indication by July 1, 2022.

(8) Precision TAVI™ Coronary Obstruction Module

DASI Simulations submitted an application for new technology add-on payments for the Precision Transcatheter Aortic Valve Implantation (TAVI)™ Coronary Obstruction Module for FY 2023. According to the applicant, the Precision TAVI Coronary Obstruction Module, which would be an added feature of the Precision TAVI Software System, is intended to provide intelligent decision support powered by artificial intelligence (AI) and machine learning to help physicians accurately predict potential coronary artery obstructions in transcatheter aortic valve replacement (TAVR) procedures. The applicant stated that the technology may assist physicians in the evaluation of patients with severe aortic stenosis when considering surgical replacement as opposed to trans-catheter replacement procedures, as well as other interventional or protection measures, when used with the Precision TAVI™ Software System.

The applicant stated that the Precision TAVI™ Coronary Obstruction Module has not yet received FDA Breakthrough Device designation, but that it expects to receive Breakthrough Device designation for the following indication: Precision TAVI™ Coronary Obstruction Module utilizes an additional proprietary software to analyze the results of the simulation module and output coronary obstruction risk biomarkers corresponding to each implantation simulation scenario. For scenarios involving TAVR in a failed surgical valve or a failed transcatheter valve, the computational test will also include use of anatomic characteristics before and after simulated bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction (BASILICA) procedure. The applicant indicated that it anticipates receiving 510(k) clearance for the Precision TAVI™ Coronary Obstruction Module from FDA by July 1, 2022 for the same indication. According to the applicant, the device will be available on the market immediately after receiving FDA clearance. We note that the proposed indication as stated in the application does not describe a disease or population to be treated and we therefore question whether this information is the expected indication or some other description of the technology.

According to the applicant, there are currently no ICD–10–PCS codes that uniquely identify the Precision TAVI™ Coronary Obstruction Module. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a unique code for FY 2023 to identify the Precision TAVI™ Coronary Obstruction Module.

With regard to the cost criterion, the applicant provided the following analysis. To identify potential cases where the Precision TAVI™ Coronary Obstruction Module could be utilized, the applicant searched the FY 2019 MedPAR Limited Data Set for cases reporting either of the two ICD–10–PCS procedure codes to describe TAVR procedures, 02RF38Z (Replacement of aortic valve with zooplastic tissue, percutaneous approach) and 02RF38H (Replacement of aortic valve with zooplastic tissue, transapical, percutaneous approach), consistent with the indication for which the applicant anticipates receiving Breakthrough Device designation.

The applicant identified 40,407 total claims across 60 MS–DRGs. The applicant stated that it did not remove charges associated with Medical/Surgical Supplies and Devices (revenue centers 027x and 0624) because the use of the Precision TAVI™ Coronary Obstruction Module is additive, and does not replace other supplies or devices utilized in the TAVR procedures analyzed. The applicant then standardized the charges and applied the 3-year inflation factor of 1.204686 used to update the outlier threshold in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542) to update the charges from FY 2019 to FY 2022. The applicant then added charges for the new technology. The applicant multiplied the cost of the technology by the national cost-to-charge ratio for radiology from the FY2022 IPPS/LTCH PPS final rule (0.136) (86 FR 44966) to calculate estimated average hospital charges associated with the device.

The applicant calculated a final inflated case-weighted average standardized charge per case of $240,685 and an average case-weighted threshold of $181,410. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

We have the following concern regarding the applicant's analysis. We note that the applicant used the ICD–10–PCS codes for TAVR to identify cases where the Precision TAVI™ Coronary Obstruction Module may be used. However, according to the applicant, the software can identify cases where TAVR should not be performed. We question whether these potentially lower cost cases are reflected in the applicant's cost analysis, as a TAVR procedure code would not be on the claim.

Subject to the applicant adequately addressing this concern, we would agree that the technology meets the cost criterion and propose to approve the Precision TAVI™ Coronary Obstruction Module for new technology add-on payments for FY 2023, subject to the technology receiving Breakthrough Device designation and FDA marketing authorization for the same indication by July 1, 2022.

Based on preliminary information from the applicant at the time of this

proposed rule, the cost of Precision TAVI™ Coronary Obstruction Module is $1,995 per patient. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of Precision TAVI™ Coronary Obstruction Module would be $1,296.75 for FY 2023 (that is, 65% of the average cost of the technology). We are inviting public comments on whether the Precision TAVI™ Coronary Obstruction Module meets the cost criterion and our proposal to approve new technology add-on payments for the Precision TAVI™ Coronary Obstruction Module for FY 2022 subject to the technology receiving Breakthrough Device designation and FDA marketing authorization by July 1, 2022 for the same indication as described previously.

(9) Thoraflex™ Hybrid Device

Terumo Aortic submitted an application for new technology-add on payments for the Thoraflex™ Hybrid Device (Thoraflex™) for FY 2023. Per the applicant, the device is a sterile single-use, gelatin sealed Frozen Elephant Trunk (FET) surgical medical device. The applicant explained that the device is deployed through an opened aortic arch and then positioned into the descending thoracic aorta. The applicant further explained that, once it is completely deployed, the collar is sutured to the aorta, and graft anastomoses are then performed in a manner depending upon the chosen product design (which the applicant specified as either the Plexus or the Ante-Flo). The device includes a proximal crimped polyester surgical graft, central polyester collar, and distal nitinol ring stents supported by thin wall polyester fabric. The applicant also noted that the device has a unique gelatin sealant that acts as a seal, preventing blood loss through the polyester fabric product wall. We note that Terumo Aortic previously submitted an application for new technology add-on payments for the Thoraflex™ Hybrid Device for FY 2022, as summarized in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25390) which was withdrawn prior to the issuance of the FY 2022 IPPS/LTCH PPS final rule (86 FR 45127).

According to the applicant, the Thoraflex™ Hybrid Device received Breakthrough Device designation on March 20, 2020 for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta, with or without involvement of the ascending aorta, in cases of aneurysm and/or dissection. The applicant is seeking premarket approval of the device for the same indication. According to the applicant, the ICD–10 Coordination and Maintenance Committee approved the following ICD–10–PCS codes to specifically describe the use of the Thoraflex™ Hybrid Device, effective October 1, 2021: X2RX0N7 (Replacement of thoracic aorta arch with branched synthetic substitute with intraluminal device, new technology group 7) and X2VW0N7 (Restriction of thoracic descending aorta with branched synthetic substitute with intraluminal device, new technology group 7).

With respect to the cost criterion, the applicant conducted two analyses based on 100% of identified claims and 74% of identified claims. To identify potential cases where the Thoraflex™ Hybrid Device could be utilized, the applicant searched the FY 2019 MedPAR file for claims reporting the following ICD–10–PCS codes for thoracic aortic replacement procedures: 02RX08Z (Replacement of thoracic aorta, ascending/arch with zooplastic tissue, open approach), 02RX0JZ (Replacement of thoracic aorta, ascending/arch with synthetic tissue, open approach), and 02RX0KZ (Replacement of thoracic aorta, ascending/arch with nonautologous tissue substitute, open approach).

For the analysis using 100% of cases, the applicant identified 5,374 cases mapping to 21 MS–DRGs. The applicant then removed charges for the technology being replaced. Per the applicant, the use of the Thoraflex™ Hybrid device is expected to replace a portion of prior technologies. The applicant explained that because an estimate of the percentage of these total charges that would be replaced could not be determined, it removed 100% of charges associated with medical/surgical supplies and devices (revenue centers 027x and 0624). The applicant then standardized the charges and applied the 3-year outlier inflation factor of 1.204686 used to update the outlier threshold in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542) to update the charges from FY 2019 to FY 2022. The applicant then added charges for the new technology. The applicant multiplied the cost of the technology by the national cost-to-charge ratio for implantable devices from the FY 2022 IPPS/LTCH PPS final rule (0.293) to calculate estimated average hospital charges associated with the device. Under this analysis, based on 100% of identified claims, the applicant calculated a final inflated case-weighted average standardized charge per case of $420,924 and an average case-weighted threshold of $230,659.

Under the analysis based on 74% of cases, the applicant used the same methodology, which identified 3,980 cases across MS–DRGs 219 and 220. The applicant determined the average case-weighted threshold of $211,423 and a final inflated average standardized charge per case of $373,273. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount under both analyses, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that the Thoraflex™ Hybrid Device meets the cost criterion and therefore are proposing to approve the Thoraflex™ Hybrid Device for new technology add-on payments for FY 2023, subject to the technology receiving FDA marketing authorization for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta, with or without involvement of the ascending aorta, in cases of aneurysm and/or dissection by July 1, 2022.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of Thoraflex™ Hybrid Device is $35,000 per patient. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of Thoraflex™ Hybrid Device would be $22,750 per patient for FY 2023 (that is, 65% of the average cost of the technology).

We are inviting public comments on whether the Thoraflex™ Hybrid Device meets the cost criterion and our proposal to approve new technology add-on payments for the Thoraflex™ Hybrid Device for FY 2023, subject to Thoraflex™ Hybrid Device receiving FDA marketing authorization by July 1, 2022 for the open surgical repair or replacement of damaged or diseased

vessels of the aortic arch and descending aorta, with or without involvement of the ascending aorta, in cases of aneurysm and/or dissection.

(10) TOPS™ System

Premia Spine, Inc., submitted an application for new technology add-on payments for the TOPS™ System for FY 2023. According to the applicant, the TOPS™ System is a motion preserving device comprised of a titanium construct with an interlocking polycarbonate urethane articulating core that is inserted into the lumbar vertebral joint and anchored using pedicle screws after posterior spinal decompression surgery. The applicant stated that the TOPS™ System replaces anatomical structures, such as the lamina and the facet joints, which are removed during spinal decompression treatment to alleviate pain. Per the applicant, unlike spinal fusion, the TOPS™ System preserves normal biomechanical motion while providing spinal stabilization after decompression.

According to the applicant, the TOPS™ System received Breakthrough Device designation from FDA on October 26, 2020, for patients between 35 and 80 years of age suffering from neurogenic claudication resulting from degenerative spondylolisthesis up to Grade I with moderate to severe lumbar spinal stenosis and either the thickening of the ligamentum flavum or scaring facet joint capsule at one level from L2 to L5. The applicant indicated that it expects to receive FDA premarket approval of the TOPS™ System by Q2, 2022 for the same indication.

According to the applicant, ICD–10–PCS procedure code 0SH00DZ (Insertion of facet replacement spinal stabilization device into lumbar vertebral joint, open approach) may be used to identify the TOPS™ System, but the code does not uniquely identify the technology. The applicant submitted a request to the ICD–10 Coordination & Maintenance Committee for a new ICD–10–PCS code to uniquely identify the TOPS™ System.

With respect to the cost criterion, the applicant provided the following cost analysis. To identify cases representing patients who may be eligible for the TOPS™ System, the applicant searched the FY 2019 MedPAR dataset for cases reporting a combination of ICD–10–PCS procedure code 0SH00DZ (Insertion of facet replacement spinal stabilization device into lumbar vertebral joint, open approach) with a relevant diagnosis code. The applicant identified the following MS–DRG for the TOPS™ System: 518 (Back and Neck Procedures except Spinal Fusion with MCC or Disc Device or Neurostimulator).

The applicant identified 2,614 cases mapping to MS–DRG 518. The applicant then removed charges for prior technology. The applicant stated that in analyzing the MedPAR data, 100% of charges associated with Medical/Surgical Supplies and Devices (revenue centers 027x and 0624) were removed. The applicant explained that use of the TOPS™ System will replace a portion of devices included in these claims but will not replace all devices, nor any medical supplies required to perform the procedure. The applicant noted that an estimate of the percentage of total charges for devices that would be replaced could not be determined and therefore, to be as conservative as possible, the analysis removed 100% of these charges. The applicant then standardized the charges and applied the three-year inflation factor of 20.4% used to update the outlier threshold in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542), to update the charges from FY 2019 to FY 2022. The applicant then added charges for the new technology by dividing the per-patient anticipated hospital cost of the TOPS™ System by the national average cost-to-charge ratio for implantable devices (0.239) from the FY 2022 IPPS/LTCH PPS final rule. The applicant calculated a final inflated case-weighted average standardized charge per case of $152,935 and an average case-weighted threshold of $109,174. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that the TOPS™ System meets the cost criterion and therefore are proposing to approve the TOPS™ System for new technology add-on payments for FY 2023, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by July 1, 2022.

Based on preliminary information from the applicant at the time of this proposed rule, the per-patient anticipated hospital cost of the TOPS™ System is $15,000. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the TOPS System would be $9,750 for FY 2023 (that is, 65% of the average cost of the technology).

We are inviting public comments on whether the TOPS™ System meets the cost criterion and our proposal to approve new technology add-on payments for the TOPS™ System for FY 2023, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by July 1, 2022.

(11) VITARIA® System

LivaNova, PLC submitted an application for new technology add-on payments for the VITARIA® System for FY 2023. According to the applicant, the VITARIA® System is an active implantable neuromodulation system that uses vagus nerve stimulation to deliver autonomic regulation therapy. The applicant reported the VITARIA® System includes a pulse generator and an electrical lead, which are implanted under the skin, without requiring a vascular procedure. Per the applicant the electrical lead attaches the pulse generator to the 10th cranial nerve (vagus nerve). The applicant stated that after implantation is completed, a hand-held wand positioned on the skin over the implanted pulse generator and a computer tablet are used together externally to adjust the intensity of the electrical impulses delivered from the pulse generator through the electrical lead to stimulate the vagus nerve. Per the applicant, the VITARIA® System is intended for use in patients with moderate to severe heart failure (New York Heart Association classification of Class II or Class III) and left ventricular dysfunction (ejection fraction (EF) of 35% or less) who remain symptomatic despite receiving medical treatment in line with current treatment guidelines.

According to the applicant, the VITARIA® System received designation under the EAP (and is therefore considered part of the Breakthrough Devices Program by FDA[594]) on October 24, 2016, for patients who have moderate to severe heart failure (NYHA Class II/III), with left ventricular dysfunction (EF of 40% or less), who remain symptomatic despite stable, optimal heart failure drug therapy and are not candidates for cardiac resynchronization therapy (CRT). Per the applicant, FDA approved an amendment to its investigational device exemption (IDE) trial on November 16,

[594] *https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.*

2018, to include CRT or CRT–D recipients who have been receiving cardiac resynchronization therapy (CRT) according to guideline directed medical therapy (GDMT) and meet all of the other indications for use. According to the applicant, FDA premarket approval of the VITARIA® System is expected by June 30, 2022 for the proposed indication for the symptomatic improvement of heart failure patients who have reduced left ventricular ejection fraction and chronic heart failure despite guideline-directed medical treatment. We note that, as previously stated, under the eligibility criteria for approval under the alternative pathway for certain transformative devices, only the use of the technology for the indication that corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-on payment for FY 2023. The applicant stated that the indication for which they are seeking the new technology add-on payment is for patients who have moderate to severe heart failure (NYHA Class II/III), with left ventricular dysfunction, who remain symptomatic despite stable, optimal heart failure drug therapy and are not candidates for cardiac resynchronization therapy (CRT).

Per the applicant, ICD–10–PCS procedure codes that can currently be used to identify procedures involving the use of the VITARIA® System are not unique to the VITARIA® System and may also be used for other cranial nerve stimulators: 00HE0MZ (Insertion of neurostimulator lead into cranial nerve, open approach) and 0JH60BZ (Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, open approach). The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a code for FY 2023 to uniquely identify procedures involving the use of the VITARIA® System. Additionally, the applicant submitted a FY 2023 MS–DRG reclassification request, as discussed further in section II.D.3.b. of the preamble of this proposed rule.

The applicant also stated that the ICD–10–CM diagnosis codes in the following table identify the EAP designation.

ICD-10-CM	Description
I50.1	Left ventricular failure, unspecified
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.82	Biventricular heart failure
I50.89	Other heart failure
I50.9	Heart failure, unspecified

We note that the ICD–10–CM diagnosis codes listed by the applicant include those for diastolic heart failure, which is not part of the indication for which the applicant stated the device had received EAP designation. As such, we would appreciate additional information regarding the rationale for inclusion of codes I50.30 through I50.33. In addition, we believe that the following additional 13 ICD–10 CM diagnosis codes could also be used to identify the EAP designation for which the applicant is seeking the new technology add-on payment:

ICD-10-CM	Description
I09.81	Rheumatic heart failure
I11.0	Hypertensive heart disease with heart failure
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.814	Right heart failure due to left heart failure
I50.83	High output heart failure
I50.84	End stage heart failure

We invite public comment regarding the extent to which this is the most appropriate list of ICD–10 CM diagnosis codes and is reflective of the indication for which the applicant is seeking the new technology add-on payment.

With respect to the cost criterion, the applicant provided the following cost analysis. To identify potential cases where the VITARIA® System could be utilized, the applicant searched the FY 2019 MedPAR dataset for claims reporting the aforementioned ICD–10–PCS codes (00HE0MZ and 0JH60BZ). Using the FY 2022 MS–DRG Grouper (Version 39.0), the applicant identified three MS–DRGs to which the preceding ICD–10–PCS codes mapped and limited discharges to these MS–DRGs: 252 (Other Vascular Procedures with MCC, 253 (Other Vascular Procedures with CC, and 254 (Other Vascular Procedures without CC/MCC).

The applicant identified 66,438 cases mapping to the three MS–DRGs. The applicant then removed charges for medical/surgical supplies and devices at revenue centers 027x and 0624, since the applicant expects the VITARIA® System to replace all of the current device charges included in the claims. The applicant then standardized the charges and applied the three-year inflation factor of 20.4% used to update the outlier threshold in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45538), to update the charges from FY 2019 to FY 2022. The applicant did not add charges for the new technology because the applicant has not yet determined the average sales price for the device. According to the applicant, no other charges related to the new technology were included in the cost calculations, as the applicant assumes no other charges are required to implant the VITARIA® System. Under the analysis, the applicant calculated a final inflated case-weighted average standardized charge per case of $97,567 and an average case-weighted threshold of $93,472. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

With regard to the cost criterion for the VITARIA® System, we note that the applicant identified MS–DRGs which may represent a population broader than those cases which are eligible for treatment by the VITARIA® System, and we question whether this cost analysis is sufficiently representative of cases which would be eligible for treatment with the technology.

Subject to the applicant adequately addressing this concern, we would agree with the applicant that the VITARIA® System meets the cost criterion and therefore are proposing to approve the VITARIA® System for new technology add-on payments for FY 2023, subject to the technology receiving FDA marketing authorization by July 1, 2022 for patients who have moderate to severe heart failure (NYHA Class II/III), with left ventricular dysfunction (EF≤40%), who remain symptomatic despite stable, optimal heart failure drug therapy and are not candidates for cardiac resynchronization therapy (CRT).

Per the applicant, the anticipated cost for the VITARIA® System will be available once the device receives FDA approval. While the applicant has not stated which components of the system would comprise the cost, the applicant has stated that the system is used in conjunction with a computer tablet and hand-held wand that are used together externally, which appear to be capital expenses. We note that as discussed in prior rulemaking (86 FR 45134) and noted previously, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs. Because the applicant has not provided an estimate for the cost of the VITARIA® System at the time of this proposed rule, we expect the applicant to submit cost information prior to the final rule, and we will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. Any new technology add-on payment for the VITARIA® System would be subject to our policy under § 412.88(a)(2) where we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case.

We are inviting public comments on whether the VITARIA® System meets the cost criterion and our proposal to approve new technology add-on payments for the VITARIA® System for FY 2023, subject to the technology receiving FDA marketing authorization by July 1, 2022 for patients who have moderate to severe heart failure (NYHA Class II/III), with left ventricular dysfunction (EF≤40%), who remain symptomatic despite stable, optimal heart failure drug therapy and are not

candidates for cardiac resynchronization therapy (CRT).

(12) ViviStim® Paired VNS System

MicroTransponder, Inc. submitted an application for new technology add-on payments for the ViviStim® Paired VNS System for FY 2023. According to the applicant, the ViviStim® Paired VNS System is a paired vagus nerve stimulation therapy intended to stimulate the vagus nerve during rehabilitation therapy to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment. The applicant stated that the Vivistim® Paired VNS System is comprised of an Implantable Pulse Generator (IPG), an implantable stimulation Lead, and an external paired stimulation controller which is composed of the external Wireless Transmitter (WT) and the external Stroke Application and Programming Software (SAPS). According to the applicant, the external paired stimulation controller (SAPS and WT) enables the implanted components (the IPG and Lead) to stimulate the vagus nerve during rehabilitation. The applicant stated that patients undergo 25–30 hours of in-clinic rehabilitation over 6 weeks, where the ViviStim® Paired VNS System is actively paired with rehabilitation by a therapist. The applicant further stated that following this in-clinic rehabilitation period, when directed by a physician and with appropriate programming to the IPG, the patient can initiate at-home use by swiping a magnet over the IPG implant site which activates the IPG to deliver stimulation while rehabilitation movements are performed.

The applicant stated that the ViviStim® Paired VNS System was designated as a Breakthrough Device on February 10, 2021 for use in stimulating the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment. According to the applicant, the ViviStim® Paired VNS System received FDA premarket approval on August 27, 2021 as a Class III implantable device for the same indication. The applicant stated that the technology is not yet commercially available due to manufacturing delays.

According to the applicant, there are no unique ICD–10–PCS procedure codes to report the implantation of the device. The applicant noted that together the following two ICD–10–PCS codes describe the insertion of the ViviStim® Paired VNS System: 0JH60BZ (Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, open approach) and 00HE0MZ (Insertion of neurostimulator lead into cranial nerve, open approach). The applicant noted that these codes may be used for any cranial nerve stimulator insertion procedure, including VNS therapy for treatment resistant depression, VNS therapy for refractory epilepsy, and upper airway stimulation to treat obstructive sleep apnea. The applicant has submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a unique code for FY 2022 to identify insertion of the ViviStim® Paired VNS System.

The applicant also provided the ICD–10–CM diagnosis codes in the table below. The applicant stated that moderate to severe upper limb impairment is described in the ICD–10–CM as monoplegia (single limb) or hemiplegia (single laterality, including upper limb). The applicant stated that the FY 2021 ICD–10–CM code set [595] includes monoplegia and hemiplegia as a sequela of infarction (stroke), and delineates codes based upon stroke type (hemorrhagic versus ischemic). Therefore, the applicant states that the ICD–10–CM diagnosis codes in the table below describe chronic moderate to severe upper arm impairment as a sequela of ischemic stroke, and are related to the use of the ViviStim® Paired VNS System.

ICD-10-CM	Description
169.331	Monoplegia of upper limb following cerebral infarction affecting right dominant side
169.332	Monoplegia of upper limb following cerebral infarction affecting left dominant side
169.333	Monoplegia of upper limb following cerebral infarction affecting right non-dominant side
169.334	Monoplegia of upper limb following cerebral infarction affecting left non-dominant side
169.339	Monoplegia of upper limb following cerebral infarction affecting unspecified side
169.351	Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side
169.352	Hemiplegia and hemiparesis following cerebral infarction affecting left dominant side
169.353	Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side
169.354	Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side
169.359	Hemiplegia and hemiparesis following cerebral infarction affecting unspecified side

With respect to the cost criterion, the applicant presented the following analysis. The applicant searched the FY 2019 MedPAR claims data set released with the FY 2022 IPPS/LTCH PPS final rule for cases representing patients who may be eligible for the ViviStim® Paired VNS System. The applicant identified cases reporting the ICD–10–PCS codes 0JH60BZ and 00HE0MZ in combination with one of the ICD–10–CM diagnosis codes above describing moderate to severe upper limb impairment. The applicant then mapped the cases to the appropriate MS–DRGs using MS–DRG Grouper Version 39.0. After imputing a case count of 11 for those MS–DRGs with fewer than 11 cases, the applicant identified 285 claims mapping to 12 MS–DRGs, with 65% of cases mapping to MS–DRGs 024 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC), 041 (Peripheral Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator) and 042 (Peripheral Cranial Nerve and Other Nervous System Procedures without CC/MCC).

The applicant then removed 100% of charges associated with Medical/Surgical Supplies and Devices (prior technology, revenue centers 027X, and

[595] *https://www.cms.gov/medicare/icd-10/2021-icd-10-cm*, effective October 1, 2020 through September 30, 2021.

0624). The applicant asserted that the use of the Vivistim® Paired VNS System is expected to replace the majority of existing technologies, although some devices will still be required to perform the procedure. The applicant stated that because it could not determine the estimated percentage of the total charges that would be replaced, it removed 100% of these total charges to be as conservative as possible. The applicant did not remove charges related to the technology being replaced, stating that the financial impact of utilizing the Vivistim® Paired VNS System on hospital resources compared to prior technologies other than on Medical Supplies is minimal, and that 100% of charges for Medical/Surgical Supplies had been removed in the previous step.

The applicant standardized the charges by applying the three-year inflation factor of 1.20469 used in the FY 2022 IPPS/LTCH PPS final rule and correction notice to calculate outlier threshold charges (86 FR 45542). The applicant then added charges for the new technology by dividing the cost of the ViviStim® Paired VNS System by the national average CCR for implantable devices which is 0.293 as published in the FY 2022 IPPS/LTCH IPPS final rule (86 FR 44966). The applicant calculated a final inflated average case-weighted standardized charge per case of $200,398 which exceeded the average case-weighted threshold amount of $107,963. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that the ViviStim® Paired VNS System meets the cost criterion.

We agree with the applicant that the ViviStim® Paired VNS System meets the cost criterion and are therefore proposing to approve the ViviStim® Paired VNS System for new technology add-on payments for FY 2023.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the ViviStim® Paired VNS System to the hospital to be $36,000 per patient. According to the applicant, this cost represents the entire per-patient cost of the system to hospital providers—specifically for the cost of the Implantable Pulse Generator and stimulation lead. Per the applicant, there is no charge associated with the external paired stimulation controller and the magnet/take-home patient programmer. The applicant stated that the external paired stimulation controller may be used on multiple patients and that it retains a service agreement with each provider to own, maintain, and update the hardware and software that resides on that device component. The applicant has also stated that they have this service agreement with providers for the magnet/take-home patient programmer. Therefore, as the applicant has stated they retain and maintain the reusable hardware components at no charge to the providers, it appears that capital components are not included in the cost of the technology. We welcome public comment on the cost information provided by the applicant for the purpose of calculating the new technology add-on payment amount.

We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the ViviStim® Paired VNS System would be $23,400 for FY 2023 (that is, 65% of the average cost of the technology).

We invite public comments on whether the ViviStim® Paired VNS System meets the cost criterion and our proposal to approve new technology add-on payments for the ViviStim® Paired VNS System for FY 2023 for use in stimulating the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment.

b. Alternative Pathways for Qualified Infectious Disease Products (QIDPs)

(1) DefenCath™ (Solution of Taurolidine (13.5 mg/mL) and Heparin (1000 USP Units/mL))

CorMedix Inc. submitted an application for new technology add-on payments for DefenCath™ (solution of taurolidine (13.5 mg/mL) and heparin (1000 USP Units/mL)) for FY 2023. The applicant stated that DefenCath™ is a proprietary formulation of taurolidine, a thiadiazinane antimicrobial, and heparin, an anti-coagulant, that is under development for use as catheter lock solution, with the aim of reducing the risk of catheter-related bloodstream infections (CRBI) from in-dwelling catheters in patients undergoing hemodialysis (HD) through a central venous catheter (CVC). According to the applicant, *in vitro* studies of DefenCath™ indicate broad antimicrobial activity against gram-positive and gram-negative bacteria, including antibiotic resistant strains as well as mycobacteria and clinically relevant fungi. The applicant stated that DefenCath™ is available in a single-dose vial, which is sufficient to fill both lumens of the HD catheter, and is instilled into the catheter lumen as a lock solution at the conclusion of each dialysis session and aspirated at the beginning of the next dialysis session. The applicant noted that DefenCath™ cannot be flushed or injected into the patient and that dosing is calibrated to the volume of the catheter lumens.

Per the applicant, DefenCath™ was designated by FDA as a Qualified Infectious Disease Product (QIDP) in 2015 for the prevention of CRBSI in patients with end-stage renal disease (ESRD) receiving HD through a central venous catheter, and has been granted FDA Fast Track status. The applicant indicated that it is pursuing an NDA under FDA's LPAD for the same indication, which the applicant also stated received Priority Review. The applicant noted that FDA issued a Complete Response Letter in 2021 denying the NDA due to concerns with the third-party manufacturing facility. The applicant stated that the NDA has been resubmitted and anticipates approval before July 1, 2022. We note that, as an application submitted under the alternative pathway for certain antimicrobial products at § 412.87(d), DefenCath™ is eligible for conditional approval for new technology add-on payments if it does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments (that is, July 1, 2023).

According to the applicant, there are no ICD–10–PCS codes that specifically identify catheter lock solutions. The applicant submitted a request for approval of a unique ICD–10–PCS procedure code to identify use of Defencath™ beginning FY 2023.

With regard to the cost criterion, the applicant provided two analyses to demonstrate that DefenCath™ meets the cost criterion. The applicant first searched the FY 2019 MedPAR file released with the FY 2022 IPPS final rule for claims based on the presence of one of the following ICD–10–CM diagnosis codes used to identify ESRD, chronic kidney disease (CKD), acute kidney injury (AKI) or acute tubular necrosis (ATN).

ICD-10-CM	Description
N17.0	Acute kidney failure with tubular necrosis
N17.9	Acute kidney failure, unspecified
N18.1	Chronic kidney disease, stage 1
N18.2	Chronic kidney disease, stage 2 (mild)
N18.30	Chronic kidney disease, stage 3 unspecified
N18.31	Chronic kidney disease, stage 3a
N18.32	Chronic kidney disease, stage 3b
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5
N18.6	End stage renal disease
N18.9	Chronic kidney disease, unspecified

Per the applicant, DefenCath™ will be used for patients receiving HD through a CVC. The applicant stated that coding to identify this population is difficult because the available CVC codes only describe the insertion of a CVC. The applicant asserted that it is not possible to identify in the MedPAR file those patients who had previously received a CVC and are now hospitalized and receiving HD. Therefore, the applicant developed two sets of selection criteria: Claims with codes for HD (Analysis A) and claims with codes for both HD and CVC (Analysis B). The applicant asserted that Analysis A overstates the population of patients eligible for DefenCath™ because it includes any patient receiving HD, regardless of whether a central venous catheter is used. The applicant also asserted that Analysis B undercounts the potential cases because CVC codes are not always available on inpatient claims.

In the first analysis (Analysis A), which included only claims with codes for chronic HD, the applicant searched for claims based on the presence of one of the ICD–10–CM diagnosis codes listed above and then limited the selection criteria to claims including ICD–10–CM diagnosis code Z49.31 (encounter for adequacy testing for HD) or one of the following ICD–10–PCS procedure codes for HD:

ICD-10-PCS	Description
5A1D00Z	Performance of urinary filtration, single
5A1D60Z	Performance of urinary filtration, multiple
5A1D70Z	Performance of urinary filtration, intermittent, less than 6 hours per day
5A1D80Z	Performance of urinary filtration, prolonged intermittent, 6 - 18 hours per day
5A1D90Z	Performance of urinary filtration, continuous, greater than 18 hours per day

After imputing a case count of 11 to any MS–DRG with fewer than 11 cases in the FY 2019 MedPAR file released with the FY 2022 IPPS final rule, the applicant identified a total of 490,790 cases mapping to 512 MS–DRGs. The table below shows the top 20 MS–DRGs, which account for 57% of all cases included in Analysis A.

MS-DRG	Description
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC
291	Heart Failure and Shock with MCC
640	Miscellaneous Disorders of Nutrition, Metabolism, Fluids and Electrolytes with MCC
252	Other Vascular Procedures with MCC
314	Other Circulatory System Diagnoses with MCC
682	Renal Failure with MCC
193	Simple Pneumonia and Pleurisy with MCC
377	Gastrointestinal Hemorrhage with MCC
853	Infectious and Parasitic Diseases with O.R. Procedures with MCC
280	Acute Myocardial Infarction, Discharged Alive with MCC
673	Other Kidney and Urinary Tract Procedures with MCC
189	Pulmonary Edema and Respiratory Failure
391	Esophagitis, Gastroenteritis and Miscellaneous Digestive Disorders with MCC
304	Hypertension with MCC
246	Percutaneous Cardiovascular Procedures with Drug-eluting Stent with MCC or 4+ Arteries or Stents
981	Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC
308	Cardiac Arrhythmia and Conduction Disorders with MCC
286	Circulatory Disorders Except AMI, with Cardiac Catheterization with MCC
870	Septicemia or Severe Sepsis with MV >96 Hours
637	Diabetes with MCC

For Analysis B, the applicant used the same case selection criteria as Analysis A (the presence of an ICD–10- procedure or diagnosis code for HD only) but further limited cases to those that include one of the following ICD–10 procedure codes for the insertion of a CVC.

ICD-10-PCS	Description
03130ZD	Bypass right subclavian artery to upper arm vein, open approach
0JH60WZ	Insertion of totally implantable vascular access device into chest subcutaneous tissue and fascia, open approach
0JH60XZ	Insertion of tunneled vascular access device into chest subcutaneous tissue and fascia, open approach
0JH63WZ	Insertion of totally implantable vascular access device into chest subcutaneous tissue and fascia, percutaneous approach
0JH63XZ	Insertion of tunneled vascular access device into chest subcutaneous tissue and fascia, percutaneous approach
0JHD0WZ	Insertion of totally implantable vascular access device into right upper arm subcutaneous tissue and fascia, open approach
0JHD0XZ	Insertion of tunneled vascular access device into right upper arm subcutaneous tissue and fascia, open approach
0JHD3WZ	Insertion of totally implantable vascular access device into right upper arm subcutaneous tissue and fascia, percutaneous approach
0JHD3XZ	Insertion of tunneled vascular access device into right upper arm subcutaneous tissue and fascia, percutaneous approach
0JHF0WZ	Insertion of totally implantable vascular access device into left upper arm subcutaneous tissue and fascia, open approach
0JHF0XZ	Insertion of tunneled vascular access device into left upper arm subcutaneous tissue and fascia, open approach
0JHF3WZ	Insertion of totally implantable vascular access device into left upper arm subcutaneous tissue and fascia, percutaneous approach
0JHF3XZ	Insertion of tunneled vascular access device into left upper arm subcutaneous tissue and fascia, percutaneous approach
0JHL0WZ	Insertion of totally implantable vascular access device into right upper leg subcutaneous tissue and fascia, open approach
0JHL0XZ	Insertion of tunneled vascular access device into right upper leg subcutaneous tissue and fascia, open approach
0JHL3WZ	Insertion of totally implantable vascular access device into right upper leg subcutaneous tissue and fascia, percutaneous approach
0JHL3XZ	Insertion of tunneled vascular access device into right upper leg subcutaneous tissue and fascia, percutaneous approach
0JHM0WZ	Insertion of totally implantable vascular access device into left upper leg subcutaneous tissue and fascia, open approach
0JHM0XZ	Insertion of tunneled vascular access device into left upper leg subcutaneous tissue and fascia, open approach
0JHM3WZ	Insertion of totally implantable vascular access device into left upper leg subcutaneous tissue and fascia, percutaneous approach
0JHM3XZ	Insertion of tunneled vascular access device into left upper leg subcutaneous tissue and fascia, percutaneous approach

The applicant asserted that the patient population in Analysis B (HD and central venous catheter) is more likely to receive DefenCath™ during an inpatient stay. After imputing a case count of 11 to any MS–DRG with fewer than 11 cases, the applicant identified a total of 60,679 cases mapping to 408 MS–DRGs. The table below shows the top 20 MS–DRGs by case count, which account for 72% of all cases included in Analysis B.

MS-DRG	Description
673	Other Kidney and Urinary Tract Procedures with MCC
314	Other Circulatory System Diagnoses with MCC
871	Septicemia or Severe Sepsis Without MV >96 Hours with MCC
291	Heart Failure and Shock with MCC
252	Other Vascular Procedures with MCC
674	Other Kidney and Urinary Tract Procedures with CC
853	Infectious and Parasitic Diseases with O.R. Procedures with MCC
870	Septicemia or Severe Sepsis with MV >96 Hours
981	Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC
264	Other Circulatory System O.R. Procedures
907	Other O.R. Procedures for Injuries with MCC
280	Acute Myocardial Infarction, Discharged Alive with MCC
286	Circulatory Disorders Except Ami, with Cardiac Catheterization with MCC
640	Miscellaneous Disorders of Nutrition, Metabolism, Fluids and Electrolytes with MCC
003	Ecmo or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures
004	Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck without Major O.R. Procedures
246	Percutaneous Cardiovascular Procedures with Drug-eluting Stent with MCC or 4+ Arteries or Stents
270	Other Major Cardiovascular Procedures with MCC
208	Respiratory System Diagnosis with Ventilator Support <=96 Hours
377	Gastrointestinal Hemorrhage with MCC

In both analyses, the applicant did not remove charges for prior technology because DefenCath™ would not replace other therapies a patient may receive during an inpatient stay. The applicant standardized the charges using the FY 2022 IPPS final rule impact file and applied a 4-year inflation factor of 1.281834 to update the charges from FY 2019 to FY 2023 based on the inflation factor used to update the outlier threshold in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542). The applicant did not add charges for new technology as the cost of DefenCath™ has not yet been determined but believes that the technology meets the cost criterion without the additional charges.

The applicant calculated a final inflated case-weighted average standardized charge per case of $116,221 for Analysis A and a final inflated case-weighted average standardized charge per case of $203,746 for Analysis B. The applicant also determined an average case weighted threshold amount of $77,290 in Scenario A and $96,645 in Scenario B. Because the final inflated case-weighted average standardized charge per case for each scenario exceeded the average case-weighted threshold amount for both scenarios, the applicant asserted that DefenCath™ meets the cost criterion.

We agree that the technology meets the cost criterion and are therefore proposing to approve DefenCath™ for new technology add on payments for FY 2023, subject to the technology receiving FDA approval for the prevention of CRBSI in patients with ESRD receiving HD through a central venous catheter by July 1, 2022.

The applicant has not provided an estimate for the cost of DefenCath™ at the time of this proposed rule. We expect the applicant to submit cost information prior to the final rule, and we will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. Any new technology add-on payment for DefenCath™ would be subject to our policy under § 412.88(a)(2) where we limit new technology add-on payments for QIDPs to the lesser of 75% of the average cost of the technology, or 75% of the costs in excess of the MS–DRG payment for the case.

We are inviting comments on whether DefenCath™ meets the cost criterion and our proposal to approve DefenCath™ for new technology add-on payments for FY 2023, subject to the technology receiving marketing authorization consistent with its QIDP designation by July 1, 2022.

8. Proposed Use of National Drug Codes (NDCs) To Identify Cases Involving Use of Therapeutic Agents Approved for New Technology Add-On Payment

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49434 through 49435), as a part of the transition to the ICD–10–CM diagnosis and ICD–10–PCS procedure coding system from the ICD–9–CM coding system, CMS established the use of Section ''X'' New Technology codes within the ICD–10–PCS classification to more specifically identify new technologies or procedures that have historically not been captured through ICD–9–CM codes, or to more precisely describe information on a specific procedure or technology than is found with the other sections of ICD–10–PCS. However, CMS has continued to receive comments from stakeholders, including representatives from hospital associations, software vendors, professional societies, and coding professionals, opposing the continued creation of new ICD–10–PCS (for example, Section X) procedure codes for the purpose of administering the new technology add-on payment for drugs and biologics. Specifically, public comments from the ICD–10 Coordination and Maintenance Committee Meetings have stated that the ICD–10–PCS classification system was not intended to represent unique drugs/therapeutic agents and is not an appropriate code set for this purpose. Commenters explained that, since the implementation of ICD–10, Section X codes have been established for procedures describing the administration of a drug/therapeutic agent, which historically were not typically coded in the inpatient hospital setting. Commenters stated their belief

that it was not logical nor should it be expected for hospital coding professionals to seek codes for the administration of drugs within the ICD–10–PCS classification system. In addition, we note that over the past three years, the number of applications for new technology add-on payments has continued to increase, which has subsequently resulted in an increasing number of requests for unique ICD–10–PCS (for example, Section X) procedure codes specifically for the purposes of administering the new technology add-on payments.

The current process of requesting, proposing, finalizing and assigning new ICD–10–PCS procedure codes to identify and describe the administration of drugs involves several steps, as described further in this section, and frequently results in a number of procedure codes that are created unnecessarily when the drug/therapeutic agents do not receive approval for the new technology add-on payments, as the administration of drugs/therapeutic agents is not typically coded in the inpatient hospital setting. Applicants seeking a unique ICD–10–PCS (for example, Section X) procedure code to identify the use of their technology for purposes of new technology add-on payments must complete the code request process prior to learning the outcome of their new technology add-on payment application. This process involves a number of steps, including: Gathering relevant information and submitting the ICD–10–PCS code request; developing a slide deck for the ICD–10 Coordination and Maintenance Committee Meeting; and reviewing the background paper draft for the ICD–10 Coordination and Maintenance Committee Meeting agenda and meeting materials. CMS also expends significant time, effort, and resources to administer this process, which is compounded by the increasing number of requests for unique ICD–10–PCS (for example, Section X) procedure codes. CMS must work with applicants to review, prepare, and present the code proposals at ICD–10 Coordination and Maintenance Committee Meetings, then review and summarize public comments received in response to the meetings, and ultimately make a decision on the codes requested for new technology add-on payment policy purposes before the outcome of the new technology add-on payment application (approval or denial) is known. Following the end of the three-year timeframe for which a code was created in connection with a new technology add-on payment application, the disposition of the Section X code is addressed at a later ICD–10 Coordination and Maintenance Committee meeting and CMS subsequently receives public comments that must be reviewed regarding this disposition.

Stakeholders submitted comments that suggested alternative options to the use of Section X procedure codes to identify therapeutic agents for the administration of the new technology add-on payment policy. The majority of commenters supported using National Drug Codes (NDCs), because it would avoid creating duplicate codes within the ICD–10–PCS and NDC code sets to identify the same technology/product, which would allow for predictive and efficient coding. Commenters also stated that using NDCs would generate product data on inpatient claims that would allow for outcomes analyses, thus providing the same benefit as a unique ICD–10–PCS code. Some commenters suggested using the 3E0 Administration Table within the ICD–10–PCS code set, as opposed to Section X, as they stated this would be a more intuitive location for coders to look for ICD–10–PCS procedure codes describing the administration of therapeutic agents. However, a commenter noted that this would be unsustainable due to the potentially large number of new products coming to market. A few commenters also suggested using different drug terminologies, such as RxNorm, in lieu of using Section X codes for the time period needed to administer the new technology add-on payment.

We also note that we have previously established the use of NDCs as an alternative code set for the purposes of administering the new technology add-on payment in circumstances where an ICD–10–PCS code was not available to uniquely identify the use of the technology. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53351 through 53354), we established the use of the NDC code set to identify oral medications where no inpatient procedure was associated, to report the oral administration of the drug DIFICID™. We finalized that the NDC for DIFICID™ would be used in conjunction with an ICD–9–CM diagnosis code to uniquely identify the indication for which administration of the drug (technology) was performed for new technology add-on payment purposes. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41311), we stated that we believed that the circumstances with respect to the identification of eligible cases reporting the use of VABOMERE™, which was administered by IV infusion, were similar to those addressed in the FY 2013 IPPS/LTCH PPS final rule with regard to DIFICID™ because we also did not have current ICD–10–PCS code(s) to uniquely identify the use of VABOMERE™ to make the new technology add-on payments. Therefore, consistent with our approach in FY 2013, we stated that we would identify cases involving the use of VABOMERE™ that were eligible for FY 2019 new technology add-on payments using its NDCs 65293–0009–01 or 70842–0120–01 [596] (VABOMERE™ Meropenem-Vaborbactam Vial). At the time of its new technology add-on payment application approval, VABOMERE™ was not assigned a corresponding ICD–10–PCS procedure or ICD–10–CM diagnosis code along with its NDCs. In addition, cases involving the use of two therapeutic agents that qualify for NCTAP, which is administered similarly to the new technology add-on payment, are identified using the NDCs for these products for the purposes of the NCTAP, because there are not currently ICD–10–PCS procedure codes that uniquely describe the administration of these therapies.[597]

We believe that our previous policies regarding the use of NDCs to identify the administration of certain therapeutic agents can be consistently applied toward broader future usage of the NDCs to identify therapeutic agents eligible for the new technology add-on payment. Additionally, we believe that the use of an existing code set to identify therapeutic agents eligible for the new technology add-on payment would address concerns raised by commenters regarding the use of the ICD–10–PCS classification system to identify these agents, and reduce the need for applicants to seek a unique ICD–10–PCS code through the ICD–10–PCS Section X code request process in advance of a determination on their new technology add-on payment applications. Therefore, as we discuss further in this section, we are proposing for FY 2024 to instead use NDCs to identify cases involving the use of therapeutic agents approved for the new technology add-on payment. We anticipate that this proposal would reduce work for hospital coding professionals in becoming familiar with newly created ICD–10–PCS Section X codes to describe the administration of

[596] We note that these are not the FDA assigned NDCs, but rather have been converted from 10-digit NDCs assigned by FDA to the HIPAA compliant 11-digit format.

[597] New COVID–19 Treatments Add-On Payment (NCTAP) *https://www.cms.gov/medicare/covid-19/new-covid-19-treatments-add-payment-nctap.*

therapeutic agents and in searching for these codes within the documentation and within the classification in what may be non-intuitive locations. We also expect this proposed change would address concerns regarding the creation of duplicative codes within the ICD–10–PCS procedure coding system to describe the administration of therapeutic agents, which would also reduce the need for vendors to incorporate additional procedure codes into their coding products; for educators to provide training on these codes; and for programmers to maintain codes that may be seldom reported on inpatient claims but for the purposes of the new technology add-on payment, in their databases. It would also reduce efforts associated with determining the disposition of procedure codes describing therapeutic agents that have reached the end of their three-year new technology add-on payment timeframe.

Furthermore, we believe that NDCs are a viable alternative to Section X codes for the administration of the new technology add-on payment for therapeutic agents. We believe inpatient hospital staff are familiar with using NDCs, and as stated earlier, we have also previously utilized NDCs to administer the new technology add-on payment. However, to allow for adequate time to implement this regular usage of NDCs with the new technology add-on payment for health care providers and hospital coding professionals, we are proposing a transitional period for FY 2023. During this transitional period, we would utilize NDCs to identify the administration of therapeutic agents for new technology add-on payment purposes. However, we would also utilize ICD–10–PCS Section X codes, including codes newly created for FY 2023, for therapeutic agents during the FY 2023 new technology add-on payment application cycle. Beginning with the FY 2024 new technology add-on payment application cycle, we would utilize only NDCs to identify claims involving the administration of therapeutic agents approved for the new technology add-on payment, with the exception of claims involving therapeutic agents that are not assigned an NDC by FDA (for example, blood, blood products, etc.) and are approved for the new technology add-on payment. Cases involving the use of these technologies approved for the new technology add-on payment would continue to be identified based on the assigned ICD–10–PCS procedure code. A unique ICD–10–PCS procedure code would also still be needed to identify cases involving the use of CAR T-cell and other immunotherapies that may be assigned to Pre-MDC MS–DRG 018, because the ICD–10 MS–DRG GROUPER logic for assignment to Pre-MDC MS–DRG 018 is comprised of the procedure codes describing these CAR T-cell and other immunotherapy products. Therefore, under this proposal, beginning with FY 2024 new technology add-on payment applications submitted for a therapeutic agent, CMS would review the information and inform the applicant, in advance of the deadline for submitting an ICD–10–PCS procedure code request to the ICD–10 Coordination and Maintenance Committee for consideration at the March meeting, if it would be necessary to submit such a code request for purposes of identifying cases involving the use of the therapeutic agent for the new technology add-on payment, if approved, or if, based on the information made available with the application, the NDC could be used to identify such cases, and therefore, the applicant would not need to submit an ICD–10–PCS procedure code request. For each applicable technology that may be approved for new technology add-on payment, we would indicate the NDC(s) to use to identify cases involving the administration of the therapeutic agent for purposes of the new technology add-on payment.

Specifically, we are proposing that, during the transitional period beginning with discharges on or after October 1, 2022 (FY 2023), the administration of therapeutic agents newly approved for new technology add-on payments would be uniquely identified using either their respective NDC(s) or ICD–10–PCS procedure code(s), in combination with ICD–10–CM codes when appropriate. As stated in our FY 2013 IPPS/LTCH PPS final rule, the use of the NDCs ''does not preclude CMS from using additional ICD–9–CM procedure or diagnosis codes to identify cases for this new technology in conjunction with this alternative code set'' (77 FR 53352). Therefore, when necessary, we may require the use of additional ICD–10–PCS procedure and/or ICD–10–CM diagnosis codes to uniquely identify cases using these technologies. We would continue the use of the existing ICD–10–PCS procedure codes to identify the administration of therapeutic agents previously approved for the new technology add-on payment and that remain eligible for the new technology add-on payment for FY 2023.

We are further proposing that, beginning with discharges on or after October 1, 2023 (FY 2024), the administration of therapeutic agents newly approved for the new technology add-on payments beginning FY 2024 or a subsequent fiscal year would be uniquely identified only by their respective NDC(s), along with the corresponding existing ICD–10 code(s) required to uniquely identify the therapeutic agents, when necessary, to make the new technology add-on payments. For technologies that were newly approved for new technology add-on payments for FY 2023 (beginning with discharges on or after October 1, 2022) and remain eligible for the new technology add-on payment for FY 2024 or a subsequent fiscal year, we would continue to allow the use of either the existing ICD–10–PCS procedure codes or NDCs to identify the administration of those therapeutic agents. For technologies that were newly approved for new technology add-on payments prior to FY 2023 and remain eligible for the new technology add-on payment for FY 2024 or a subsequent fiscal year, we would continue to use the existing ICD–10–PCS procedure codes to identify the administration of those therapeutic agents.

We are inviting public comments on our proposal to utilize NDCs to identify claims involving the use of therapeutic agents approved for new technology add-on payments, including any potential concerns regarding adoption of this code set for the identification of therapeutic agents for purposes of new technology add-on payments.

9. Proposal to Publicly Post New Technology Add-On Payment Applications

As noted in section II.F.1.f. of the preamble of this proposed rule, applicants for new technology add-on payments for new medical services or technologies must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement (unless the application is under one of the alternative pathways), along with a significant sample of data to demonstrate the new medical service or technology meets the high-cost threshold (OMB–0938–1347). See section II.F.1.f. of the preamble of this proposed rule for further details on the data and evidence that can be submitted. We post complete application information and final deadlines for submitting a full application on the CMS website at

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech. We also post on the same website tracking forms completed by each applicant, which include the name of each applicant, name of the technology, and a brief description so that interested parties can identify the new medical services or technologies under review before the annual proposed rule. Additionally, section 1886(d)(5)(K)(viii) of the Act provides for a mechanism for public input before the publication of a proposed rule regarding whether a medical service or technology represents a substantial clinical improvement. Consistent with the Act, we hold an annual Town Hall meeting, typically in December following notice of the meeting in the **Federal Register**.

As set forth in 42 CFR 412.87(e)(1), CMS considers whether a technology meets the criteria for the new technology add-on payment and announces the results as part of its annual updates and changes to the IPPS. Accordingly, in drafting the proposed rule, CMS reviews each new technology add-on payment application it receives under the pathway specified by the applicant at the time of application submission, along with supplemental information [598] obtained from the applicant, information provided at the Town Hall meeting, and comments received in response to the Town Hall meeting. In the proposed rule, CMS summarizes the information contained in the application, including the applicant's explanation of what the technology does, background on the disease process, information about the FDA approval/clearance, and the applicant's assertions and supporting data on how the technology meets the new technology add-on payment criteria under § 412.87. In summarizing this information for inclusion in the proposed rule, CMS restates or paraphrases information contained in the application and attempts to avoid misrepresenting or omitting any of an applicant's claims. CMS also tries to ensure that sufficient information is provided in the proposed rule to facilitate public comments on whether the medical service or technology meets the new technology add-on payment criteria. Currently, however, CMS does not make the applications themselves, as completed by the applicants, publicly available. In addition, CMS generally does not take into consideration information that is marked as confidential when determining whether a technology meets the criteria for new technology add-on payments.

We note that in the past, CMS has received requests from the public to access and review the new technology add-on payment applications to further facilitate comment on whether a technology meets the new technology add-on payment criteria. In consideration of this issue, we agree that review of the original source information from the applications for new technology add-on payments may help to inform public comment. Further, making this information publicly available may foster greater input from experts in the stakeholder community based on their review of the completed application forms and related materials. Accordingly, as we discuss further in this section, we believe that providing additional information to the public by publicly posting the applications and certain related materials online may help to further engage the public and foster greater input and insights on the various new medical services and technologies presented annually for consideration for new technology add-on payments.

We also believe that posting the applications online would reduce the risk that we may inadvertently omit or misrepresent relevant information submitted by applicants, or are perceived as misrepresenting such information, in our summaries in the rules. It also would streamline our evaluation process, including the identification of critical questions in the proposed rule, particularly as the number and complexity of the applications have been increasing over time. That is, by making the applications available to the public online, we would afford more time for CMS to process and analyze the supporting data and evidence rather than reiterate parts of the application in the rule.

Therefore, to increase transparency, enable increased stakeholder engagement, and further improve and streamline our evaluation process, we are proposing to publicly post online future applications for new technology add-on payments. Specifically, beginning with the FY 2024 application cycle, we propose to post online the completed application forms and certain related materials (for example, attachments, uploaded supportive materials) that we receive from applicants. Additionally, we propose to post information acquired subsequent to the application submission (for example, comments received after the New Technology Town Hall, updated application information, additional clinical studies, etc.). We propose that we would not post the cost and volume information the applicant provides in the application form itself or as attached materials, or any material included with the application that the applicant indicates is not releasable to the public because the applicant does not own the copyright or the applicant does not have the appropriate license to make the material available to the public, as further described in the next paragraph. We propose that we would publicly post the completed application forms and related materials no later than the issuance of the proposed rule, which would afford the public the full public comment period to review the information provided by the applicant in its application.

With respect to copyrighted materials, we propose that on the application form itself, the applicant would be asked to provide a representation that the applicant owns the copyright or otherwise has the appropriate license to make all the copyrighted material included with its application public with the exception of those materials identified by the applicant as not releasable to the public, as applicable. For any material included with the application that the applicant indicates as copyrighted and/or not otherwise releasable to the public, we propose that the applicant must either provide a link to where the material can be accessed or provide an abstract or summary of the material that CMS can make public, and CMS will then post that link or abstract or summary online, along with the other posted application materials. We invite comments on this proposal.

Under our current practice, we include in the final rule information on the cost of each technology that is approved for the new technology add-on payment for the purposes of calculating the maximum add-on payment, and information on the anticipated volume of the technology for purposes of the impact analysis. For the proposed rule, specifically for applications submitted under the alternative pathway, our current practice is to propose whether or not to approve the application based on the eligibility criteria for the alternative pathway under 42 CFR 412.87(c) or (d) and, where cost information is available from the applicant, to use this information in proposing a maximum add-on payment amount. Where cost information is not yet available, we note our expectation is that the applicant will submit cost information prior to the final rule, and indicate that we will provide an update

[598] For the FY 2023 new technology add-on payment applications, the supplemental information deadline to guarantee inclusion in the IPPS proposed rule was December 17, 2021.

regarding the new technology add-on payment amount for the technology, if approved, in the final rule. We note that we would continue this same approach with respect to including cost and volume information in the proposed and final rules. However, as noted, under our proposal to post online the new technology add-on payment applications, we would not include cost and volume information for either traditional or alternative pathway applications as part of the application materials that would be posted online.

We note that at times an applicant may furnish information marked as proprietary or trade secret information along with its application for new technology add-on payments. Currently, the application specifies that data provided in the application or tracking form may be subject to disclosure and instructs the applicant to mark any proprietary or trade secret information so that CMS can attempt, to the extent allowed under Federal law, to keep the information protected from public view.[599] This instruction would change under our proposal such that information included in the application, other than cost and volume information, would be made publicly available online through posting of the application. Therefore, the applicant should not submit as part of its application any such proprietary or trade secret information that it does not want to be made publicly available online. As noted, under our existing practice we generally do not consider information that is marked as confidential, proprietary, or trade secret when determining whether a technology meets the criteria for new technology add-on payments.

This proposal would not change the current timeline or evaluation process for new technology add-on payments, the criteria used to assess applications, or the deadlines for various data submissions. Additionally, we do not expect added burdens on prospective applicants as a result of this proposal since we are not proposing to fundamentally change the information collected in the application itself or the supplemental information that would be furnished to support the application. As noted, the aim of this proposed policy change is to increase accuracy, transparency, and efficiency for both CMS and stakeholders.

In connection with this proposal to post the new technology applications online, we expect we would also make changes to the summaries that appear in the annual proposed and final rules, given that the public would have access to the submitted applications themselves (excluding certain information and materials as described previously), while also continuing to provide sufficient information in the rules to facilitate public comments on whether a medical service or technology meets the new technology add-on payment criteria. Specifically, we do not anticipate summarizing each entire application in the **Federal Register** as we have in the past, given the expanded and public access to the applications under the proposal. In some instances, such as the discussion of the substantial clinical improvement criterion, we expect to provide a more concise summary of the evidence or a more targeted discussion of the applicant's claims about how that criterion is met based on the evidence and supporting data (although this may vary depending on the application, new medical service or technology, and the nature of supporting materials provided). We expect that we would continue to generally include, at a high-level, the following information in the proposed and final rules: The technology and applicant name; a description of what the technology does; background on the disease process; the FDA approval/clearance status; and a summary of the applicant's assertions. We also expect to provide more succinct information as part of the summaries in the proposed and final rules regarding the applicant's assertions as to how the medical service or technology meets the newness, cost, and substantial clinical improvement criteria. For example, we would provide a list of the applicant's assertions for whether the technology meets the three sub-criteria under the substantial clinical improvement criterion[600] and a list of the sources of data submitted in support of the assertions, along with references to the application in support of these lists. In the proposed rule, we would also continue to provide discussion of the concerns or issues we identified with respect to applications submitted under the traditional pathway, and for an alternative pathway application, we intend to continue to propose whether to approve or disapprove the application, including noting any concerns we have identified, and, as applicable, the maximum add-on payment amount, where cost information is available. In the final rule, we would continue to provide an explanation of our determination of whether a medical service or technology meets the applicable new technology add-on payment criteria and, for approved technologies, the final add-on payment amounts. As noted, we believe the proposal to post online the completed application forms and other information described previously would afford greater transparency during the annual rulemaking, for purposes of determining whether a medical service or technology is eligible for new technology add-on payments.

We are seeking public comment on our proposal to publicly post online the completed application forms and certain related materials and updated application information submitted subsequent to the initial application submission for new technology add-on payments, beginning with applications for FY 2024.

III. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the proposed FY 2023 hospital wage index based on the statistical areas appears under section III.A.2. of the preamble of this proposed rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. (CMS collects these data on the Medicare cost report, CMS Form 2552–10, Worksheet S–3, Parts II, III, IV. The OMB control number for this information collection request is 0938–0050, which expired on March 31, 2022. A reinstatement of the information collection request is currently being developed. The public will have an opportunity to review and submit

[599] See new technology add-on payment application included in the FY 2023 New Technology Application Packet, available at: *https://www.cms.gov/files/zip/fy-2023-new-technology-application-packet.zip*; and FY 2023 Tracking Forms, available at: *https://www.cms.gov/files/document/fy-2023-tracking-forms-applicants.pdf*.

[600] Sub-criteria referenced are those listed in Question 36 of the new technology add-on payment application, specifically Questions 36a–36c.

comments on the reinstatement through a public notice and comment period separate from this rulemaking. This provision also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The proposed adjustment for FY 2023 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed in section III.I. of the preamble of this proposed rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2023 is discussed in section II.A.4.b. of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. (The OMB control number for approved collection of this information is 0938–0907, which expires on September 30, 2022.) A discussion of the occupational mix adjustment that we are proposing to apply to the FY 2023 wage index appears under sections III.E. and F. of the preamble of this proposed rule.

2. Core-Based Statistical Areas (CBSAs) for the Proposed FY 2023 Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published in the June 28, 2010, **Federal Register** (75 FR 37246 through 37252). We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963 and 49973 through 49982)) for a full discussion of our implementation of the OMB statistical area delineations beginning with the FY 2015 wage index.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses through OMB Bulletins. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012, and July 1, 2013. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted the updates set forth in OMB Bulletin No. 15–01 effective October 1, 2016, beginning with the FY 2017 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 15–01, we refer readers to the FY 2017 IPPS/LTCH PPS final rule. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), we continued to use the OMB delineations that were adopted beginning with FY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin No. 15–01 specified in the FY 2017 IPPS/LTCH PPS final rule.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17–01 provided detailed information on the update to statistical areas since July 15, 2015, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014 and July 1, 2015. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41363), we adopted the updates set forth in OMB Bulletin No. 17–01 effective October 1, 2018, beginning with the FY 2019 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 17–01, we refer readers to the FY 2019 IPPS/LTCH PPS final rule. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42300 through 42301), we continued to use the OMB delineations that were adopted beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01.

On April 10, 2018 OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017, OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. Historically OMB bulletins issued between decennial censuses have only contained minor modifications to CBSA delineations based on changes in population counts. However, OMB's 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates created a larger mid-decade redelineation that takes into account commuting data from the American Commuting Survey. As a result, the September 14, 2018, OMB Bulletin No. 18–04 included more modifications to the CBSAs than are typical for OMB bulletins issued between decennial censuses.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58743 through 58755) we adopted the updates set forth in OMB Bulletin No. 18–04 effective October 1, 2020, beginning with the FY 2021 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 18–04, we refer readers to the FY 2021 IPPS/LTCH PPS final rule.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the update to statistical areas since September 14, 2018, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2017, and July 1, 2018. After reviewing OMB Bulletin No. 20–01, we determined that the changes in Bulletin 20–01 encompassed delineation changes that would not affect the Medicare wage index for FY 2022. While we adopted the updates set forth in OMB Bulletin No. 20–01 in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45163 through

45164) consistent with our general policy of adopting OMB delineation updates, we also noted that specific wage index updates would not be necessary for FY 2022 as a result of adopting these updates. In other words, the updates set forth in OMB Bulletin No. 20–01 would not affect any hospital's geographic area for purposes of the wage index calculation for FY 2022. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 20–01, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45163 through 45164. For FY 2023, we would continue to use the OMB delineations that were adopted beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01, 17–01, 18–04 and 20–01, although as noted previously OMB Bulletin No. 20–01 did not require any wage area updates.

In connection with our adoption in FY 2021 of the updates in OMB Bulletin 18–04, we adopted a policy to place a 5 percent cap, for FY 2021, on any decrease in a hospital's wage index from the hospital's final wage index in FY 2020 so that a hospital's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58753 through 58755) for a complete discussion of this transition. As finalized in the FY 2021 IPPS/LTCH PPS final rule, this transition was set to expire at the end of FY 2021. However, given the unprecedented nature of the ongoing COVID–19 public health emergency (PHE), we adopted a policy in the FY 2022 IPPS/LTCH PPS final rule to apply an extended transition to the FY 2022 wage index for hospitals that received the transition in FY 2021. Specifically, we continued a wage index transition for FY 2022 (for hospitals that received the transition in FY 2021) under which we applied a 5 percent cap on any decrease in the hospital's wage index compared to its wage index for FY 2021 to mitigate significant negative impacts of, and provide additional time for hospitals to adapt to, the CMS decision to adopt the revised OMB delineations. We also applied a budget neutrality adjustment to the standardized amount so that our transition in FY 2022 was implemented in a budget neutral manner under our authority in section 1886(d)(5)(I) of the Act. We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (85 FR 45164 through 45165) for a complete discussion of this transition. We also refer readers to section III.N. of the preamble of this proposed rule which discusses our proposal with regard to a permanent wage index transition for a hospital's wage index that applies a 5 percent cap on any decrease in the hospital's wage index compared to its wage index from the prior fiscal year.

3. Codes for Constituent Counties in CBSAs

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. There are two different lists of codes associated with counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS has listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the hospital wage index. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we have learned that SSA county codes are no longer being maintained and updated. However, the FIPS codes continue to be maintained by the U.S. Census Bureau. We believe that using the latest FIPS codes will allow us to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions.

The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2020. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at *https://www.census.gov/programs-surveys/geography/technical-documentation/county-changes.html*. We believe that it is important to use the latest counties or county equivalent entities in order to properly crosswalk hospitals from a county to a CBSA for purposes of the hospital wage index used under the IPPS.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we adopted a policy to discontinue the use of the SSA county codes and began using only the FIPS county codes for purposes of cross walking counties to CBSAs. In addition, in the same rule, we implemented the latest FIPS code updates, which were effective October 1, 2017, beginning with the FY 2018 wage indexes. These updates have been used to calculate the wage indexes in a manner generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule. We refer the reader to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130) for a complete discussion of our adoption of FIPS county codes.

Based on the latest information included in the Census Bureau's website at *https://www.census.gov/programs-surveys/geography/technical-documentation/county-changes.2010.html*, the Census Bureau has made the following updates to the FIPS codes for counties or county equivalent entities:

- Chugach Census Area, AK (FIPS State County Code 02–063) and Copper River Census Area, AK (FIPS State County Code 02–066), were created from former Valdez-Cordova Census Area (02–261) which was located in CBSA 02. The CBSA code for these two new county equivalents remains 02.

We believe that it is important to use the latest counties or county equivalent entities in order to properly crosswalk hospitals from a county to a CBSA for purposes of the hospital wage index used under the IPPS. In addition, we believe that using the latest FIPS codes allows us to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. Therefore, we are proposing to implement these FIPS code updates listed previously, effective October 1, 2022, beginning with the FY 2023 wage indexes. We are proposing to use these update changes to calculate area wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule (69 FR 49026 through 49034) and the 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963). We note that while the county update changes listed above changed the county names, the CBSAs to which these counties map did not change from the prior counties. Therefore, there would be no impact or change to hospitals in these counties for purposes of the hospital wage index as a result of our implementation of these FIPS code updates.

For FY 2023, Tables 2 and 3 associated with this proposed rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS website reflect the latest FIPS code updates. We are inviting public comments on our proposals.

B. Worksheet S–3 Wage Data for the Proposed FY 2023 Wage Index

The proposed FY 2023 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2019 (the FY 2022 wage indexes were based on data

from cost reporting periods beginning during FY 2018).

1. Included Categories of Costs

The proposed FY 2023 wage index includes all of the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty).
- Home office costs and hours.
- Certain contract labor costs and hours, which include direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315 through 47317)).
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590) and modified in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49505 through 49508)) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2022, the proposed wage index for FY 2023 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2023 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally Qualified Health Centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398). For FY 2020 and subsequent years, other wage-related costs are also excluded from the calculation of the wage index. As discussed in the FY 2019 IPPS/LTCH final rule (83 FR 41365 through 41369), other wage-related costs reported on Worksheet S–3, Part II, Line 18 and Worksheet S–3, Part IV, Line 25 and subscripts, as well as all other wage-related costs, such as contract labor costs, are excluded from the calculation of the wage index.

3. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers.

C. Verification of Worksheet S–3 Wage Data

The wage data for the proposed FY 2023 wage index were obtained from Worksheet S–3, Parts II, III and IV of the Medicare cost report, CMS Form 2552–10 for cost reporting periods beginning on or after October 1, 2018, and before October 1, 2019. (As noted in section III.A.1 of the preamble of this proposed rule, the OMB control number for this information collection request is 0938–0050, which expired on March 31, 2022. A reinstatement of the information collection request is currently being developed. The public will have an opportunity to review and submit comments on the reinstatement through a public notice and comment period separate from this rulemaking). For wage index purposes, we refer to cost reports beginning on or after October 1, 2018, and before October 1, 2019 as the ''FY 2019 cost report,'' the ''FY 2019 wage data,'' or the ''FY 2019 data.'' Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. 15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the proposed FY 2023 wage index includes FY 2019 data submitted to us as of February 5, 2022. As in past years, we performed an extensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

Consistent with the IPPS and LTCH PPS ratesetting, our policy principles with regard to the wage index include generally using the most current data and information available which is usually data on a four year lag (for example, for the FY 2022 wage index we used cost report data from FY 2018) . In section I.F. of the preamble of this proposed rule, we discuss our analysis of the best available data for use in the development of this FY 2023 IPPS/LTCH PPS proposed rule given the potential impact of the public health emergency (PHE) for the Coronavirus Disease (COVID–19). For the FY 2023 wage index, the best available data typically would be from the FY 2019 wage data. Our review and analysis of the FY 2019 wage data shows that the data is not significantly impacted by COVID–19 PHE. A comparison of providers shows similar trends in those with cost reports ending during the PHE as compared to providers without cost reports ending during the PHE. The data also shows that changes in the Average Hourly Wage (AHW) for providers were consistent between providers with cost reports ending during the PHE as compared to providers without cost reports ending during the PHE. It appears that the overall impact of the COVID–19 PHE on the FY 2019 wage data has been minimal.

Additionally, the changes in the wage data from FY 2018 to FY 2019 show similar trends in the change of the data from FY 2017 to FY 2018. Therefore, we are proposing to use the FY 2019 wage data for the FY 2023 wage index.

We asked our MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2023 wage index, we identified and excluded 86 providers with aberrant data that should not be included in the wage index. If data elements for some of these providers are corrected, we intend to include data from those providers in the final FY 2023 wage index. We also adjusted certain aberrant data and included these data in the wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). We instructed MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than March 19, 2022.

In constructing the proposed FY 2023 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2019, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage

index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398); that is, any hospital that is designated as a CAH by 7 days prior to the publication of the preliminary wage index public use file (PUF) is excluded from the calculation of the wage index. For the proposed rule, we removed 3 hospitals that converted to CAH status on or after January 24, 2021, the cut-off date for CAH exclusion from the FY 2022 wage index, and through and including January 21, 2022, the cut-off date for CAH exclusion from the FY 2023 wage index. In summary, we calculated the proposed FY 2023 wage index using the Worksheet S–3, Parts II and III wage data of 3,112 hospitals.

For the proposed FY 2023 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located using campus full-time equivalent (FTE) percentages as originally finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51591). Table 2, which contains the proposed FY 2023 wage index associated with this proposed rule (available via the internet on the CMS website), includes separate wage data for the campuses of 26 multicampus hospitals. The following chart lists the multicampus hospitals by CSA certification number (CCN) and the FTE percentages on which the wages and hours of each campus were allotted to their respective labor market areas:

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CCN of Multicampus Hospital	Full-Time Equivalent (FTE) Percentages
050121	0.86
05B121	0.14
070010	0.96
07B010	0.04
070022	0.99
07B022	0.01
070033	0.93
07B033	0.07
100029	0.53
10B029	0.47
100167	0.56
10B167	0.44
140010	0.82
14B010	0.18
220074	0.89
22B074	0.11
310069	0.82
31B069	0.18
310108	0.97
31B108	0.03
330195	0.89
33B195	0.11
330103	0.67
33B103	0.33
330214	0.74
33B214	0.26

CCN of Multicampus Hospital	Full-Time Equivalent (FTE) Percentages
330234	0.78
33B234	0.22
340115	0.95
34B115	0.05
360020	0.96
36B020	0.04
390006	0.96
39B006	0.04
390115	0.86
39B115	0.14
390142	0.84
39B142	0.16
450033	0.99
45B033	0.01
450330	0.96
45B330	0.04
460051	0.78
46B051	0.22
510022	0.94
51B022	0.06
520009	0.69
52B009	0.31
670062	0.69
67B062	0.31
670107	0.69
67B107	0.31

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We note that, in past years, in Table 2, we have placed a ''B'' to designate the subordinate campus in the fourth position of the hospital CCN. However, for the FY 2019 IPPS/LTCH PPS proposed and final rules and subsequent rules, we have moved the ''B'' to the third position of the CCN. Because all IPPS hospitals have a ''0'' in the third position of the CCN, we believe that placement of the ''B'' in this third position, instead of the ''0'' for the subordinate campus, is the most efficient method of identification and interferes the least with the other, variable, digits in the CCN.

D. Method for Computing the Proposed FY 2023 Unadjusted Wage Index

The method used to compute the proposed FY 2023 wage index without an occupational mix adjustment follows the same methodology that we used to compute the wage indexes without an occupational mix adjustment in the FY 2021 IPPS/LTCH PPS final rule (see 85 FR 58758 through 58761, September 18, 2020), and we are not proposing any changes to this methodology. We have restated our methodology in this section of this rule.

Step 1.—We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period relevant to the proposed wage index (in this case, for FY 2023, these were data from cost reports for cost reporting periods beginning on or after October 1, 2018, and before October 1, 2019). In addition, we included data from some hospitals that had cost reporting periods beginning before October 2018 and reported a cost reporting period covering all of FY 2019. These data were included because no other data from these hospitals would be available for the cost reporting period as previously described, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 2019 data. We note that, if a hospital had more than one cost reporting period beginning during FY 2019 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 2018, and before October 1, 2019), we include wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

Step 2.—Salaries.—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. (We note that, beginning with FY 2008 (72 FR 47315), we included what were then Lines 22.01, 26.01, and 27.01 of Worksheet S–3, Part II of CMS Form 2552–96 for overhead services in the wage index. Currently, these lines are lines 28, 33,

and 35 on CMS Form 2552–10. However, we note that the wages and hours on these lines are not incorporated into Line 101, Column 1 of Worksheet A, which, through the electronic cost reporting software, flows directly to Line 1 of Worksheet S–3, Part II. Therefore, the first step in the wage index calculation is to compute a ''revised'' Line 1, by adding to the Line 1 on Worksheet S–3, Part II (for wages and hours respectively) the amounts on Lines 28, 33, and 35.) In calculating a hospital's Net Salaries (we note that we previously used the term ''average'' salaries in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592), but we now use the term ''net'' salaries) plus wage-related costs, we first compute the following: Subtract from Line 1 (total salaries) the GME and CRNA costs reported on CMS Form 2552–10, Lines 2, 4.01, 7, and 7.01, the Part B salaries reported on Lines 3, 5 and 6, home office salaries reported on Line 8, and exclude salaries reported on Lines 9 and 10 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtract from Line 1 the salaries for which no hours were reported. Therefore, the formula for Net Salaries (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)).

To determine Total Salaries plus Wage-Related Costs, we add to the Net Salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 11, 12 and 13), home office salaries and wage-related costs reported by the hospital on Lines 14.01, 14.02, and 15, and nonexcluded area wage-related costs (Lines 17, 22, 25.50, 25.51, and 25.52). We note that contract labor and home office salaries for which no corresponding hours are reported are not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 22) are excluded if no corresponding salaries are reported for those employees on Line 4. The formula for Total Salaries plus Wage-Related Costs (from Worksheet S–3, Part II) is the following: ((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15) + (Line 17 + Line 22 + 25.50 + 25.51 + 25.52).

Step 3.—Hours.—With the exception of wage-related costs, for which there are no associated hours, we compute total hours using the same methods as described for salaries in Step 2. The formula for Total Hours (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15).

Step 4.—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocate overhead costs to areas of the hospital excluded from the wage index calculation. First, we determine the ''excluded rate'', which is the ratio of excluded area hours to Revised Total Hours (from Worksheet S–3, Part II) with the following formula: (Line 9 + Line 10)/(Line 1 + Line 28 + Line 33 + Line 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, and 8 and Lines 26 through 43). We then compute the amounts of overhead salaries and hours to be allocated to the excluded areas by multiplying the above ratio by the total overhead salaries and hours reported on Lines 26 through 43 of Worksheet S–3, Part II. Next, we compute the amounts of overhead wage-related costs to be allocated to the excluded areas using three steps:

- We determine the ''overhead rate'' (from Worksheet S–3, Part II), which is the ratio of overhead hours (Lines 26 through 43 minus the sum of Lines 28, 33, and 35) to revised hours excluding the sum of lines 28, 33, and 35 (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, 9, 10, 28, 33, and 35). We note that, for the FY 2008 and subsequent wage index calculations, we have been excluding the overhead contract labor (Lines 28, 33, and 35) from the determination of the ratio of overhead hours to revised hours because hospitals typically do not provide fringe benefits (wage-related costs) to contract personnel. Therefore, it is not necessary for the wage index calculation to exclude overhead wage-related costs for contract personnel. Further, if a hospital does contribute to wage-related costs for contracted personnel, the instructions for Lines 28, 33, and 35 require that associated wage-related costs be combined with wages on the respective contract labor lines. The formula for the Overhead Rate (from Worksheet S–3, Part II) is the following: (Lines 26 through 43 − Lines 28, 33 and 35)/((((Line 1 + Lines 28, 33, 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, and 26 through 43)) − (Lines 9 and 10)) + (Lines 26 through 43 − Lines 28, 33, and 35)).
- We compute overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 17, 22, 25.50, 25.51, and 25.52.
- We multiply the computed overhead wage-related costs by the previously described excluded area hours ratio.

Finally, we subtract the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5.—For each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2018, through April 15, 2020, for private industry hospital workers from the Bureau of Labor Statistics' (BLS') Compensation and Working Conditions. We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. We also note that, since April 2006 with the publication of March 2006 data, the BLS' ECI uses a different classification system, the North American Industrial Classification System (NAICS), instead of the Standard Industrial Codes (SICs), which no longer exist. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing to make any changes to the usage of the ECI for FY 2023. The factors used to adjust the hospital's data are based on the midpoint of the cost reporting period, as indicated in this rule.

Step 6.—Each hospital is assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B), 1886(d)(8)(E), or 1886(d)(10) of the Act. Within each urban or rural labor market area, we add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7.—We divide the total adjusted salaries plus wage-related costs obtained under Step 6 by the sum of the corresponding total hours (from Step 4)

for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8.—We add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the Nation and then divide the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage.

Step 9.—For each urban or rural labor market area, we calculate the hospital wage index value, unadjusted for occupational mix, by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10.—For each urban labor market area for which we do not have any hospital wage data (either because there are no IPPS hospitals in that labor market area, or there are IPPS hospitals in that area but their data are either too new to be reflected in the current year's wage index calculation, or their data are aberrant and are deleted from the wage index), we finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42305) that, for FY 2020 and subsequent years' wage index calculations, such CBSA's wage index would be equal to total urban salaries plus wage-related costs (from Step 5) in the State, divided by the total urban hours (from Step 4) in the State, divided by the national average hourly wage from Step 8 (see 84 FR 42305 and 42306, August 16, 2019). We stated that we believe that, in the absence of wage data for an urban labor market area, it is reasonable to use a statewide urban average, which is based on actual, acceptable wage data of hospitals in that State, rather than impute some other type of value using a different methodology. For calculation of the proposed FY 2023 wage index, we note there is one urban CBSA for which we do not have IPPS hospital wage data. In Table 3 (which is available via the internet on the CMS website) which contains the area wage indexes, we include a footnote to indicate to which CBSAs this policy applies. These CBSAs' wage indexes would be equal to total urban salaries plus wage-related costs (from Step 5) in the respective State, divided by the total urban hours (from Step 4) in the respective State, divided by the national average hourly wage (from Step 8) (see 84 FR 42305 and 42306, August 16, 2019). Under this step, we also apply our policy with regard to how dollar amounts, hours, and other numerical values in the wage index calculations are rounded, as discussed in this section of this rule.

We refer readers to section II. of the Appendix of the proposed rule for the policy regarding rural areas that do not have IPPS hospitals.

Step 11.—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. The areas affected by this provision are identified in Table 2 listed in section VI. of the Addendum to the proposed rule and available via the internet on the CMS website.

Following is our policy with regard to rounding of the wage data (dollar amounts, hours, and other numerical values) in the calculation of the unadjusted and adjusted wage index, as finalized in the FY 2020 IPPS/LTCH final rule (84 FR 42306, August 16, 2019). For data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we use such data ''as is,'' and do not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round the dollar amounts to 2 decimals. For any hour amounts within the wage index calculations, we round such hour amounts to the nearest whole number. For any numbers not expressed as dollars or hours within the wage index calculations, which could include ratios, percentages, or inflation factors, we round such numbers to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2018, through April 15, 2020, for private industry hospital workers from the BLS' *Compensation and Working Conditions.* We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing any changes to the usage of the ECI for FY 2023. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment Factor
10/14/2018	11/15/2018	1.03404
11/14/2018	12/15/2018	1.03168
12/14/2018	01/15/2019	1.02929
01/14/2019	02/15/2019	1.02694
02/14/2019	03/15/2019	1.02462
03/14/2019	04/15/2019	1.02237
04/14/2019	05/15/2019	1.02026
05/14/2019	06/15/2019	1.01826
06/14/2019	07/15/2019	1.01630
07/14/2019	08/15/2019	1.01429
08/14/2019	09/15/2019	1.01223
09/14/2019	10/15/2019	1.01015
10/14/2019	11/15/2019	1.00808
11/14/2019	12/15/2019	1.00601
12/14/2019	01/15/2020	1.00397
01/14/2020	02/15/2020	1.00196
02/14/2020	03/15/2020	1.00000
03/14/2020	04/15/2020	0.99808

For example, the midpoint of a cost reporting period beginning January 1, 2019, and ending December 31, 2019, is June 30, 2019. An adjustment factor of 1.01630 was applied to the wages of a hospital with such a cost reporting period.

Previously, we also would provide a Puerto Rico overall average hourly wage. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico specific wage index that was applied to the labor-related share of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915 through 56916), because Puerto Rico hospitals are no longer paid with a Puerto Rico specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) and the national wage index, which is applied to the national labor-related share of the national standardized amount. Therefore, for FY 2023, there is no Puerto Rico-specific overall average hourly wage or wage index.

Based on the methodology, as previously discussed, the proposed FY 2023 unadjusted national average hourly wage is the following:

Proposed FY 2023 Unadjusted National Average Hourly Wage	$47.77

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E. Proposed Occupational Mix Adjustment to the FY 2023 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Use of 2019 Medicare Wage Index Occupational Mix Survey for the FY 2023 Wage Index

Section 304(c) of the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute

care hospital participating in the Medicare program. As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25402 through 25403) and final rule (86 FR 45173), we collected data in 2019 to compute the occupational mix adjustment for the FY 2022, FY 2023, and FY 2024 wage indexes. The FY 2023 occupational mix adjustment is based on the calendar year (CY) 2019 survey. Hospitals were required to submit their completed 2019 surveys (Form CMS–10079, OMB Number 0938–0907, expiration date September 30, 2022) to their MACs by September 3, 2020. It should be noted that this collection of information was approved under OMB control number 0938–0907 with an expiration date of September 30, 2022. Prior to the expiration date, CMS will submit an extension request to OMB. The extension request will be announced in the **Federal Register** via the required 60-day and 30-day notice and comment periods. The preliminary, unaudited CY 2019 survey data were posted on the CMS website on September 8, 2020. As with the Worksheet S–3, Parts II and III cost report wage data, as part of the FY 2022 desk review process, the MACs revised or verified data elements in hospitals' occupational mix surveys that resulted in certain edit failures.

2. Calculation of the Occupational Mix Adjustment for FY 2023

For FY 2023, we are proposing to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index (76 FR 51582 through 51586) and to apply the occupational mix adjustment to 100 percent of the proposed FY 2023 wage index. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308), we modified our methodology with regard to how dollar amounts, hours, and other numerical values in the unadjusted and adjusted wage index calculation are rounded, in order to ensure consistency in the calculation. According to the policy finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308 and 42309), for data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we continue to use these data ''as is'', and not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round such dollar amounts to 2 decimals. We round any hour amounts within the wage index calculations to the nearest whole number. We round any numbers not expressed as dollars or hours in the wage index calculations, which could include ratios, percentages, or inflation factors, to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

Similar to the method we use for the calculation of the wage index without occupational mix, salaries and hours for a multicampus hospital are allotted among the different labor market areas where its campuses are located. Table 2 associated with this proposed rule (which is available via the internet on the CMS website), which contains the proposed FY 2023 occupational mix adjusted wage index, includes separate wage data for the campuses of multicampus hospitals. We refer readers to section III.C. of the preamble of this proposed rule for a chart listing the multicampus hospitals and the FTE percentages used to allot their occupational mix data.

Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the proposed FY 2023 wage index. For the proposed FY 2023 wage index, we are using the Worksheet S–3, Parts II and III wage data of 3,112 hospitals, and we used the occupational mix surveys of 3,010 hospitals for which we also had Worksheet S–3 wage data, which represented a ''response'' rate of 97 percent (3,010/3,112). For the proposed FY 2023 wage index, we are applying proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the proposed FY 2023 occupational mix adjusted national average hourly wage is the following:

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Proposed FY 2023 Occupational Mix Adjusted National Average Hourly Wage	$47.71

F. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2023 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this proposed rule, for FY 2023, we are applying the occupational mix adjustment to 100 percent of the FY 2023 wage index. We calculated the occupational mix adjustment using data from the 2019 occupational mix survey data, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586).

The proposed FY 2023 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational Mix Nursing Subcategory	Average Hourly Wage
National RN	$37.43
National LPN and Surgical Technician	$26.86
National Nurse Aide, Orderly, and Attendant	$18.56
National Medical Assistant	$19.54
National Nurse Category	$44.49

The proposed national average hourly wage for the entire nurse category is computed in Step 5 of the occupational mix calculation. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2019 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) the following:

National Percentage of Hospital Employees in the Nurse Category	42%
National Percentage of Hospital Employees in the All Other Occupations Category	58%
Range of Percentage of Hospital Employees in the Nurse Category (CBSA Level)	Low of 20 Percent in one CBSA to a high of 66 percent in another CBSA

We compared the proposed FY 2023 occupational mix adjusted wage indexes for each CBSA to the proposed unadjusted wage indexes for each CBSA. Applying the occupational mix adjustment to the wage data resulted in the following:

Comparison of the FY 2023 Proposed Occupational Mix Adjusted Wage Indexes to the Proposed Unadjusted Wage Indexes by CBSA	
Number of Urban Areas Wage Index Increasing	230 (55.8%)
Number of Rural Areas Wage Index Increasing	27 (57.4%
Number of Urban Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	122 (29.6%)
Number of Urban Areas Wage Index Increasing by 5 percent or More	4 (1.0%
Number of Rural Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	13 (27.7%
Number of Rural Areas Wage Index Increasing by 5 Percent or More	0 (0%)
Number of Urban Areas Wage Index Decreasing	181 (43.9%
Number of Rural Areas Wage Index Decreasing	20 (42.6%
Number of Urban Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	78 (18.9%
Number of Urban Areas Wage Index Decreasing by 5 Percent or More	3 (0.7%
Number of Rural Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less than 5 Percent	8 (17.0%
Number of Rural Areas Wage Index Decreasing by 5 Percent or More	0 (0%)
Largest Positive Impact for an Urban Area	7.23%
Largest Positive Impact for a Rural Area	4.19%
Largest Negative Impact for an Urban Area	-5.48%
Largest Negative Impact for a Rural Area	-2.52%
Urban Areas Unchanged by Application of the Occupational Mix Adjustment	1 (0.2%)
Rural Areas Unchanged by Application of the Occupational Mix Adjustment	0 (0%)

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These results indicate that a smaller percentage of urban areas (55.8 percent) would benefit from the occupational mix adjustment than would rural areas (57.4 percent).

III. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

G. Application of the Rural Floor, Application of the Imputed Floor, Application of the State Frontier Floor, Continuation of the Low Wage Index Hospital Policy, and Proposed Budget Neutrality Adjustment

1. Rural Floor

Section 4410(a) of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the rural floor. Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we removed urban to rural reclassifications from the calculation of the rural floor to prevent inappropriate payment increases under the rural floor due to rural reclassifications, such that, beginning in FY 2020, the rural floor is calculated without including the wage data of hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103). For FY 2023, we are proposing to continue to calculate the rural floor without the wage data of hospitals that have reclassified as rural under § 412.103. Also, for the purposes of applying the provisions of section 1886(d)(8)(C)(iii) of the Act, effective beginning in FY 2020, we remove the data of hospitals reclassified from urban to rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103) from the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii)

of the Act. We are proposing to continue to apply this policy for FY 2023.

We note that the FY 2020 rural floor policy and the related budget neutrality adjustment are the subject of pending litigation, including in *Citrus HMA, LLC, d/b/a Seven Rivers Regional Medical Center* v. *Becerra,* No. 1:20–cv–00707 (D.D.C.) (hereafter referred to as *Citrus*). On April 8, 2022, the district court in *Citrus* granted in part the plaintiff hospitals' motion for summary judgment and denied the Secretary's cross-motion for summary judgment. The court found that the Secretary did not have authority under section 4410(a) of the Balanced Budget Act of 1997 to establish a rural floor lower than the rural wage index for a state. While *Citrus* involves only FY 2020, the court's decision—which is subject to potential appeal—may have implications for FY 2023 payment rates. We are continuing to evaluate the court's decision, and although we are proposing for the rural floor wage index policy (and the related budget neutrality adjustment) to continue for FY 2023, we may decide to take a different approach in the final rule, depending on public comments or developments in the court proceedings.

Based on the FY 2023 wage index associated with this proposed rule (which is available via the internet on the CMS website) and based on the calculation of the rural floor without the wage data of hospitals that have reclassified as rural under § 412.103, we estimate that 192 hospitals would receive an increase in their FY 2023 proposed wage index due to the application of the rural floor.

2. Imputed Floor

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the imputed floor policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban States that have argued that they are disadvantaged by the absence of rural hospitals to set a wage index floor for those States. We extended the imputed floor policy eight times since its initial implementation, the last of which was adopted in the FY 2018 IPPS/LTCH PPS final rule and expired on September 30, 2018. (We refer readers to further discussions of the imputed floor in the IPPS/LTCH PPS final rules from FYs 2014 through 2019 (78 FR 50589 through 50590, 79 FR 49969 through 49971, 80 FR 49497 through 49498, 81 FR 56921 through 56922, 82 FR 38138 through 38142, and 83 FR 41376 through 41380, respectively) and to the regulations at 42 CFR 412.64(h)(4).) For FYs 2019, 2020, and 2021, hospitals in all-urban states received a wage index that was calculated without applying an imputed floor, and we no longer included the imputed floor as a factor in the national budget neutrality adjustment.

In computing the imputed floor for an all-urban State under the original methodology established beginning in FY 2005, we calculated the ratio of the lowest-to-highest CBSA wage index for each all-urban State as well as the average of the ratios of lowest-to-highest CBSA wage indexes of those all-urban States. We then compared the State's own ratio to the average ratio for all-urban States and whichever was higher was multiplied by the highest CBSA wage index value in the State—the product of which established the imputed floor for the State.

We adopted a second, alternative methodology beginning in FY 2013 (77 FR 53368 through 53369) to address the concern that the original imputed floor methodology guaranteed a benefit for one all-urban State with multiple wage indexes (New Jersey) but could not benefit another all-urban State, Rhode Island, which had only one CBSA. Under the alternative methodology, we first determined the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (without rural floor budget neutrality applied) for all CBSAs receiving the rural floor. The lowest post-reclassified wage index assigned to a hospital in an all-urban State having a range of such values then was increased by this factor, the result of which established the State's alternative imputed floor. Under the updated OMB labor market area delineations adopted by CMS beginning in FY 2015, Delaware became an all-urban State, along with New Jersey and Rhode Island, and was subject to an imputed floor as well. In addition, we adopted a policy, as reflected at § 412.64(h)(4)(vi), that, for discharges on or after October 1, 2012, and before October 1, 2018, the minimum wage index value for a State is the higher of the value determined under the original methodology or the value determined under the alternative methodology. The regulations implementing the imputed floor wage index, both the original methodology and the alternative methodology, were set forth at § 412.64(h)(4).

Section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) enacted on March 11, 2021, amended section 1886(d)(3)(E)(i) of the Act (42 U.S.C. 1395ww(d)(3)(E)(i)) and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index for hospitals in all-urban States for discharges occurring on or after October 1, 2021. Specifically, section 1886(d)(3)(E)(iv)(I) and (II) of the Act provides that for discharges occurring on or after October 1, 2021, the area wage index applicable to any hospital in an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. Thus, effective beginning October 1, 2021 (FY 2022), section 1886(d)(3)(E)(iv) of the Act reinstates the imputed floor wage index policy for all-urban States, with no expiration date, using the methodology described in 42 CFR 412.64(h)(4)(vi) as in effect for FY 2018. As discussed previously, under § 412.64(h)(4)(vi), the minimum wage index value for hospitals in an all-urban State is the higher of the value determined using the original methodology (as set forth at § 412.64(h)(4)(i) through (v)) or the value determined using alternative methodology (as set forth at § 412.64(h)(4)(vi)(A) and (B)) for calculating an imputed floor. Therefore, as provided in § 412.64(h)(4)(vi), we apply the higher of the value determined under the original or alternative methodology for calculating a minimum wage index, or imputed floor, for all-urban States effective beginning with FY 2022. We note that the rural floor values used in the alternative methodology at § 412.64(h)(4)(vi)(A) and (B) would not include the wage data of hospitals reclassified under § 412.103, because we currently calculate the rural floor without the wage data of such hospitals.

Unlike the imputed floor that was in effect from FYs 2005 through 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. Specifically, section 9831(b) of Public Law 117–2 amends section 1886(d)(3)(E)(i) of the Act to exclude the imputed floor from the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act. In other words, the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act, as amended, must be applied without taking into account the imputed floor adjustment under section 1886(d)(3)(E)(iv) of the Act. When the imputed floor was in effect from FY 2005 through FY 2018, to budget neutralize the increase in payments resulting from application of the imputed floor, we calculated the increase in payments resulting from the imputed floor together with the increase

in payments resulting from the rural floor and applied an adjustment to reduce the wage index. By contrast, for FY 2022 and subsequent years, we apply the imputed floor after the application of the rural floor and apply no reductions to the standardized amount or to the wage index to fund the increase in payments to hospitals in all-urban States resulting from the application of the imputed floor required under section 1886(d)(3)(E)(iv) of the Act.

The imputed floor under section 1886(d)(3)(E)(iv) of the Act applies to all-urban States, as defined in new subclause (IV). Section 1886(d)(3)(E)(iv)(IV) provides that, for purposes of the imputed floor wage index under clause (iv), the term all-urban State means a State in which there are no rural areas (as defined in section 1886(d)(2)(D) of the Act) or a State in which there are no hospitals classified as rural under section 1886 of the Act. Under this definition, given that it applies for purposes of the imputed floor wage index, we consider a hospital to be classified as rural under section 1886 of the Act if it is assigned the State's rural area wage index value. Therefore, under the definition at section 1886(d)(3)(E)(iv)(IV) of the Act, ''a State in which there are no hospitals classified as rural under this section'' includes a State that has a rural area but no hospitals that receive the rural area wage index under section 1886(d) of the Act. For purposes of this definition, hospitals redesignated as rural under section 1886(d)(8)(E) of the Act (412.103 rural reclassifications) are considered classified as rural if they receive the rural wage index; however, hospitals that are deemed urban under section 1886(d)(8)(B) of the Act (in Lugar counties), or are reclassified to an urban area under section 1886(d)(10) of the Act (Medicare Geographic Classification Review Board (MGCRB) reclassifications) are not considered classified as rural because they do not receive the rural wage index. In contrast, we note that in the imputed floor policy in effect from FY 2005 through FY 2018, we did not consider a State to qualify for ''all urban status'' if there were one or more hospitals geographically located in the rural area of the State, even if all such hospitals subsequently reclassified to receive an urban area wage index. There is one State, Connecticut, that would be eligible for the imputed floor because there are currently no hospitals in Connecticut that are classified as rural under section 1886(d) for purposes of the wage index—in other words, there are no hospitals that receive the rural wage index. There is currently one rural county in Connecticut. All hospitals in this county are either deemed urban under section 1886(d)(8)(B) of the Act or receive an MGCRB reclassification under section 1886(d)(10) of the Act. While several Connecticut hospitals were approved for rural reclassification under section 1886(d)(8)(E) of the Act, at this point all have received a subsequent urban reclassification under section 1886(d)(10) of the Act.

Additionally, under section 1861(x) of the Act, the term State has the meaning given to it in section 210(h) of the Act. Because section 210(h) of the Act defines the word State to also include the District of Columbia and the Commonwealth of Puerto Rico, Washington, DC and Puerto Rico may also qualify as all-urban States for purposes of the imputed floor if the requirements of section 1886(d)(3)(E)(iv)(IV) of the Act are met. Based on data available for this proposed rule, the following States would be all-urban States as defined in section 1886(d)(3)(E)(iv)(IV) of the Act, and thus hospitals in such States would be eligible to receive an increase in their wage index due to application of the imputed floor for FY 2023: New Jersey, Rhode Island, Delaware, Connecticut, and Washington, DC.

In the FY 2022 IPPS/LTCH PPS final rule, we revised the regulations at § 412.64(e)(1) and (4) and (h)(4) and (5) to implement the imputed floor required by section 1886(d)(3)(E)(iv) of the Act for discharges occurring on or after October 1, 2021. The imputed floor will be applied for FY 2023 in accordance with the policies adopted in the FY 2022 IPPS/LTCH PPS final rule. For more information regarding our implementation of the imputed floor required by section 1886(d)(3)(E)(iv) of the Act, we refer readers to the discussion in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45176 through 45178).

3. State Frontier Floor for FY 2023

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000. (We refer readers to the regulations at 42 CFR 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161).) In this FY 2023 IPPS/LTCH PPS proposed rule, we are not proposing any changes to the frontier floor policy for FY 2023. In this proposed rule, 44 hospitals would receive the frontier floor value of 1.0000 for their FY 2023 proposed wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming. We note that while Nevada meets the criteria of a frontier State, all hospitals within the State currently receive a wage index value greater than 1.0000.

The areas affected by the rural and frontier floor policies for the proposed FY 2023 wage index are identified in Table 2 associated with this proposed rule, which is available via the internet on the CMS website.

4. Continuation of the Low Wage Index Hospital Policy; Proposed Budget Neutrality Adjustment

To help mitigate wage index disparities, including those resulting from the inclusion of hospitals with rural reclassifications under 42 CFR 412.103 in the rural floor, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized policies to reduce the disparity between high and low wage index hospitals by increasing the wage index values for certain hospitals with low wage index values and doing so in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals, as well as by changing the calculation of the rural floor. We also provided for a transition in FY 2020 for hospitals experiencing significant decreases in their wage index values as compared to their final FY 2019 wage index, and made these changes in a budget neutral manner.

We increase the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals (the low wage index hospital policy). We stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42328) our intention that this policy will be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. We note that the FY 2020 low wage index hospital policy and the related budget neutrality adjustment are the subject of pending litigation, including in *Bridgeport Hospital, et al.,* v. *Becerra,* No. 1:20–cv–01574 (D.D.C.) (hereafter referred to as *Bridgeport*). On March 2, 2022, the district court in *Bridgeport* granted in part the plaintiff hospitals' motion for summary judgment and denied the Secretary's cross-motion for summary judgment. The court found that the

Secretary did not have authority under section 1886(d)(3)(E) or 1886(d)(5)(I)(i) of the Act to adopt the low wage index hospital policy and ordered additional briefing on the appropriate remedy. While *Bridgeport* involves only FY 2020, the court's decision—which is not final at this time and is also subject to potential appeal—may have implications for FY 2023 payment rates. We are continuing to evaluate the court's decision, and although we are proposing for the low wage index hospital policy (and the related budget neutrality adjustment, proposed below) to continue for FY 2023, we may decide to take a different approach in the final rule, depending on public comments or developments in the court proceedings.

In order to offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile wage index value, for FY 2023 and for subsequent fiscal years during which the low wage index hospital policy is in effect, we are proposing to apply a budget neutrality adjustment in the same manner as we applied it in FYs 2020, 2021, and 2022, as a uniform budget neutrality factor applied to the standardized amount. We refer readers to section II.A.4.f. of the addendum to this proposed rule for further discussion of the budget neutrality adjustment for FY 2023. For purposes of the low wage index hospital policy, based on the data for this proposed rule, the table displays the 25th percentile wage index value across all hospitals for FY 2023.

FY 2023 Proposed 25th Percentile Wage Index Value	0.8401

H. Proposed FY 2023 Wage Index Tables

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49498 and 49807 through 49808), we finalized a proposal to streamline and consolidate the wage index tables associated with the IPPS proposed and final rules for FY 2016 and subsequent fiscal years. Effective beginning FY 2016, with the exception of Table 4E, we streamlined and consolidated 11 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4F, 4J, 9A, and 9C) into 2 tables (Tables 2 and 3). In this FY 2023 IPPS/LTCH PPS proposed rule, as provided beginning with the FY 2021 IPPS/LTCH PPS final rule, we have included Table 4A which is titled ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act'' and Table 4B titled ''Counties redesignated under section 1886(d)(8)(B) of the Act (Lugar Counties).'' We refer readers to section VI. of the Addendum to this proposed rule for a discussion of the wage index tables for FY 2023.

I. Proposed Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General Policies and Effects of Reclassification and Redesignation

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (usually by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations and the policies for the effects of hospitals' reclassifications and redesignations on the wage index are discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596). We note that rural hospitals reclassifying under the MGCRB to another State's rural area are not eligible for the rural floor, because the rural floor may apply only to urban, not rural, hospitals.

In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we finalized a policy to exclude the wage data of urban hospitals reclassifying to rural areas under 42 CFR 412.103 from the calculation of the rural floor. Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of 42 CFR 412.103.

On April 21, 2016, we published an interim final rule with comment period (IFC) in the **Federal Register** (81 FR 23428 through 23438) that included provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 and MGCRB reclassifications. For reclassifications effective beginning FY 2018, a hospital may acquire rural status under § 412.103 and subsequently apply for a reclassification under the MGCRB using distance and average hourly wage criteria designated for rural hospitals. In addition, we provided that a hospital that has an active MGCRB reclassification and is then approved for redesignation under § 412.103 will not lose its MGCRB reclassification; such a hospital receives a reclassified urban wage index during the years of its active MGCRB reclassification and is still considered rural under section 1886(d) of the Act and for other purposes.

We discussed that when there is both a § 412.103 redesignation and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes. We exclude hospitals with § 412.103 redesignations from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area. That is, if an application for urban reclassification through the MGCRB is approved, and is not withdrawn or terminated by the hospital within the established timelines, we consider the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation. We refer readers to the April 21, 2016 IFC (81 FR 23428 through 23438) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56922 through 56930), in which we finalized the April 21, 2016 IFC, for a full discussion of the effect of simultaneous reclassifications under both the § 412.103 and the MGCRB processes on wage index calculations. For a discussion on the effects of reclassifications under § 412.103 on the rural area wage index and the calculation of the rural floor, we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336).

On May 10, 2021, we published an interim final rule with comment period

(IFC) in the **Federal Register** (86 FR 24735 through 24739) that included provisions amending our regulations to allow hospitals with a rural redesignation to reclassify through the MGCRB using the rural reclassified area as the geographic area in which the hospital is located. We revised our regulation so that the redesignated rural area, and not the hospital's geographic urban area, is considered the area a § 412.103 hospital is located in for purposes of meeting MGCRB reclassification criteria, including the average hourly wage comparisons required by § 412.230(a)(5)(i) and (d)(1)(iii)(C). Similarly, we revised the regulations to consider the redesignated rural area, and not the geographic urban area, as the area a § 412.103 hospital is located in for the prohibition at § 412.230(a)(5)(i) on reclassifying to an area with a pre-reclassified average hourly wage lower than the prereclassified average hourly wage for the area in which the hospital is located. Effective for reclassification applications due to the MGCRB for reclassification beginning in FY 2023, a § 412.103 hospital could apply for a reclassification under the MGCRB using the state's rural area as the area in which the hospital is located. We refer readers to the May 10, 2021 IFC (86 FR 24735 through 24739) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45187 through 45190), in which we finalized the May 10, 2021 IFC, for a full discussion of these policies.

2. MGCRB Reclassification and Redesignation Issues for FY 2023

a. FY 2023 Reclassification Application Requirements and Approvals

As previously stated, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280. At the time this proposed rule was drafted, the MGCRB had completed its review of FY 2023 reclassification requests. Based on such reviews, there are 491 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2023. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2023, hospitals reclassified beginning in FY 2021 or FY 2022 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 288 hospitals approved for wage index reclassifications in FY 2021 that will continue for FY 2023, and 304 hospitals approved for wage index reclassifications in FY 2022 that will continue for FY 2023. Of all the hospitals approved for reclassification for FY 2021, FY 2022 and FY 2023, based upon the review at the time of the proposed rule, 1,083 hospitals are in a MGCRB reclassification status for FY 2023 (with 192 of these hospitals reclassified back to their geographic location).

Under the regulations at 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications if the request for withdrawal is received by the MGCRB any time before the MGCRB issues a decision on the application, or after the MGCRB issues a decision, provided the request for withdrawal is received by the MGCRB within 45 days of the date that CMS' annual notice of proposed rulemaking is issued in the **Federal Register** concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application has been filed. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to § 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887 through 39888) and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and ''fallback'' reclassifications were included in the FY 2008 IPPS final rule (72 FR 47333) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148 through 38150).

We note that in the FY 2021 IPPS/LTCH final rule (85 FR 58771–58778), CMS finalized an assignment policy for hospitals reclassified to CBSAs from which one or more counties moved to a new or different urban CBSA under the revised OMB delineations based on OMB Bulletin 18–04. We provided a table in that rule (85 FR 58777 and 58778) which described the assigned CBSA for all the MGCRB cases subject to this policy. For such reclassifications that continue to be active or are reinstated for FY 2023, the CBSAs assigned in the FY 2021 IPPS/LTCH final rule continue to be in effect.

Applications for FY 2024 reclassifications are due to the MGCRB by September 1, 2022. We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under 42 CFR 412.273(d). Applications and other information about MGCRB reclassifications may be obtained beginning in mid-July 2022, via the internet on the CMS website at *https://www.cms.gov/Regulations/and Guidance/Review/Boards/MGCRB/index.html*, or by calling the MGCRB at (410) 786–1174. This collection of information was previously approved under OMB Control Number 0938–0573 which expired on January 31, 2021. A reinstatement of this PRA package is currently being developed. The public will have an opportunity to review and submit comments regarding the reinstatement of this PRA package through a public notice and comment period separate from this rulemaking.

b. Clarification of Method for Submission Under § 412.273

The regulations at 42 CFR 412.273 set forth the procedures for withdrawing an MGCRB application, terminating an approved 3-year reclassification, or canceling a previous withdrawal or termination (also referred to as a reinstatement). The timing of such requests is specified at § 412.273(c) for terminations and withdrawals and at paragraph (d)(2) for canceling a previous withdrawal or termination. However, the method of submission is not clearly specified in the regulations, other than the requirement that a request to cancel a previous withdrawal or termination (a reinstatement), or to withdraw an application or terminate an approved reclassification, be in writing according to § 412.273(d)(2) and (e). It has come to our attention that this may be a source of confusion for hospital representatives seeking to submit such requests. It is possible that hospital representatives would attempt to send such requests to the MGCRB via mail, email, or fax, rather than in the manner that the MGCRB can most efficiently track and process.

Beginning with applications from hospitals to reclassify for FY 2020, the MGCRB requires applications, supporting documents, and subsequent correspondence to be filed electronically through the MGCRB module of the Office of Hearings Case and Document Management System (''OH CDMS''). The MGCRB issues all of its notices and decisions via email and these documents are accessible electronically through OH CDMS. Registration instructions and the system user manual are available at *https://www.cms.gov/Regulations-and-Guidance/ReviewBoards/MGCRB/Electronic-Filing.html.*

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42313), we revised the regulations at § 412.256(a)(1) to require

applications for reclassification to be submitted to the MGCRB according to the method prescribed by the MGCRB. However, the regulations at § 412.273 for withdrawals, terminations, or cancelations of a previous withdrawal or termination (reinstatement) do not similarly specify a required manner of submission. Therefore, to eliminate potential confusion about how to submit withdrawal, termination, or cancelation (reinstatement) requests, we are proposing to align the regulations at § 412.273 for withdrawal, termination, or cancelation (reinstatement) requests with the regulations at § 412.256 for new applications by specifying that withdrawal, termination, or cancelation (reinstatement) requests also must be submitted to the MGCRB according to the method prescribed by the MGCRB.

Specifically, we are proposing to revise § 412.273(d)(2) for timing and process of cancellation requests and § 412.273(e) for withdrawal and termination requests. We are proposing to revise § 412.273(d)(2) to state that cancellation requests must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB no later than the deadline for submitting reclassification applications for the following fiscal year, as specified in § 412.256(a)(2). We are also proposing to revise § 412.273(e) by adding that requests to withdraw an application or terminate an approved reclassification must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB. We believe these proposed revisions to the regulations would eliminate potential confusion; align our policy for withdrawals, terminations, and cancelations (reinstatements) with our policy for applications; and ensure requests are submitted to the MGCRB through the method for submission that they can most efficiently process.

3. Redesignations Under Section 1886(d)(8)(B) of the Act (Lugar Status Determinations)

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS effective for the fiscal year in which the hospital receives the outmigration adjustment. In addition, in that rule, we adopted a minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the publication of the proposed rule) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56930), we further clarified that if a hospital wishes to reinstate its urban status for any fiscal year within this 3-year period, it must send a request to CMS within 45 days of publication of the proposed rule for that particular fiscal year. We indicated that such reinstatement requests may be sent electronically to *wageindex@cms.hhs.gov*. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38147 through 38148), we finalized a policy revision to require a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status, to notify CMS within 45 days from the date of public display of the proposed rule at the Office of the Federal Register. These revised notification timeframes were effective beginning October 1, 2017. In addition, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148), we clarified that both requests to waive and to reinstate ''Lugar'' status may be sent to *wageindex@cms.hhs.gov*. To ensure proper accounting, we request hospitals to include their CCN, and either ''waive Lugar'' or ''reinstate Lugar'', in the subject line of these requests.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42314 and 42315), we clarified that in circumstances where an eligible hospital elects to receive the outmigration adjustment within 45 days of the public display date of the proposed rule at the Office of the Federal Register in lieu of its Lugar wage index reclassification, and the county in which the hospital is located would no longer qualify for an out-migration adjustment when the final rule (or a subsequent correction notice) wage index calculations are completed, the hospital's request to accept the outmigration adjustment would be denied, and the hospital would be automatically assigned to its deemed urban status under section 1886(d)(8)(B) of the Act. We stated that final rule wage index values would be recalculated to reflect this reclassification, and in some instances, after taking into account this reclassification, the out-migration adjustment for the county in question could be restored in the final rule. However, as the hospital is assigned a Lugar reclassification under section 1886(d)(8)(B) of the Act, it would be ineligible to receive the county outmigration adjustment under section 1886(d)(13)(G) of the Act.

J. Proposed Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the ''out-migration'' adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When the provision of section 1886(d)(13) of the Act was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the ''long-form'' survey, which the Census Bureau used at that time and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was ''short form'' only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked in 2010, for use in developing a new outmigration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016.

To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-year)

Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in prior IPPS/LTCH PPS final rules, most recently in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58787), we have applied the same policies, procedures, and computations since FY 2012. We are proposing to use them again for FY 2023, as we believe they continue to be appropriate. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source.

For FY 2023, the out-migration adjustment will continue to be based on the data derived from the custom tabulation of the ACS utilizing 2008 through 2012 (5-year) Microdata. For future fiscal years, we may consider determining out-migration adjustments based on data from the next Census or other available data, as appropriate. For FY 2023, we are not proposing any changes to the methodology or data source that we used for FY 2016 (81 FR 25071). (We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602).)

Table 2 associated with this proposed rule (which is available via the internet on the CMS website) includes the proposed out-migration adjustments for the FY 2023 wage index. In addition, Table 4A associated with this proposed rule, ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act'' (also available via the internet on the CMS website) consists of the following: A list of counties that are eligible for the out-migration adjustment for FY 2023 identified by FIPS county code, the proposed FY 2023 out-migration adjustment, and the number of years the adjustment will be in effect.

K. Reclassification From Urban to Rural Under Section 1886(d)(8)(E) of the Act Implemented at 42 CFR 412.103

Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers to the regulations at 42 CFR 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act. The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336) for a discussion on our current policy to calculate the rural floor without the wage data of urban hospitals reclassifying to rural areas under 42 CFR 412.103.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41369 through 41374), we codified certain policies regarding multicampus hospitals in the regulations at 42 CFR 412.92, 412.96, 412.103, and 412.108. We stated that reclassifications from urban to rural under 42 CFR 412.103 apply to the entire hospital (that is, the main campus and its remote location(s)). We also stated that a main campus of a hospital cannot obtain an SCH, RRC, or MDH status, or rural reclassification under 42 CFR 412.103, independently or separately from its remote location(s), and vice versa. However, we are aware that some urban hospitals operate one or more remote location(s) in a State's rural area. In light of this scenario, we wish to clarify that rural reclassification under 42 CFR 412.103 applies to the main campus and any remote location located in an urban area. Under section 1886(d)(8)(E) of the Act, rural reclassification is available only to a hospital that is located in an urban area and satisfies the criteria specified in the statute. Thus, a remote location that is located in a rural area would not qualify for rural reclassification under section 1886(d)(8)(E) of the Act, as implemented under 42 CFR 412.103. We are proposing to add 42 CFR 412.103(a)(8) to clarify that for a multicampus hospital, approved rural reclassification status applies to the main campus and any remote location located in an urban area, including a main campus or any remote location deemed urban under section 1886(d)(8)(B) of the Act.

We are also aware that CMS has not consistently reflected the 412.103 rural reclassification status in Table 2 of the annual IPPS/LTCH PPS rulemaking for certain remote locations of hospitals that are located in a different CBSA than the main campus. If a remote location of a hospital is located in a different CBSA than the main campus of the hospital, it is CMS's longstanding policy to assign that remote location a wage index based on its own geographic area in order to comply with the statutory requirement to adjust for geographic differences in hospital wage levels (section 1886(d)(3)(E) of the Act). Hospitals are required to identify and allocate wages and hours based on FTEs for remote locations located in different CBSA on Worksheet S–2, Part I, Lines 165 and 166 of form CMS–2552–10. In calculating wage index values, CMS identifies the allocated wage data for these remote locations in Table 2 with a ''B'' in the 3rd position of the CCN.

As discussed previously, for a multicampus hospital, rural reclassification under 42 CFR 412.103 applies to the main campus and any remote location located in an urban area. The wage index implications of this policy are that, barring another form of wage index reclassification (for example, MGCRB reclassification), a main campus or remote location with approved 412.103 rural reclassification status would be assigned the rural wage index of its State. For FY 2023, we will list the 412.103 rural reclassification status for remote locations (a remote location is listed with a ''B'' in the third digit of the CCN) in Table 2 of the appendix to the proposed rule. We note that, as of the date this proposed rule is issued, only one ''B'' location (36B020) would be assigned its State's rural wage index in FY 2023 due to the 412.103 rural reclassification status of the main provider (360020). This location appears to have ceased inpatient activities, so we do not expect a negative financial impact for FY 2023. However, hospitals with 412.103 rural reclassification status and a remote location in a different CBSA should evaluate potential wage index outcomes for its remote location(s) when withdrawing or terminating MGCRB reclassification, or canceling 412.103 rural reclassification status. For example, if a hospital with 412.103 rural reclassification status withdraws a separate active MGCRB reclassification for a remote location, that remote location may be assigned the State's rural wage index value, effective for FY 2023.

L. Process for Requests for Wage Index Data Corrections

1. Process for Hospitals To Request Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files and the CY 2019 occupational mix data files for the proposed FY 2023 wage index were

made available on May 24, 2021 through the internet on the CMS website at *https://www.cms.gov/medicare medicare-fee-service-paymentacute inpatientppswage-index-files/fy2023-wage-index-home-page*.

On January 28, 2022, we posted a public use file (PUF) at *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy2023-wage-index-home-page* containing FY 2023 wage index data available as of January 28, 2022. This PUF contains a tab with the Worksheet S–3 wage data (which includes Worksheet S–3, Parts II and III wage data from cost reporting periods beginning on or after October 1, 2018 through September 30, 2019; that is, FY 2019 wage data), a tab with the occupational mix data (which includes data from the CY 2019 occupational mix survey, Form CMS–10079), a tab containing the Worksheet S–3 wage data of hospitals deleted from the January 28, 2022 wage data PUF, and a tab containing the CY 2019 occupational mix data of the hospitals deleted from the January 28, 2022 occupational mix PUF. In a memorandum dated January 20, 2022, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the January 28, 2022 wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2023 Hospital Wage Index Development Time Table available at *https://www.cms.gov/files/document/fy2023-wi-time-table.pdf*.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on the CMS website that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door Forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and about the dates of the Hospital Open Door Forums at the CMS website at *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums*.

In a memorandum dated May 11, 2021, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the preliminary wage index data files and the CY 2019 occupational mix survey data files posted on May 24, 2021, and the process and timeframe for requesting revisions.

If a hospital wished to request a change to its data as shown in the May 24, 2021, preliminary wage data files and occupational mix data files, the hospital had to submit corrections along with complete, detailed supporting documentation to its MAC so that the MAC received them by September 2, 2021. Hospitals were notified of these deadlines and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the internet, through the letters sent to them by their MACs. We note, CMS issued a waiver due to Hurricane Ida and modified the September 2, 2021, deadline specified in the FY 2023 Hospital Wage Index Development Time Table for certain hospitals. Specifically, CMS granted an extension until October 4, 2021, for hospitals in the States of Louisiana and Mississippi to request revisions to and provide documentation for their FY 2019 Worksheet S–3 wage data and CY 2019 occupational mix data as included in the May 24, 2021 preliminary Public Use Files (PUFs), respectively. According to the waiver, MACs must receive the revision requests and supporting documentation by October 4, 2021. If hospitals encountered difficulty meeting the extended deadline, hospitals were to communicate their concerns to CMS via their MAC for CMS to consider an additional extension if CMS determined it was warranted. Details regarding this waiver are available on the CMS website at *https://www.cms.gov/current-non-covid-emergencies*, Additional IPPS Hospital Blanket Waivers (*https://www.cms.gov/files/document/hurrican-ida-additional-ipps-hospital-blanket-waivers.pdf*). November 15, 2021, was the deadline for MACs to complete all desk reviews for hospital wage and occupational mix data and transmit revised Worksheet S–3 wage data and occupational mix data to CMS.

November 4, 2021, was the date by when MACs notified State hospital associations regarding hospitals that failed to respond to issues raised during the desk reviews. Additional revisions made by the MACs were transmitted to CMS throughout January 2022. CMS published the wage index PUFs that included hospitals' revised wage index data on January 28, 2022. Hospitals had until February 15, 2022, to submit requests to the MACs to correct errors in the January 28, 2022 PUF due to CMS or MAC mishandling of the wage index data, or to revise desk review adjustments to their wage index data as included in the January 28, 2022, PUF. Hospitals also were required to submit sufficient documentation to support their requests. Hospitals' requests and supporting documentation must be received by the MAC by the February deadline (that is, by February 15, 2022, for the FY 2023 wage index).

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 18, 2022. Under our current policy as adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38153), the deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's handling of wage data on any basis (including a policy, factual, or other dispute) was April 1, 2022. Data that were incorrect in the preliminary or January 28, 2022 wage index data PUFs, but for which no correction request was received by the February 15, 2022 deadline, are not considered for correction at this stage. In addition, April 1, 2022, was the deadline for hospitals to dispute data corrections made by CMS of which the hospital was notified after the January 28, 2022, PUF and at least 14 calendar days prior to April 1, 2022 (that is, March 18, 2022), that do not arise from a hospital's request for revisions. The hospital's request and supporting documentation must be received by CMS (and a copy received by the MAC) by the April deadline (that is, by April 1, 2022, for the FY 2023 wage index). We refer readers to the FY 2023 Hospital Wage Index Development Time Table for complete details.

Hospitals are given the opportunity to examine Table 2 associated with this proposed rule, which is listed in section VI. of the Addendum to the proposed rule and available via the internet on the CMS website at *https://www.cms.gov/medicare/acute-inpatient-pps/fy-2023-ipps-proposed-rule-home-page*. Table 2 associated with the proposed rule contains each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the proposed FY 2023 wage index which was constructed from FY 2019 data. We note that the proposed hospital average hourly wages shown in Table 2 only reflected changes made to a hospital's data that were transmitted to CMS by early February 2022.

We plan to post the final wage index data PUFs in late April 2022 on the CMS website at *https://www.cms.gov/medicaremedicare-fee-service-payment acuteinpatientppswage-index-files/fy2023-wage-index-home-page*. The April 2022 PUFs are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the

final wage index data that resulted from the correction process previously described (the process for disputing revisions submitted to CMS by the MACs by March 18, 2022, and the process for disputing data corrections made by CMS that did not arise from a hospital's request for wage data revisions as discussed earlier).

After the release of the April 2022 wage index data PUFs, changes to the wage and occupational mix data can only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 18, 2022.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 28, 2022, wage index PUFs.
- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2022 final wage index data PUFs, a hospital believes that its wage or occupational mix data are incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital is given the opportunity to notify both its MAC and CMS regarding why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital is required to send its request to CMS and to the MAC so that it is received no later than May 27, 2022. May 27, 2022, is also the deadline for hospitals to dispute data corrections made by CMS of which the hospital is notified on or after 13 calendar days prior to April 1, 2022 (that is, March 19, 2022), and at least 14 calendar days prior to May 27, 2022 (that is, May 13, 2022), that do not arise from a hospital's request for revisions. (Data corrections made by CMS of which a hospital was notified on or after 13 calendar days prior to May 27, 2022 (that is, May 14, 2022), may be appealed to the Provider Reimbursement Review Board (PRRB)). In accordance with the FY 2023 Hospital Wage Index Development Time Table posted on the CMS website at *https://www.cms.gov/files/document/fy2023-wi-time-table.pdf*, the May appeals are required to be sent via mail and email to CMS and the MACs. We refer readers to the FY 2023 Hospital Wage Index Development Time Table for complete details.

Verified corrections to the wage index data received timely (that is, by May 27, 2022) by CMS and the MACs will be incorporated into the final FY 2023 wage index, which will be effective October 1, 2022.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2023 payment rates. Accordingly, hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines as previously set forth (requiring requests to MACs by the specified date in February and, where such requests are unsuccessful, requests for intervention by CMS by the specified date in April) will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections. As finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156), this policy also applies to a hospital disputing corrections made by CMS that do not arise from a hospital's request for a wage index data revision. That is, a hospital disputing an adjustment made by CMS that did not arise from a hospital's request for a wage index data revision is required to request a correction by the first applicable deadline. Hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute CMS' decision with respect to changes.

Again, we believe the wage index data correction process described earlier provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals had access to the final wage index data PUFs by late April 2022, they have an opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2023 wage index by August 2022, and the implementation of the FY 2023 wage index on October 1, 2022. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after May 27, 2022, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, ''before the beginning of the fiscal year'' means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 27, 2022, for the FY 2023 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS website prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 27, 2022, deadline for the FY 2023 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 27, 2022 deadline for the FY 2023 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in 42 CFR 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

2. Process for Data Corrections by CMS After the January 28 Public Use File (PUF)

The process set forth with the wage index time table discussed in section III.L.1. of the preamble of this proposed rule allows hospitals to request corrections to their wage index data within prescribed timeframes. In addition to hospitals' opportunity to request corrections of wage index data errors or MACs' mishandling of data, CMS has the authority under section 1886(d)(3)(E) of the Act to make corrections to hospital wage index and occupational mix data in order to ensure the accuracy of the wage index. As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56914), section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic areas of the hospital compared to the national average hospital wage level. We believe that, under section 1886(d)(3)(E) of the Act, we have discretion to make corrections to hospitals' data to help ensure that the costs attributable to wages and wage-related costs in fact accurately reflect the relative hospital wage level in the hospitals' geographic areas.

We have an established multistep, 15-month process for the review and correction of the hospital wage data that is used to create the IPPS wage index for the upcoming fiscal year. Since the origin of the IPPS, the wage index has been subject to its own annual review process, first by the MACs, and then by CMS. As a standard practice, after each annual desk review, CMS reviews the results of the MACs' desk reviews and focuses on items flagged during the desk review, requiring that, if necessary, hospitals provide additional documentation, adjustments, or corrections to the data. This ongoing communication with hospitals about their wage data may result in the discovery by CMS of additional items that were reported incorrectly or other data errors, even after the posting of the January 28 PUF, and throughout the remainder of the wage index development process. In addition, the fact that CMS analyzes the data from a regional and even national level, unlike the review performed by the MACs that review a limited subset of hospitals, can facilitate additional editing of the data that may not be readily apparent to the MACs. In these occasional instances, an error may be of sufficient magnitude that the wage index of an entire CBSA is affected. Accordingly, CMS uses its authority to ensure that the wage index accurately reflects the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, by continuing to make corrections to hospital wage data upon discovering incorrect wage data, distinct from instances in which hospitals request data revisions.

We note that CMS corrects errors to hospital wage data as appropriate, regardless of whether that correction will raise or lower a hospital's average hourly wage. For example, as discussed in section III.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41364), in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). Furthermore, if CMS discovers after conclusion of the desk review, for example, that a MAC inadvertently failed to incorporate positive adjustments resulting from a prior year's wage index appeal of a hospital's wage-related costs such as pension, CMS would correct that data error and the hospital's average hourly wage would likely increase as a result.

While we maintain CMS' authority to conduct additional review and make resulting corrections at any time during the wage index development process, in accordance with the policy finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156) and as first implemented with the FY 2019 wage index (83 FR 41389), hospitals are able to request further review of a correction made by CMS that did not arise from a hospital's request for a wage index data correction. Instances where CMS makes a correction to a hospital's data after the January 28 PUF based on a different understanding than the hospital about certain reported costs, for example, could potentially be resolved using this process before the final wage index is calculated. We believe this process and the timeline for requesting review of such corrections (as described earlier and in the FY 2018 IPPS/LTCH PPS final rule) promote additional transparency to instances where CMS makes data corrections after the January 28 PUF, and provide opportunities for hospitals to request further review of CMS changes in time for the most accurate data to be reflected in the final wage index calculations. These additional appeals opportunities are described earlier and in the FY 2023 Hospital Wage Index Development Time Table, as well as in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156).

M. Proposed Labor-Related Share for the FY 2023 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs that are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the

Act to provide that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate from time to time the proportion of hospitals' costs that are attributable to wages and wage-related costs. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45208), we rebased and revised the hospital market basket. We established a 2018-based IPPS hospital market basket to replace the FY 2014-based IPPS hospital market basket, effective October 1, 2021. Using the 2018-based IPPS market basket, we finalized a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2021. In addition, in FY 2022, we implemented this revised and rebased labor-related share in a budget neutral manner (86 FR 45193). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45204 through 45207), we included in the labor-related share the national average proportion of operating costs that are attributable to the following cost categories in the 2018-based IPPS market basket: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; and All Other: Labor-related Services. In this proposed rule, for FY 2023, we are not proposing to make any further changes to the labor-related share. For FY 2023, we are proposing to continue to use a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2022.

As discussed in section V.A. of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national labor-related share and nonlabor-related share percentages that are applied to the national standardized amount. Accordingly, for FY 2023, we are not proposing a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2023 IPPS/LTCH PPS proposed rule and available via the internet on the CMS website, reflect the proposed national labor-related share. Table 1C, in section VI. of the Addendum to this FY 2023 IPPS/LTCH PPS proposed rule and available via the internet on the CMS website, reflects the proposed national labor-related share for hospitals located in Puerto Rico. For FY 2023, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2023, we are proposing to apply the wage index to a proposed labor-related share of 67.6 percent of the national standardized amount.

N. Proposed Permanent Cap on Wage Index Decreases

1. Proposed Permanent Cap Policy for the Wage Index

In the FY 2020 IPPS/LTCH PPS final rule, CMS implemented a transition policy for FY 2020 to place a 5 percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019 so that a hospital's final wage index for FY 2020 will not be less than 95 percent of its final wage index for FY 2019 (84 FR 42336 through 42337). We implemented this transition due to the combined effect of the policy changes for the FY 2020 wage index (including policies to address wage index disparities between high and low wage index hospitals), which we believed could lead to significant decreases in the wage index values for some hospitals. We stated that this transition would allow the effects of our proposed policies to be phased in over 2 years with no estimated reduction in the wage index of more than 5 percent in FY 2020 (that is, no cap would be applied the second year). We also stated that we believed 5 percent is a reasonable level for the cap because it would effectively mitigate any significant decreases in the wage index for FY 2020. We applied a budget neutrality adjustment factor to the FY 2020 standardized amount for all hospitals to achieve budget neutrality for the transition policy (84 FR 42337 through 42338).

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58753 through 58755), to mitigate the effect of our adoption of the revised OMB delineations in OMB Bulletin 18–04, we implemented for FY 2021 the same 5 percent cap transition policy that we had implemented for FY 2020. Specifically, we placed a 5 percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2020 so that a hospital's final wage index for FY 2021 will not be less than 95 percent of its final wage index for FY 2020. We stated that for FY 2021, we did not believe it was necessary to implement the multifaceted transitions (including a 1-year blended wage index) we established in FY 2015 for the adoption of the new OMB delineations based on the new decennial census data. The 5 percent cap transition policy resulted in some hospitals receiving a transition adjustment that were not directly affected by the adoption of the revised OMB delineations (85 FR 58754). We applied a budget neutrality adjustment to the FY 2021 standardized amount to achieve budget neutrality for the transition policy (85 FR 58755).

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25397), given the unprecedented nature of the ongoing COVID–19 PHE, we solicited comments on whether it would be appropriate to continue to apply a transition to the FY 2022 wage index for hospitals negatively impacted by our adoption of the updates in OMB Bulletin 18–04. We received several comments strongly recommending CMS extend a transition policy similar to that implemented in FY 2020 and FY 2021. Commenters also recommended CMS consider making a permanent 5 percent maximum reduction policy to protect hospitals from large year-to-year variations in wage index values as a means to reduce overall volatility. While we did not adopt the commenters' suggestion for a permanent 5 percent cap policy, we did finalize a transition policy for FY 2022 in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45164). Specifically, for hospitals that received the transition in FY 2021, we continued a wage index transition for FY 2022 under which we apply a 5 percent cap on any decrease in the hospital's wage index compared to its wage index for FY 2021 to mitigate significant negative impacts of, and provide additional time for hospitals to adapt to, the CMS decision to adopt the revised OMB delineations. We applied a budget neutrality adjustment to the FY 2022 standardized amount so that the transition is implemented in a budget neutral manner (86 FR 45165).

For FY 2023 and subsequent years, we have further considered the comments we received during the FY 2022 rulemaking recommending a permanent 5 percent cap policy to prevent large year-to-year variations in wage index values as a means to reduce overall volatility for hospitals. In the past, we have established temporary transition policies (as described above) when there have been significant changes to wage index policy, and we have limited the duration of each transition in order to phase in the effects of those policy changes. In taking this temporary approach in the past, we have sought to mitigate short-term instability and fluctuations that can negatively impact hospitals. We also recognize that, absent any specific change in wage index policy, significant year-to-year fluctuations in an area's wage index can occur due to external factors beyond a hospital's control, such as the COVID–19 PHE. For an individual hospital, these fluctuations can be difficult to predict. We recognize that predictability in Medicare payments is important to enable hospitals to budget and plan their operations.

In light of these considerations, we are proposing a permanent approach to smooth year-to-year decreases in hospitals' wage indexes. We are proposing a policy that we believe increases the predictability of IPPS payments for hospitals and mitigates instability and significant negative impacts to hospitals resulting from changes to the wage index. We also believe our proposed permanent policy would eliminate the need for temporary and potentially uncertain transition adjustments to the wage index in the future due to specific policy changes or circumstances outside hospitals' control (for example, in the event we adopt any future OMB revisions to the CBSA delineations). As a result of this proposed policy, an otherwise rare but relatively large year-to-year decrease in the wage index value for an individual hospital would be phased in, providing the hospital with additional time to plan appropriately and explore potential reclassification options, if applicable. For example, if a change in OMB delineations resulted in a hospital's wage index decreasing by more than 10 percent in any given year, this proposed policy could provide at least one additional year to phase in the decrease beyond a single ''transition'' year methodology, such as the transition policy finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49962).

Typical year-to-year variation in the wage index has historically been within 5 percent, and we expect this will continue to be the case in future years. Because hospitals are usually experienced with this level of wage index fluctuation, we believe applying a 5-percent cap on all wage index decreases each year, regardless of the reason for the decrease, would effectively mitigate instability in IPPS payments due to any significant wage index decreases that may affect hospitals in a year. In addition, we believe that the predictability resulting from a 5 percent cap on all wage index decreases would enable hospitals to more effectively budget and plan their operations. Because applying a 5-percent cap on all wage index decreases would represent a small overall impact on the labor market area wage index system, we believe it would ensure the wage index is a relative measure of the value of labor in prescribed labor market areas. We estimate that applying a 5-percent cap on all wage index decreases would have a very small effect on the proposed budget neutrality factor associated with the proposed cap applied to the standardized amount for FY 2023 (discussed in section III.N.2 of the preamble of this proposed rule). Because the wage index is a measure of the value of labor (wage and wage-related costs) in a prescribed labor market area relative to the national average, we anticipate that in the absence of proposed policy changes most hospitals will not experience year-to-year wage index declines greater than 5 percent in any given year. Therefore, we anticipate that the impact to the proposed budget neutrality factor associated with the proposed cap in future years would continue to be minimal. We also believe that when the 5-percent cap would be applied under this proposal, in general it is likely that it would be applied similarly to all hospitals in the same labor market area, as the hospital average hourly wage data in the CBSA (and any relative decreases compared to the national average hourly wage) would be similar. While in certain circumstances this policy may result in some hospitals in a CBSA receiving a higher wage index than others in the same area, we believe the impact would be temporary.

For the reasons discussed in this section, we believe a 5-percent cap on wage index decreases would be appropriate for the IPPS. Therefore, for FY 2023 and subsequent years, we are proposing to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, we are proposing that a hospital's wage index for FY 2023 would not be less than 95 percent of its final wage index for FY 2022, and that for subsequent years, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. This also means that if a hospital's prior FY wage index is calculated with the application of the 5-percent cap, the following year's wage index would not be less than 95 percent of the hospital's capped wage index in the prior FY. For example, if a hospital's wage index for FY 2023 is calculated with the application of the 5-percent cap, then its wage index for FY 2024 would not be less than 95 percent of its capped wage index in FY 2023. We would reflect the proposed wage index cap policy at 42 CFR 412.64(h). Specifically, we are proposing to add a new paragraph at 42 CFR 412.64(h)(7) to state that beginning with fiscal year 2023, if CMS determines that a hospital's wage index value for a fiscal year would decrease by more than 5 percent as compared to the hospital's wage index value for the prior fiscal year, CMS limits the decrease to 5 percent for the fiscal year.

We have authority to implement this proposed wage index cap policy and the associated proposed budget neutrality adjustment (discussed below in section III.N.2. of the preamble of this proposed rule) under section 1886(d)(3)(E) of the Act, which gives the Secretary broad authority to adjust for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, and requires those adjustments to be budget neutral. In addition, we have authority to implement this proposed wage index cap policy and the associated proposed budget neutrality adjustment (discussed below in section III.N.2. of the preamble of this proposed rule) as an adjustment under section 1886(d)(5)(I)(i) of the Act, which similarly gives the Secretary broad authority to provide by regulation for such other exceptions and adjustments to such payment amounts under subsection (d) as the Secretary deems appropriate.

We are proposing to apply the proposed wage index cap policy described above for a FY using the final wage index applicable to the hospital on the last day of the prior FY (except for newly opened hospitals, as discussed below). In general, the final wage index applicable to the hospital on the last day of the prior FY would be the wage index value listed for the hospital in Table 2 of the IPPS/LTCH PPS final rule for that prior FY (including any correction notices, if applicable). In rulemaking for a FY, we intend to relist the wage index values from Table 2 of the IPPS/LTCH PPS final rule for the prior FY, with updates as described below. Under the proposed wage index cap policy described above, we would use these values to determine a hospital's wage index for a FY by capping it at 95 percent of the final wage index applicable to the hospital on the last day of the prior FY (in general, the wage index value listed for the hospital in Table 2 of the IPPS/LTCH PPS final rule for the prior FY). We note, consistent with our past application of the 5 percent cap transition policy (see the FY 2020 IPPS/LTCH PPS final rule (84 FR 42337)), the proposed wage index cap policy described above would apply to hospitals whose wage index is reduced by obtaining a urban to rural reclassification under 42 CFR 412.103. Specifically, a hospital that obtains a rural reclassification under 42 CFR 412.103 may be assigned its State's rural wage index.[601] While other forms of wage index reclassification are effective with the start of a Federal fiscal year, pursuant to 42 CFR 412.103(d)(1), the effective date of an approved rural reclassification is the filing date of the application. Therefore, the wage index values for hospitals that obtain rural reclassification under 42 CFR 412.103 may change in the middle of a Federal fiscal year and thus may not be reflected in Table 2 of the IPPS/LTCH PPS final rule for that year. For example, if a hospital was assigned its geographic wage index of 1.0001 in Table 2 of the FY 2022 IPPS/LTCH PPS final rule, but obtained a rural reclassification on December 1, 2021 and was assigned its state's rural wage index of 0.9600 for the remainder of FY 2022; the FY 2023 cap would be based on the 0.9600 value, not the 1.0001 value listed in Table 2 of the FY 2022 IPPS/LTCH PPS final rule. As in previous years, we would instruct hospitals that obtain a rural reclassification under 42 CFR 412.103 to contact their MAC to ensure that their assigned wage index does not result in a greater than 5 percent decrease from the hospital's prior year wage index value (see the FY 2020 IPPS/LTCH PPS final rule (84 FR 42337) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58754)).

In Table 2 associated with this proposed rule, which is available via the internet on the CMS website, we list the FY 2022 final wage index value for all hospitals in column C. For additional clarity, we have identified hospitals that have obtained rural reclassification after the FY 2022 lock-in date, as described in 42 CFR 412.103(b)(6), and that were assigned a different wage index than what was listed in Table 2 associated with the FY 2022 IPPS/LTCH PPS correction notice (available on the internet at *https://www.cms.gov/files/zip/fy-2022-ipps-fr-tables-2-3-4a-4b.zip*). In Table 2 associated with this proposed rule, the FY 2022 wage index column for these hospitals will not use the values listed in Table 2 associated with the FY 2022 IPPS/LTCH PPS correction notice (available on the internet at *https://www.cms.gov/files/zip/fy-2022-ipps-fr-tables-2-3-4a-4b.zip*), but will instead be updated with the wage index value that is currently assigned to the hospitals. Under our proposal described above, we would apply the proposed wage index cap using the actual final wage index value assigned to the hospital on the last day of the prior Federal fiscal year rather than the value listed in Table 2 of the prior FY final rule. We are providing a supplemental data file (posted on the FY 2023 proposed rule web page at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*) which lists all hospitals that have obtained rural reclassification under 42 CFR 412.103 after the FY 2022 lock-in date and that have no other form of wage index reclassification applicable to them at this time. This list will be revised for the final rule to add additional hospitals without another form of reclassification that obtain rural reclassification under 42 CFR 412.103 before the FY 2023 lock-in date as described in 42 CFR 412.103(b)(6).

Hospitals that obtain rural reclassification after the FY 2023 lock-in date will not be listed as being reclassified as rural in the FY 2023 IPPS/LTCH PPS final rule. If we finalize the proposed wage index cap policy described above, these hospitals should contact their MAC to ensure that the assigned rural wage index value is not less than 95 percent of their final wage index value for FY 2022 (that is, the wage index assigned to the hospital as of September 30, 2022).

For newly opened hospitals, we propose to apply the proposed wage index cap policy described previously for a FY using the wage index value the hospital was assigned for the prior FY. A new hospital would be paid the wage index for the area in which it is geographically located for its first full or partial fiscal year, and it would not receive a cap for that first year because it would not have been assigned a wage index in the prior year. Also, it is possible a new hospital may not be listed in Table 2 for several years since the hospitals listed in Table 2 are based on historical data. If we finalize the proposed wage index cap policy described above, a new hospital may contact their MAC to ensure that their assigned wage index value for the upcoming FY is not less than 95 percent of the value assigned to them for the prior Federal fiscal year. For example, if a hospital begins operations on July 1, 2022, and is assigned its area wage index of 0.9000 for the remainder of FY 2022, its FY 2023 wage index would be capped at 95 percent of that value, and could not be lower than 0.8550 (0.95×0.9000) regardless of whether it was listed in Table 2 in the FY 2022 IPPS/LTCH PPS final rule. A hospital that opens on December 1, 2022 would not be eligible for a capped wage index in FY 2023, as it was not assigned a wage index during FY 2022.We finally note

[601] As discussed in the FY 2016 IFC (81 FR 23428 through 23438), hospitals with simultaneous reclassifications under 412.103 and either Lugar or MGCRB reclassification process are not assigned their State's rural wage index.

that if we adopt these proposals as final policy, we would examine the effects of the policy on an ongoing basis in the future in order to assess whether it effectively and appropriately accomplishes the goal of increasing predictability and stability in IPPS payments.

2. Proposed Permanent Cap Budget Neutrality

We are proposing to implement the proposed wage index cap policy (discussed above in section III.N.1 of the preamble of this proposed rule) in a budget neutral manner through a national adjustment to the standardized amount each fiscal year as we have implemented similar past transition policies involving a cap on wage index decreases (for example, see the FY 2021 IPPS/LTCH PPS final rule (85 FR 58755) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45164 through 45165)). We believe application of the proposed wage index cap policy should not increase estimated aggregate Medicare payments beyond the payments that would be made had we never applied the cap.

Specifically, we are proposing to apply a budget neutrality adjustment to ensure that estimated aggregate payments under our proposed wage index cap policy for hospitals that would have a decrease in their wage indexes for the upcoming fiscal year of more than 5 percent would equal what estimated aggregate payments would have been without the proposed wage index cap policy. To determine the proposed associated budget neutrality factor, we compare estimated aggregate IPPS payments with and without the proposed wage index cap policy. As discussed above in section III.N.1 of the preamble of this proposed rule, we have authority to implement this proposed budget neutrality adjustment under sections 1886(d)(3)(E) and (d)(5)(I)(i) of the Act. We note that the proposed budget neutrality adjustment would be updated, as appropriate, based on the final rule data. We refer readers to the Addendum of this proposed rule for further information regarding the proposed budget neutrality calculations.

IV. Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2023 (§ 412.106)

A. General Discussion

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: The ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the statutory references to ''days'' in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at 42 CFR 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act, as amended by section 10316 of the same Act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. (For purposes of this proposed rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.) Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

Section 1886(r) of the Act requires that, for FY 2014 and each subsequent fiscal year, a subsection (d) hospital that would otherwise receive DSH payments made under section 1886(d)(5)(F) of the Act receives two separately calculated payments. Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such subsection (d) hospital (including a Pickle hospital) 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to Congress. We refer to this payment as the ''empirically justified Medicare DSH payment.''

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospital an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are

made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year. Therefore, this factor amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FY 2018 and subsequent fiscal years, 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS), and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus a statutory adjustment of 0.2 percentage point for FYs 2018 and 2019.

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the ''uncompensated care payment.''

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which was established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or the periods selected in order to develop such estimates.

B. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As explained earlier, the payment methodology under section 3133 of the Affordable Care Act applies to ''subsection (d) hospitals'' that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year in order to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to such subsection (d) hospitals an additional amount. Because section 1886(r)(1) of the Act refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) of the Act is limited to hospitals that receive empirically justified Medicare DSH payments in accordance with section 1886(r)(1) of the Act for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we provided that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). For this proposed rule, we estimated DSH status for all hospitals using the most recent available SSI ratios and information from the most recent available Provider Specific File. We note FY 2019 SSI ratios available on the CMS website are the most recent available SSI ratios at the time of developing this proposed rule. If more recent data on DSH eligibility become available before the final rule, then we would use such data in the final rule. Our final determination on a hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and in the rulemaking for subsequent fiscal years, we have specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. In this FY 2023 IPPS/LTCH PPS proposed rule, we discuss our specific policies regarding eligibility to receive empirically justified Medicare DSH payments and uncompensated care payments for FY 2023 with respect to the following hospitals:

- *Subsection (d) Puerto Rico hospitals* that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology (78 FR 50623 and 79 FR 50006).
- *Maryland hospitals* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41402 through 41403), CMS and the State have entered into an agreement to govern payments to Maryland hospitals under a new payment model, the Maryland Total Cost of Care (TCOC) Model, which began on January 1, 2019. Under the Maryland TCOC Model, Maryland hospitals will not be paid under the IPPS in FY 2023, and will be ineligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act.
- *Sole community hospitals* (*SCHs) that are paid under their hospital-specific rate* are not eligible for Medicare DSH payments. SCHs that are paid under the IPPS Federal rate receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the Federal fiscal year (based on the best available data at that time) subject to settlement through the cost report, and if they receive interim empirically justified

Medicare DSH payments in a fiscal year, they also will receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject as well to settlement through the cost report. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).

• *Medicare-dependent, small rural hospitals (MDHs)* are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate that is used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted on February 9, 2018, extended the MDH program for discharges on or after October 1, 2017, through September 30, 2022. Because MDHs are paid based on the IPPS Federal rate, they continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent, and we apply the same process to determine MDHs' eligibility for interim empirically justified Medicare DSH and interim uncompensated care payments as we do for all other IPPS hospitals.

We note that there has not been legislation at the time of development of this proposed rule that would extend the MDH program beyond September 30, 2022. However, if the MDH program were to be extended beyond its current expiration date, similar to how it was extended under the Bipartisan Budget Act of 2018, we would continue to make a determination concerning an MDH's eligibility for interim uncompensated care payments based on the hospital's estimated DSH status for the applicable fiscal year.

• *IPPS hospitals that elect to participate in the Bundled Payments for Care Improvement Advanced (BPCI Advanced) model starting October 1, 2018,* will continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. The BPCI Advanced Model's final performance year will end on December 31, 2023. For further information regarding the BPCI Advanced model, we refer readers to the CMS website at *https://innovation.cms.gov/initiatives/bpci-advanced/*.

• *IPPS hospitals that participate in the Comprehensive Care for Joint Replacement Model* (80 FR 73300) continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. We refer the reader to the interim final rule with request for comments that appeared in the November 6, 2020, **Federal Register** for a discussion of the Model (85 FR 71167 through 71173). In that interim final rule, we extended the Model's Performance Year 5 to September 30, 2021. In a subsequent final rule that appeared in the May 3, 2021 **Federal Register** (86 FR 23496), we further extended the Model for an additional three performance years. The Model's Performance Year 8 will end on December 31, 2024.

• *Hospitals participating in the Rural Community Hospital Demonstration Program* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act because they are not paid under the IPPS (78 FR 50625 and 79 FR 50008). The Rural Community Hospital Demonstration Program was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 114–255). The period of performance for this 5-year extension period ended December 31, 2016. Section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, again amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act), therefore requiring an additional 5-year participation period for the demonstration program. Section 15003 of Public Law 114–255 also required a solicitation for applications for additional hospitals to participate in the demonstration program. The period of performance for this 5-year extension period ended December 31, 2021. The Consolidated Appropriations Act, 2021 (Pub. L. 116–260) amended section 410A of Public Law 108–173 to extend the Rural Community Hospital Demonstration Program for an additional 5-year period. The period of participation for the last hospital in the demonstration under this most recent legislative authorization would extend until June 30, 2028, as outlined in section V.K. of the preamble of this proposed rule. Under the payment methodology that applies during the third 5-year extension period for the demonstration program, participating hospitals do not receive empirically justified Medicare DSH payments, and they are also excluded from receiving interim and final uncompensated care payments. At the time of development of this proposed rule, we believe 26 hospitals may participate in the demonstration program at the start of FY 2023.

C. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the program to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising Medicare Administrative Contractors (MACs) to simply adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments can be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html*.

D. Uncompensated Care Payments

As we discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors. These three factors represent our estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of

uninsurance in 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. In this section of the preamble of this proposed rule, we discuss the data sources and methodologies for computing each of these factors, our final policies for FYs 2014 through 2022, and our proposed policies for FY 2023.

1. Proposed Calculation of Factor 1 for FY 2023

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. Section 1886(r)(2)(A) of the Act states that this factor is equal to the difference between: (1) The aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year (as estimated by the Secretary); and (2) the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year (as so estimated). Therefore, section 1886(r)(2)(A)(i) of the Act represents the estimated Medicare DSH payments that would have been made under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amount that would be paid for a Federal fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the Federal fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount, by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, section 1886(r)(2)(A)(ii) of the Act represents the estimated empirically justified Medicare DSH payments to be made in a fiscal year, as prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount. Therefore, Factor 1 is the difference between our estimates of: (1) The amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act. In other words, this factor represents our estimate of 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

In this FY 2023 IPPS/LTCH PPS proposed rule, in order to determine Factor 1 in the uncompensated care payment formula for FY 2023, we are proposing to continue the policy established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194) of determining Factor 1 by developing estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments to hospitals under section 1886(r)(1) of the Act. Consistent with the policy that has applied in previous years, these estimates will not be revised or updated subsequent to the publication of our final projections in the FY 2023 IPPS/LTCH PPS final rule.

Therefore, in order to determine the two elements of proposed Factor 1 for FY 2023 (Medicare DSH payments prior to the application of section 1886(r)(1) of the Act, and empirically justified Medicare DSH payments after application of section 1886(r)(1) of the Act), for this proposed rule, we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by CMS' Office of the Actuary (OACT) using the most recently filed Medicare hospital cost reports with Medicare DSH payment information and the most recent Medicare DSH patient percentages and Medicare DSH payment adjustments provided in the IPPS Impact File. The determination of the amount of DSH payments is partially based on OACT's Part A benefits projection model. One of the results of this model is inpatient hospital spending. Projections of DSH payments require projections for expected increases in utilization and case-mix. The assumptions that were used in making these projections and the resulting estimates of DSH payments for FY 2020 through FY 2023 are discussed in the table titled ''Factors Applied for FY 2020 through FY 2023 to Estimate Medicare DSH Expenditures Using FY 2019 Baseline.''

For purposes of calculating Factor 1 and modeling the impact of this FY 2023 IPPS/LTCH PPS proposed rule, we used the Office of the Actuary's January 2022 Medicare DSH estimates, which were based on data from the September 2021 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2022 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2022 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are excluded from the application of section 1886(r) of the Act, these hospitals also were excluded from the January 2022 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified Medicare DSH payment (25 percent of DSH payments that would be made without regard to section 1886(r) of the Act), Maryland hospitals, which are not eligible to receive DSH payments, were also excluded from the Office of the Actuary's January 2022 Medicare DSH estimates. The 26 hospitals that are anticipated to participate in the Rural Community Hospital Demonstration Program in FY 2023 were also excluded from these estimates, because under the payment methodology that applies during the third 5-year extension period, these hospitals are not eligible to receive empirically justified Medicare DSH payments or uncompensated care payments.

For this proposed rule, using the data sources as previously discussed, the Office of the Actuary's January 2022 estimate of Medicare DSH payments for FY 2023 without regard to the application of section 1886(r)(1) of the Act, is approximately $13.266 billion. Therefore, also based on the January 2022 estimate, the estimate of empirically justified Medicare DSH payments for FY 2023, with the application of section 1886(r)(1) of the Act, is approximately $3.316 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2023). Under § 412.106(g)(1)(i) of the regulations, Factor 1 is the difference between these two OACT estimates. Therefore, in this proposed rule, we are proposing that Factor 1 for FY 2023 would be $9,949,258,556.56, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2023 ($13,266 million minus $3,316 million). We note that consistent with our approach in previous rulemakings, OACT intends to use more recent data that may become available for purposes of projecting the final Factor 1 estimates for the FY 2023 IPPS/LTCH PPS final rule.

The Factor 1 estimates for proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and

the Factor 1 estimates for the final rule are generally consistent with those used for the Midsession Review of the President's Budget. As we have in the past, for additional information on the development of the President's Budget, we refer readers to the Office of Management and Budget website at *https://www.whitehouse.gov/omb/budget*. Consistent with historical practice, we expect that the Midsession Review will have updated economic assumptions and actuarial analysis, which would be used for the development of Factor 1 estimates in the final rule.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2021 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'' available on the CMS website at *https://www.cms.gov/research/statistics/data/and-systems/statistics/trends/and/reports/reportstrustfunds* under ''Downloads.'' We note that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

We also refer readers to the 2018 Actuarial Report on the Financial Outlook for Medicaid for a discussion of general issues regarding Medicaid projections (available at *https://www.cms.gov/Research/Statistics/Data-and/Systems/Research/Actuarial Studies/MedicaidReport*).

In this proposed rule, we include information regarding the data sources, methods, and assumptions employed by the actuaries in determining the OACT's estimate of Factor 1. In summary, we indicate the historical HCRIS data update OACT used to identify Medicare DSH payments, we explain that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provide the components of all the update factors that were applied to the historical data to estimate the Medicare DSH payments for the upcoming fiscal year, along with the associated rationale and assumptions. This discussion also includes a description of the ''Other'' and ''Discharges'' assumptions, and also provides additional information regarding how we address the Medicaid and CHIP expansion.

The Office of the Actuary's estimates for FY 2023 for this proposed rule began with a baseline of $13.808 billion in Medicare DSH expenditures for FY 2019. The following table shows the factors applied to update this baseline through the current estimate for FY 2023:

Factors Applied for FY 2020 through FY 2023 to Estimate Medicare DSH Expenditures Using FY 2019 Baseline

FY	Update	Discharges	Case-Mix	Other	Total	Estimated DSH Payment (in billions)*
2020	1.031	0.862	1.038	0.9890	0.9123	12.598
2021	1.029	0.947	1.029	0.9842	0.9869	12.432
2022	1.025	1.007	0.990	1.0084	1.0304	12.811
2023	1.032	1.010	0.990	1.0035	1.0355	13.266

*Rounded.

In this table, the discharges column shows the changes in the number of Medicare fee-for-service (FFS) inpatient hospital discharges. The discharge figures for FY 2020 and FY 2021 are based on Medicare claims data that have been adjusted by a completion factor to account for incomplete claims data. We note that these claims include the impact of the pandemic. The discharge figure for FY 2022 is based on preliminary data. The discharge figure for FY 2023 is an assumption based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare Advantage (MA) plans. The discharge figures for FY 2020 to FY 2023 reflect the actual impact and estimated future impact of the COVID–19 pandemic. The case-mix column shows the estimated change in case-mix for IPPS hospitals. The case-mix figures for FY 2020 and FY 2021 are based on actual claims data adjusted by a completion factor. We note that these claims include the impact of the pandemic. The case-mix figure for FY 2022 is based on preliminary data. The case-mix factor figures for FY 2020 to FY 2023 reflect the actual impact and estimated future impact of the COVID–19 pandemic. The ''Other'' column shows the increase in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and the IPPS discharges, and various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the change in rates for the 2-midnight stay policy and the 20 percent add-on for COVID–19 discharges). In addition, the ''Other'' column includes a factor for the Medicaid expansion due to the Affordable Care Act. The factor for Medicaid expansion was developed using public information and statements for each State regarding its intent to implement the expansion. Based on the information available at the time of development of this proposed rule, it is assumed that approximately 55 percent of all individuals who were potentially newly eligible Medicaid enrollees in 2018, 2019, and 2020 resided in States that had elected to expand Medicaid eligibility, and approximately 60 percent of all individuals who were potentially newly eligible Medicaid enrollees in 2021–2023 and approximately 75 percent in 2024 and thereafter, resided in States that had elected to expand Medicaid eligibility. In the future, these assumptions may change based on actual participation by States. The ''Other'' column also includes the estimated impacts on Medicaid enrollment from the COVID–19 pandemic. We note that, based on the

most recent available data, Medicaid enrollment is estimated to change as follows: 2.0 percent in FY 2020, 9.5 percent in FY 2021, 4.2 percent in FY 2022, and -5.7 percent in FY 2023.

For a discussion of general issues regarding Medicaid projections, we refer readers to the 2018 Actuarial Report on the Financial Outlook for Medicaid, which is available on the CMS website at *https://www.cms.gov/Researc/Statistics/Data/and/Systems/Research/ActuarialStudies/MedicaidReport*. We note that, in developing their estimates of the effect of Medicaid expansion on Medicare DSH expenditures, our actuaries have assumed that the new Medicaid enrollees are healthier than the average Medicaid recipient and, therefore, use fewer hospital services. Specifically, based on the most recent available data at the time of developing this proposed rule, the OACT assumed per capita spending for Medicaid beneficiaries who enrolled due to the expansion to be 80 percent of the average per capita expenditures for a pre-expansion Medicaid beneficiary due to the better health of these beneficiaries. The same assumption was used for the new Medicaid beneficiaries who enrolled in 2020 and thereafter due to the COVID–19 pandemic. This assumption is consistent with recent internal estimates of Medicaid per capita spending pre-expansion and post-expansion. In the future, the assumption about the average per-capita expenditures of Medicaid beneficiaries who enrolled due to the COVID–19 pandemic may change, given that the pandemic is ongoing.

The following table shows the factors that are included in the ''Update'' column of the previous table:

FY	Market Basket Percentage	Affordable Care Act Payment Reductions	Productivity Adjustment	Documentation and Coding	Total Update Percentage
2020	3.0	0	-0.4	0.5	3.1
2021	2.4	0	0	0.5	2.9
2022	2.7	0	-0.7	0.5	2.5
2023	3.1	0	-0.4	0.5	3.2

Note: All numbers are the inpatient hospital updates for the applicable year, except for the FY 2023 percentages, which are based on the most recent forecast. We refer readers to section V.A. of the preamble of this proposed rule for a complete discussion of the proposed changes in the inpatient hospital update for FY 2023.

2. Calculation of Proposed Factor 2 for FY 2023

(a) Background

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Section 1886(r)(2)(B)(ii) of the Act provides that, for FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019. In FY 2020 and subsequent fiscal years, there is no longer a reduction. We note that, unlike section 1886(r)(2)(B)(i) of the Act, which governed the calculation of Factor 2 for FYs 2014, 2015, 2016, and 2017, section 1886(r)(2)(B)(ii) of the Act permits the use of a data source other than the CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. In addition, for FY 2018 and subsequent years, the statute does not require that the estimate of the percent of individuals who are uninsured be limited to individuals who are under 65 years of age. We are proposing to use a methodology similar to the one that was used in FY 2018 through FY 2022 to determine Factor 2 for FY 2023.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197 and 38198), we explained that we determined the data source for the rate of uninsurance that, on balance, best meets all of our considerations and is consistent with the statutory requirement that the estimate of the rate of uninsurance be based on data from the Census Bureau or other sources the Secretary determines appropriate is the uninsured estimates produced by OACT as part of the development of the National Health Expenditure Accounts (NHEA). The NHEA represents the government's official estimates of economic activity (spending) within the health sector. The information contained in the NHEA has been used to study numerous topics related to the health care sector, including, but not limited to, changes in the amount and cost of health services purchased and the payers or programs that provide or purchase these services; the economic causal factors at work in the health sector; the impact of policy changes, including major health reform; and comparisons to other countries' health spending. Of relevance to the determination of Factor 2 is that the comprehensive and integrated structure of the NHEA creates an ideal tool for evaluating changes to the health care system, such as the mix of the insured and uninsured, because this information is integral to the well-established NHEA methodology. A full description of the methodology used to develop the NHEA is available on the CMS website at *https://www.cms.gov/files/document/definitions-sources-and-methods.pdf*. We note that the NHEA estimates of uninsurance are for the total resident-based U.S. population, including all people who usually reside in the 50 States or the District of Columbia, but excluding individuals living in Puerto Rico and areas under U.S. sovereignty, members of the U.S. Armed Forces overseas, and U.S. citizens whose usual place of residence is outside the U.S., plus a small (typically less that 0.2 percent of population) adjustment to reflect Census undercounts. Thus, the NHEA estimates of uninsurance are for U.S. residents of all ages and are not limited to a specific age cohort, such as the population under the age of 65. As we explained in the FY 2018 IPPS/

LTCH PPS proposed and final rules, we believe it is appropriate to use an estimate that reflects the rate of uninsurance in the U.S. across all age groups. In addition, we continue to believe that a resident-based population estimate more fully reflects the levels of uninsurance in the U.S. that influence uncompensated care for hospitals than an estimate that reflects only legal residents.

The NHEA includes comprehensive enrollment estimates for total private health insurance (PHI) (including direct and employer-sponsored plans), Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and other public programs, and estimates of the number of individuals who are uninsured. Estimates of total PHI enrollment are available for 1960 through 2020, estimates of Medicaid, Medicare, and CHIP enrollment are available for the length of the respective programs, and all other estimates (including the more detailed estimates of direct-purchased and employer-sponsored insurance) are available for 1987 through 2020. The NHEA data are publicly available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html*.

In order to compute Factor 2, the first metric that is needed is the proportion of the total U.S. population that was uninsured in 2013. In developing the estimates for the NHEA, OACT's methodology included using the number of uninsured individuals for 1987 through 2009 based on the enhanced Current Population Survey (CPS) from the State Health Access Data Assistance Center (SHADAC). The CPS, sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics (BLS), is the primary source of labor force statistics for the population of the United States. (We refer readers to the website at *https://www.census.gov/programs-surveys/cps.html*.) The enhanced CPS, available from SHADAC (available at *http://datacenter.shadac.org*) accounts for changes in the CPS methodology over time. OACT further adjusts the enhanced CPS for an estimated undercount of Medicaid enrollees (a population that is often not fully captured in surveys that include Medicaid enrollees due to a perceived stigma associated with being enrolled in the Medicaid program or confusion about the source of their health insurance).

To estimate the number of uninsured individuals for 2010 through 2018, OACT extrapolates from the 2009 CPS data through 2018 using data from the National Health Interview Survey (NHIS). The NHIS is one of the major data collection programs of the National Center for Health Statistics (NCHS), which is part of the Centers for Disease Control and Prevention (CDC). The 2019 estimate was extrapolated using the 2019/2018 trend from the American Community Survey (ACS). The 2020 estimate was extrapolated using the 2020/2018 trend from the CPS as published by the Census Bureau. The U.S. Census Bureau is the data collection agent for the NHIS, the ACS, and the CPS. The results from these data sources have been instrumental over the years in providing data to track health status, health care access, and progress toward achieving national health objectives. For further information regarding the NHIS, we refer readers to the CDC website at *https://www.cdc.gov/nchs/nhis/index.htm*. For further information regarding the ACS, we refer readers to the Census Bureau's website at *https://www.census.gov/programs-surveys/acs/*. For information regarding the data collection issues regarding the 2020 ACS, we refer readers to the Census Bureau's website at *https://www.census.gov/newsroom/blogs/random-samplings/2021/10/pandemic-impact-on-2020-acs-1-year-data.html*. Since the 2020 ACS data were not available, the ACS data were not used for purposes of estimating the number of uninsured individuals for 2020.

The next metrics needed to compute Factor 2 for FY 2023 are projections of the rate of uninsurance in both CY 2022 and CY 2023. On an annual basis, OACT projects enrollment and spending trends for the coming 10-year period. The most recent projections are for 2021 through 2030. Those projections use the latest NHEA historical data, available at the time of their construction. The NHEA projection methodology accounts for expected changes in enrollment across all of the categories of insurance coverage previously listed. The sources for projected growth rates in enrollment for Medicare, Medicaid, and CHIP include the latest Medicare Trustees Report and other updated estimates as produced by OACT. Projected rates of growth in enrollment for private health insurance and the uninsured are based largely on OACT's econometric models, which rely on the set of macroeconomic assumptions underlying the latest Medicare Trustees Report. Greater detail can be found in OACT's report titled ''Projections of National Health Expenditure: Methodology and Model Specification,'' which is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf*.

(b) Proposed Factor 2 for FY 2023

Using these data sources and the previously described methodologies, OACT estimated that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2022 and 2023 is 8.9 percent and 9.3 percent, respectively. As required by section 1886(r)(2)(B)(ii) of the Act, the Chief Actuary of CMS has certified these estimates. We refer readers to OACT's Memorandum on Certification of Rates of Uninsured prepared for this FY 2023 IPPS/LTCH PPS proposed rule for further details on the methodology and assumptions that were used in the projection of these rates of uninsurance.[602]

As with the CBO estimates on which we based Factor 2 for fiscal years before FY 2018, the NHEA estimates are for a calendar year. Under the approach originally adopted in the FY 2014 IPPS/LTCH PPS final rule, we have used a weighted average approach to project the rate of uninsurance for each fiscal year. We continue to believe that, in order to estimate the rate of uninsurance during a fiscal year accurately, Factor 2 should reflect the estimated rate of uninsurance that hospitals will experience during the fiscal year, rather than the rate of uninsurance during only one of the calendar years that the fiscal year spans. Accordingly, we are proposing to continue to apply the weighted average approach used in past fiscal years in order to estimate the rate of uninsurance for FY 2023.

The OACT has certified the estimate of the rate of uninsurance for FY 2023 determined using this weighted average approach to be reasonable and appropriate for purposes of section 1886(r)(2)(B)(ii) of the Act. We note that we may also consider the use of more recent data that may become available for purposes of estimating the rates of uninsurance used in the calculation of the final Factor 2 for FY 2023.

The calculation of the proposed Factor 2 for FY 2023 is as follows:

Percent of individuals without insurance for CY 2013: 14 percent.

Percent of individuals without insurance for CY 2022: 8.9 percent.

Percent of individuals without insurance for CY 2023: 9.3 percent.

[602] OACT Memorandum on Certification of Rates of Uninsured. March 28, 2022. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInPatientPPS/dsh.html*.

Percent of individuals without insurance for FY 2023 (0.25 times 0.089) + (0.75 times 0.093): 9.2 percent.

$1 - |((0.092 - 0.14)/0.14)| = 1 - 0.3429 = 0.6571$ (65.71 percent).

For FY 2020 and subsequent fiscal years, section 1886(r)(2)(B)(ii) of the Act no longer includes any reduction to the previous calculation in order to determine Factor 2. Therefore, we are proposing that Factor 2 for FY 2023 would be 65.71 percent.

The proposed FY 2023 uncompensated care amount is equivalent to this proposed rule's Factor 1 multiplied by this proposed rule's Factor 2, which is $9,949,258,556.56 * 0.6571 = $6,537,657,797.52.

Proposed FY 2023 Uncompensated Care Amount	$6,537,657,797.52

In addition, it has recently come to our attention that the provision of the regulations that addresses Factor 2 inadvertently omits any reference to the statutory methodology in section 1886(r)(2)(B)(ii) of the Act for determining Factor 2 for FY 2018 and subsequent fiscal years. Accordingly, we are proposing a technical change to the regulation at § 412.106 to update paragraph (g)(1)(ii) to reflect the statutory requirements governing the determination of Factor 2 for FY 2018 and subsequent fiscal years. We have determined Factor 2 for FY 2018 through FY 2022 consistent with the plain language of section 1886(r)(2)(B)(ii) of the Act; therefore, this proposed technical change is intended merely to update our regulations to reflect the methodology for determining Factor 2 that has applied since FY 2018 and will continue to apply for FY 2023 and subsequent fiscal years.

We are inviting public comments on our proposed Factor 2 for FY 2023 and on the proposed technical change to the regulation at § 412.106(g)(1)(ii).

3. Calculation of Proposed Factor 3 for FY 2023

(a) General Background

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of: (1) The amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary to determine: (1) The definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, we note that the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

In the course of considering how to determine Factor 3 during the rulemaking process for FY 2014, the first year for which section 1886(r) of the Act was in effect, we considered defining the amount of uncompensated care for a hospital as the uncompensated care costs of that hospital and determined that Worksheet S–10 of the Medicare cost report would potentially provide the most complete data regarding uncompensated care costs for Medicare hospitals. However, because of concerns regarding variations in the data reported on Worksheet S–10 and the completeness of these data, we did not use Worksheet S–10 data to determine Factor 3 for FY 2014, or for FYs 2015, 2016, or 2017. Instead, we used alternative data on the utilization of insured low-income patients, as measured by patient days, which we believed would be a better proxy for the costs of hospitals in treating the uninsured and therefore appropriate to use in calculating Factor 3 for these years. Of particular importance in our decision to use proxy data was the relative newness of Worksheet S–10, which went into effect on May 1, 2010. At the time of the rulemaking for FY 2014, the most recent available cost reports would have been from FYs 2010 and 2011 and submitted on or after May 1, 2010, when the new Worksheet S–10 went into effect. However, we indicated our belief that Worksheet S–10 could ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3 once hospitals were submitting more accurate and consistent data through this reporting mechanism.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38202), we stated that we could no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Hospitals were on notice as of FY 2014 that Worksheet S–10 could eventually become the data source for CMS to calculate uncompensated care payments. Furthermore, hospitals' cost reports from FY 2014 had been publicly available for some time, and CMS had analyses of Worksheet S–10, conducted both internally and by stakeholders, demonstrating that Worksheet S–10 accuracy had improved over time. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38201 through

38203) for a complete discussion of these analyses.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38206), we recognized commenters' concerns that, in continuing to use Medicaid days as part of the proxy for uncompensated care, it would be possible for hospitals in States that choose to expand Medicaid to receive higher uncompensated care payments because they may have more Medicaid patient days than hospitals in a State that does not choose to expand Medicaid. In the FY 2018 IPPS/LTCH PPS final rule, we finalized a methodology under which we calculated Factor 3 for all eligible hospitals, with the exception of Puerto Rico hospitals and Indian Health Service (IHS) and Tribal hospitals, using Worksheet S–10 data from FY 2014 cost reports in conjunction with low-income insured days proxy data based on Medicaid days and SSI days. The time period for the Medicaid days data was FY 2012 and FY 2013 cost reports, which reflected the most recent available information regarding these hospitals' low-income insured days before any expansion of Medicaid (82 FR 38208 through 38212).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41414), we stated that with the additional steps we had taken to ensure the accuracy and consistency of the data reported on Worksheet S–10 since the publication of the FY 2018 IPPS/LTCH PPS final rule, we continued to believe that we could no longer conclude that alternative data to the Worksheet S–10 were currently available for FY 2014 or FY 2015 that would be a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41428), we advanced the time period of the data used in the calculation of Factor 3 forward by 1 year and used Worksheet S–10 data from FY 2014 and FY 2015 cost reports in combination with the low income insured days proxy for FY 2013 to determine Factor 3 for FY 2019. We note that, as discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42366), the use of 3 years of data to determine Factor 3 for FY 2018 and FY 2019 had the effect of smoothing the transition from the use of low-income insured days to the use of Worksheet S–10 data.

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41424), we received overwhelming feedback from commenters emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10. We began auditing the Worksheet S–10 data for selected hospitals in the Fall of 2018 so that the audited uncompensated care data from these hospitals would be available in time for use in the FY 2020 IPPS/LTCH PPS proposed rule.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42368), we finalized our proposal to use a single year of audited Worksheet S–10 cost report data from FY 2015 in the methodology for determining Factor 3 for FY 2020. Although some commenters expressed support for the alternative policy of using the more recent FY 2017 Worksheet S–10 data to determine each hospital's share of uncompensated care costs in FY 2020, given the feedback from commenters in response to both the FY 2019 and FY 2020 IPPS/LTCH PPS proposed rules, emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10, we concluded that the FY 2015 Worksheet S–10 data were the best available audited data to be used in determining Factor 3 for FY 2020. We also noted that we had begun auditing the FY 2017 data in July 2019, with the goal of having the FY 2017 audited data available for future rulemaking.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58823 through 58825), we finalized our proposal to use the most recent available single year of audited Worksheet S–10 data to determine Factor 3 for FY 2021 and subsequent fiscal years. We explained our belief that using the most recent audited data available before the applicable Federal fiscal year, will more accurately reflect a hospital's uncompensated care costs, as opposed to averaging multiple years of data. We explained that mixing audited and unaudited data for individual hospitals by averaging multiple years of data could potentially lead to a less smooth result. We also noted that if a hospital has relatively different data between cost report years, we potentially would be diluting the effect of our considerable auditing efforts and introducing unnecessary variability into the calculation if we were to use multiple years of data to calculate Factor 3. Therefore, we also believed using a single year of audited cost report data would be an appropriate methodology to determine Factor 3 for FY 2021 and subsequent years, except for IHS and Tribal hospitals and hospitals located in Puerto Rico. For IHS and Tribal hospitals and Puerto Rico hospitals, we finalized the use of a low-income insured days proxy to determine Factor 3 for FY 2021. We did not finalize a methodology to determine Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals for FY 2022 and subsequent years because we believed further consideration and review of these hospitals' Worksheet S–10 data was necessary (85 FR 58825).

In the FY 2021 IPPS/LTCH PPS final rule, we finalized the definition of ''uncompensated care'' for FY 2021 and subsequent fiscal years, for purposes of determining uncompensated care costs and calculating Factor 3 (85 FR 58825 through 58828). Specifically, ''uncompensated care'' is defined as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29). This is the same definition that we initially adopted in the FY 2018 IPPS/LTCH PPS final rule. We refer readers to the FY 2021 IPPS/LTCH PPS rule (85 FR 58825 through 58828) for a discussion of additional topics related to the definition of uncompensated care. We noted in the FY 2021 IPPS/LTCH PPS final rule that the Paper Reduction Act (PRA) package for Form CMS–2552–10 would offer an additional opportunity to comment on the cost reporting instructions. A PRA package with comment period appeared in the November 10, 2020, **Federal Register** (85 FR 71653). We thank stakeholders for their comments on the PRA package and we will respond to those comments in a separate **Federal Register** document. The OMB control number for this information collection request is 0938–0050, which expired on March 31, 2022. A reinstatement of the information collection request is currently being developed. The public will have an opportunity to review and submit comments on the reinstatement through a public notice and comment period separate from this rulemaking.

(b) Background on the Methodology Used To Calculate Factor 3 for FY 2022

Section 1886(r)(2)(C) of the Act governs both the selection of the data to be used in calculating Factor 3, and also allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for a subsection (d) hospital for a period selected by the Secretary. Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we adopted a process of making interim payments with final cost report

settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments and for those hospitals that we do not estimate will qualify for Medicare DSH payments but that may ultimately qualify for Medicare DSH payments at the time of cost report settlement.

In the FY 2022 IPPS/LTCH PPS final rule, we continued to apply the following policies as part of the Factor 3 methodology: (1) The policy regarding newly merged hospitals that was initially adopted in the FY 2015 IPPS/LTCH PPS final rule; (2) the policies regarding annualization and long cost reports that were adopted in the FY 2018 and FY 2019 IPPS/LTCH PPS final rules, including a modified policy for the rare cases where a provider has no cost report for the fiscal year that is used in the Factor 3 methodology because the cost report for the previous fiscal year spans both years; (3) the modified new hospital policy that was finalized in the FY 2020 IPPS/LTCH PPS final rule; (4) the new merger policy adopted in the FY 2021 IPPS/LTCH PPS final rule that accounts for the merger effective date; and (5) the policies regarding the application of statistical trim methodologies to potentially aberrant CCRs and potentially aberrant uncompensated care costs reported on the Worksheet S–10. We discuss these policies in greater detail in this section.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45244), we continued to treat hospitals that merge after the development of the final rule for the applicable fiscal year similar to new hospitals. As explained in the FY 2015 IPPS/LTCH PPS final rule, for these newly merged hospitals, we do not have data currently available to calculate a Factor 3 amount that accounts for the merged hospital's uncompensated care burden (79 FR 50021). In the FY 2015 IPPS/LTCH PPS final rule, we finalized a policy under which Factor 3 for hospitals that we do not identify as undergoing a merger until after the public comment period and additional review period following the publication of the final rule or that undergo a merger during the fiscal year would be recalculated similar to new hospitals (79 FR 50021 and 50022). Consistent with past policy, interim uncompensated care payments for newly merged hospitals are based only on the data for the surviving hospital's CCN available the time of the development of the final rule. However, at cost report settlement, we will determine the newly merged hospital's final uncompensated care payment based on the uncompensated care costs reported on its cost report for the applicable fiscal year. That is, for FY 2022, we will revise the numerator of Factor 3 for a newly merged hospital to reflect the uncompensated care costs reported on the newly merged hospital's FY 2022 cost report.

In FY 2022 IPPS/LTCH PPS final rule, we continued the policy that was finalized in the FY 2018 IPPS/LTCH PPS final rule of annualizing uncompensated care cost data reported on the Worksheet S–10 if a hospital's cost report does not equal 12 months of data, except in the case of mergers, which would be subject to the modified merger policy originally adopted in FY 2021. In addition, we continued the policies that were finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41415) regarding the use of the longest cost report available within the Federal fiscal year. We also applied the modified policy that was adopted in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58829) for those rare situations where a hospital has a cost report that starts in one fiscal year but spans the entirety of the following fiscal year such that the hospital has no cost report starting in that subsequent fiscal year. Under this modified policy, we use the cost report that spans both fiscal years for purposes of calculating Factor 3 when data from the latter fiscal year are used in the Factor 3 methodology.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 25454), we continued the modified new hospital policy for new hospitals that do not have data for the cost reporting period(s) used in the Factor 3 calculation (that is, the most recent cost reporting year for which audits have been conducted). Under the modified policy originally adopted for FY 2020, new hospitals that have a preliminary projection of being eligible for Medicare DSH based on their most recent available disproportionate patient percentages may receive interim empirically justified DSH payments during the fiscal year. However, because these hospitals do not have a cost report for the cost reporting period used in the Factor 3 calculation and the projection of eligibility for DSH payments is still preliminary, we are unable to calculate a prospective Factor 3 for these hospitals and they do not receive interim uncompensated care payments. The MAC will make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments for the fiscal year at cost report settlement. Thus, for FY 2022, if a new hospital is ultimately determined to be eligible for Medicare DSH payments for FY 2022, the hospital will receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2022 cost report, and the denominator is the same denominator that was used in the prospective Factor 3 calculation for FY 2022 (that is, the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2018 cost reports for all DSH-eligible hospitals).

In the FY 2022 IPPS/LTCH PPS final rule, we continued the new merger policy that accounts for the merger effective date, that was originally adopted in FY 2021. To more accurately estimate uncompensated care costs (UCC) for the hospitals involved in a merger when the merger effective date occurs partway through the surviving hospital's cost reporting period, we apply a policy of not annualizing the acquired hospital's data. Under this policy, we use only the portion of the acquired hospital's unannualized UCC data that reflects the UCC incurred prior to the merger effective date, but after the start of the surviving hospital's current cost reporting period. To do this, we calculate a multiplier to be applied to the acquired hospital's UCC. This multiplier represents the portion of the UCC data from the acquired hospital that should be incorporated with the surviving hospital's data to determine UCC for purposes of determining Factor 3 for the surviving hospital. This multiplier is obtained by calculating the number of days between the start of the applicable cost reporting period for the surviving hospital and the merger effective date, and then dividing this result by the total number of days in the reporting period of the acquired hospital. Applying this multiplier to the acquired hospital's unannualized UCC data will determine the final portion of the acquired hospital's UCC that should be added to the UCC of the surviving hospital for purposes of determining Factor 3 for the merged hospital.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 25454 and 25455), we continued to apply a CCR trim methodology similar to the CCR trim methodology policy that has been used for purposes of determining uncompensated care payments since FY 2018. This CCR trim methodology is consistent with the approach used in

the outlier payment methodology under § 412.84(h)(3)(ii), which states that the Medicare contractor may use a statewide average CCR for hospitals whose operating or capital CCR is in excess of 3 standard deviations above the corresponding national geometric mean. We refer readers to the discussion in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58831) for a detailed description of the steps used to determine the applicable CCR.

In addition, we continued the UCC data trim methodology for rare situations where a hospital has potentially aberrant data that are unrelated to its CCR (86 FR 45245). However, because we audit the Worksheet S–10 data for a number of hospitals, we no longer believe it is necessary to apply the trim methodology for hospitals whose cost report has been audited. Accordingly, for FY 2022, we continued the policy adopted in FY 2021 under which we exclude hospitals that were part of the audits for the fiscal year used in the Factor 3 calculation from the trim methodology for potentially aberrant UCC. We also continued to apply a modified trim methodology for all-inclusive rate providers (AIRPs) with potentially aberrant UCC (86 FR 45235). Under this modified trim methodology, when an AIRP's total UCC are greater than 50 percent of its total operating costs when calculated using the CCR included on its cost report for the most recent cost reporting year for which audits have been conducted, we recalculate the AIRP's UCC using the CCR reported on Worksheet S–10, line 1 of the hospital's most recent available prior year cost report that does not result in UCC of over 50 percent of total operating costs.

In addition, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45245 and 452456), we finalized an alternative trim specific to hospitals that are not projected to be DSH-eligible and that do not have audited FY 2018 Worksheet S–10 data for use in determining Factor 3. We explained that we believe this new alternative trim more appropriately addresses potentially aberrant insured patient charity care costs compared to the existing trim, because the existing trim is based solely on the ratio of total uncompensated care costs to total operating costs and does not consider the level of insured patients' charity care costs. Specifically, we finalized that, for the hospitals that would be subject to the trim, if the hospital is ultimately determined to be DSH-eligible at cost report settlement, then the MAC would calculate a Factor 3 after reviewing the uncompensated care information reported on Worksheet S–10 of the hospital's FY 2022 cost report. We stated that we believe if a hospital subject to this trim is ultimately determined to be DSH-eligible at cost report settlement, its uncompensated care payment should be calculated only after the hospital's reporting of insured charity care costs on its FY 2022 Worksheet S–10 has been reviewed. We noted that this approach is comparable to the policy for new hospitals for which we cannot calculate a prospective Factor 3 because they do not have Worksheet S–10 data for the relevant fiscal year.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45242 and 45243), we continued the policy we first adopted for FY 2018 of substituting data regarding FY 2013 low-income insured days for the Worksheet S–10 data when determining Factor 3 for IHS and Tribal hospitals and subsection (d) Puerto Rico hospitals that have a FY 2013 cost report. We stated our belief that this approach was appropriate as the FY 2013 data reflect the most recent available information regarding these hospitals' low-income insured days before any expansion of Medicaid. In addition, because we continued to use 1 year of insured low income patient days as a proxy for uncompensated care for Puerto Rico hospitals and residents of Puerto Rico are not eligible for SSI benefits, we continued to use a proxy for SSI days for Puerto Rico hospitals consisting of 14 percent of the hospital's Medicaid days, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956).

We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45236) for a discussion of the approach that we continued to apply in FY 2022 to determine Factor 3 for new Puerto Rico hospitals. In brief, Puerto Rico hospitals that do not have a FY 2013 cost report were considered new hospitals and subject to the new hospital policy, as discussed previously. Specifically, the numerator of the Factor 3 calculation will be the uncompensated care costs reported on Worksheet S–10 of the hospital's cost report for the applicable fiscal year and the denominator is the same denominator that is determined prospectively for purposes of determining Factor 3 for all DSH-eligible hospitals.

Consistent with the policy adopted in the FY 2021 IPPS/LTCH PPS final rule and codified in the regulations at § 412.106(g)(8) for subsequent fiscal years, in the FY 2022 IPPS/LTCH PPS final rule we used a single year of Worksheet S–10 data from FY 2018 cost reports to calculate Factor 3 for FY 2022 for all eligible hospitals with the exception of IHS and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013.

Therefore, for FY 2022, we applied the following methodology to compute Factor 3 for each hospital:

Step 1: Select the provider's longest cost report from its Federal fiscal year (FFY) 2018 cost reports. (Alternatively, in the rare case when the provider has no FFY 2018 cost report because the cost report for the previous Federal fiscal year spanned the FFY 2018 time period, the previous Federal fiscal year cost report will be used in this step.)

Step 2: Annualize the uncompensated care costs (UCC) from Worksheet S–10 Line 30, if the cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combine adjusted and/or annualized uncompensated care costs for hospitals that merged using the merger policy.

Step 4: Calculate Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013 using the low-income insured days proxy based on FY 2013 cost report data and the most recent available SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days). The denominator is calculated using the low-income insured days proxy data from all DSH eligible hospitals.

Step 5: Calculate Factor 3 for the remaining DSH eligible hospitals using annualized uncompensated care costs (Worksheet S–10 Line 30) based on FY 2018 cost report data (from Step 1, 2 or 3). New hospitals and the hospitals for which Factor 3 was calculated in Step 4 are excluded from this calculation.

We amended the regulation at § 412.106 by adding a new paragraph (g)(1)(iii)(C)(*9*) to reflect the methodology for computing Factor 3 for FY 2022 for IHS and Tribal hospitals and for Puerto Rico hospitals that have a 2013 cost report. We also finalized a conforming change to limit the reference to Puerto Rico hospitals in § 412.106(g)(1)(iii)(C)(*8*) to those Puerto Rico hospitals that have a cost report for 2013.

(c) Proposed Changes to the Methodology for Calculating Factor 3 for FY 2023 and Subsequent Fiscal Years

As described in the FY 2022 IPPS/LTCH PPS final rule, commenters expressed concerns that the use of only one year of data to determine Factor 3 would lead to significant variations in year-to-year uncompensated care

payments. Some stakeholders recommended the use of two years of historical Worksheet S–10 data (86 FR 45237). In the FY 2022 IPPS/LTCH PPS final rule, we stated that we would consider using multiple years of data when the vast majority of providers have been audited for more than one fiscal year under the revised reporting instructions. The audits of FY 2019 cost reports began in 2021 and those audited reports are now available, in time for the development of this proposed rule. Feedback from previous audits and lessons learned were incorporated into the audit process for the FY 2019 reports.

In consideration of the comments discussed in the FY 2022 IPPS/LTCH PPS final rule, for FY 2023, we are proposing to determine Factor 3 using the average of the audited FY 2018 and audited FY 2019 reports. We believe this proposal addresses concerns from stakeholders regarding year-to-year fluctuations in uncompensated care payments. In addition, taking into consideration the comments recommending that CMS transition to the use of three years of audited data, we expect that FY 2024 will be the first year that three years of audited data will be available at the time of rulemaking. Accordingly, for FY 2024 and subsequent fiscal years, we propose to use a three-year average of the uncompensated care data from the three most recent fiscal years for which audited data are available to determine Factor 3. Specifically, for FY 2024, we would expect to use data from FY 2018, FY 2019, and FY 2020 reports to calculate uncompensated care payments. In other words, for each of the three most recent fiscal years for which audited data are available at the time of rulemaking for the applicable fiscal year, we would divide a hospital's uncompensated care costs for the fiscal year by the estimated total uncompensated care costs of all DSH hospitals for that fiscal year. We would then calculate an average of those proportions to determine the hospital's Factor 3 for the applicable Federal fiscal year. We believe this proposed approach is generally consistent with our past practice of using the most recent single year of audited data from the Worksheet S–10, while also addressing commenters' concerns regarding year-to-year fluctuations in uncompensated care payments. Consistent with past methodology when multiple years of data were used in the Factor 3 methodology, we propose that if a hospital does not have data for all three years, we would determine Factor 3 based on an average of the hospital's available data.

As discussed in the earlier background section describing the methodology used to calculate Factor 3 for FY 2022, since the FY 2014 final rule, we have determined Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals, based on the low-income insured days proxy for uncompensated care costs. In the FY 2022 IPPS/LTCH PPS final rule, we discussed comments we had received from IHS/Tribal hospitals and Puerto Rico hospitals about the significant challenges they face in relation to uncompensated care reporting (86 FR 45242 and45243). For example, a commenter stated that the information technology systems used by IHS and Tribal hospitals are not equipped to collect the necessary data for the Worksheet S–10, noting that while IHS recently received funding to upgrade its information technology system, it will take some time, potentially years, before it is fully functional (86 FR 45242). Another commenter expressed concerns that Puerto Rico hospitals were understating the components of uncompensated care costs, and indicated that technical education is needed to address the challenges Puerto Rico hospitals have regarding charity care and bad debt reporting, which the commenter stated would take years to address (86 FR 45243).

To the extent the commenters have identified specific challenges for IHS/Tribal hospitals and Puerto Rico hospitals in reporting uncompensated care costs on Worksheet S–10, it is possible that after a sufficient number of years these reporting challenges could be addressed. However, despite the reporting challenges described by commenters, we are concerned that the historical 2013-based data on low-income insured days, which has been used as an alternative to data on uncompensated care costs from the Worksheet S–10 to determine Factor 3 for IHS/Tribal hospitals and Puerto Rico hospitals, is no longer a good proxy for the costs of these hospitals in treating the uninsured, given the time that has elapsed since 2013. In 2023, this data will be ten years old and there is no obvious way to update the information given our stated concerns surrounding the differential impact of state Medicaid expansions after 2013. In light of these concerns, we can no longer conclude that alternative data to the data on uncompensated care costs reported on Worksheet S–10 are currently available for IHS/Tribal hospitals and Puerto Rico hospitals that are a better proxy for the costs of these hospitals in treating the uninsured. Accordingly, for FY 2023 and subsequent fiscal years, we are proposing to discontinue the use of low-income insured days as a proxy for the uncompensated care costs of these hospitals and are proposing to use the same data to determine Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals as for other hospitals. Specifically, we would determine Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals based on the average of the uncompensated care data reported on Worksheet S–10 of their FY 2018 and FY 2019 cost reports. However, we are seeking comments on alternatives both to our proposal to use data on uncompensated care costs from the Worksheet S–10 to determine Factor 3 for IHS/Tribal hospitals and Puerto Rico hospitals and to the continued use of low-income insured days as a proxy for the uncompensated care costs of these hospitals. We are also seeking comments on how to best measure and define the uncompensated care costs associated with these hospitals that might not otherwise be captured in Factor 3 calculations based on Worksheet S–10 data. Because we recognize that our proposal to discontinue the use of the low-income insured days proxy and to rely solely on Worksheet S–10 data to calculate Factor 3 of the uncompensated care payment methodology for IHS/Tribal hospitals and Puerto Rico hospitals could result in a significant financial disruption for these hospitals, we are proposing to establish a new supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals, beginning in FY 2023. We refer readers to section IV.E of the preamble of this proposed rule for a complete discussion of the proposed new supplemental payment.

Prior to the proposed rulemaking for FY 2023, CMS consulted with IHS and Tribes regarding our policies for determining uncompensated care payments. They expressed that uncompensated care payments are critical to the providers and should be maintained at their current levels, at a minimum. We have considered this recent input along with previous input from stakeholders in the development of our proposed policies. We also welcome additional input from stakeholders regarding the unique circumstances of IHS/Tribal hospitals and Puerto Rico hospitals and/or any mitigating factors, as this will inform our considerations about our proposal to determine Factor 3 for these hospitals using data from Worksheet S–10 and the related proposal to establish a new

supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

For purposes of this FY 2023 proposed rule, we have used the December 2021 HCRIS extract to calculate Factor 3. We note that we intend to use the March 2022 update of HCRIS to calculate Factor 3 for the FY 2023 IPPS/LTCH PPS final rule. However, we may consider the use of more recent data that may become available after March 2022, but prior to the development of the final rule, if appropriate, for purposes of calculating the final Factor 3 for the FY 2023 IPPS/LTCH PPS final rule.

For purposes of determining Factor 3 for FY 2023 and subsequent fiscal years, we will apply the following policies: (1) The merger policies that were initially adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50021), as modified in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58828 and 58829) to incorporate the use of a multiplier to account for merger effective date; (2) the policy for hospitals with multiple cost reports, beginning in the same fiscal year, of using the longest cost report and annualizing uncompensated care data if a hospital's cost report does not equal 12 months of data; (3) the policy, as modified in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58829) and as further modified as proposed in this section, for the rare case where a hospital has a cost report that starts in one fiscal year and spans the entirety of the following fiscal year, such that the hospital has no cost report for that subsequent fiscal year, of using the cost report that spans both fiscal years for the latter fiscal year; (4) the new hospital policy, as modified in the FY 2020 IPPS/LTCH PPS final rule and as further modified as proposed in this section; (5) the newly merged hospital policy, as modified as proposed in this section; and (6) the policies regarding the application of statistical trim methodologies to potentially aberrant CCRs and potentially aberrant uncompensated care costs reported on the Worksheet S–10, as modified as proposed in this section.

Because we are proposing to use multiple years of cost reports to determine Factor 3 starting in FY 2023, we have determined that it is also necessary to make a further modification to the policy regarding cost reports that start in one fiscal year and span the entirety of the following fiscal year. Specifically, in the rare cases when we use a cost report that starts in one fiscal year and spans the entirety of the subsequent Federal fiscal year to determine uncompensated care costs for the subsequent Federal fiscal year, we would not use the same cost report to determine the hospital's uncompensated care costs for the earlier fiscal year. Using the same cost report to determine uncompensated care costs for both fiscal years would not be consistent with our intent to smooth year-to-year variation in uncompensated care costs. As an alternative, we propose to use the hospital's most recent prior cost report, if that cost report spans the applicable period. In other words, in determining Factor 3 for FY 2023, we would not use the same cost report to determine the hospital's uncompensated care costs for both FY 2018 and FY 2019. Rather, we would use the cost report that spans the entirety of FY 2019 to determine uncompensated care costs for FY 2019 and we would use the hospital's most recent prior cost report to determine its uncompensated care costs for FY 2018, provided that cost report spans some portion of Federal fiscal year 2018.

- Proposed Scaling Factor

To address the effects of the calculating Factor 3 using data from multiple fiscal years, we are proposing to apply a scaling factor to the Factor 3 values calculated for all DSH eligible hospitals so that total uncompensated care payments to hospitals that are projected to be eligible for DSH for a fiscal year will be consistent with the estimated amount available to make uncompensated care payments for that fiscal year. Specifically, we are proposing to adopt a policy under which we divide 1 (the expected sum of all DSH-eligible hospitals' Factor 3 values) by the actual sum of all DSH-eligible hospitals' Factor 3 values and then multiply the quotient by the uncompensated care payment determined for each DSH-eligible hospital to obtain a scaled uncompensated care payment amount for each hospital. This process is designed to ensure that the sum of the scaled uncompensated care payments for all hospitals that are projected to be DSH-eligible is consistent with the estimate of the total amount available to make uncompensated care payments for the applicable fiscal year. We note that a similar scaling factor methodology was previously used in both FY 2018 (82 FR 38214 and 38215) and FY 2019 (83 FR 41414), when the Factor 3 calculation also included multiple years of data.

- Proposed Modifications to New Hospital Policy for Purposes of Factor 3

We are proposing to modify the new hospital policy that was initially adopted in the FY 2020 IPPS/LTCH PPS final rule to determine Factor 3 for new hospitals. Consistent with our proposal to use multiple years of cost reports to determine Factor 3, we are proposing to define new hospitals as hospitals that do not have cost report data for the most recent year of data being used in the Factor 3 calculation. In other words, the cut-off date for the new hospital policy is the beginning of the Federal fiscal year after the most recent year for which audits of the Worksheet S–10 data have been conducted. For FY 2023, the FY 2019 cost reports are the most recent year of cost reports for which audits of Worksheet S–10 data have been conducted. Thus, hospitals with CCNs established on or after October 1, 2019, would be subject to the new hospital policy in FY 2023.

Under this proposed modification to the new hospital policy, we would continue the policy established in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42370) that if a new hospital has a preliminary projection of being eligible for DSH payments based on its most recent available disproportionate patient percentage, it may receive interim empirically justified DSH payments. However, new hospitals would not receive interim uncompensated care payments during FY 2023 because we would have no FY 2018 or FY 2019 uncompensated care data on which to determine what those interim payments should be. The MAC will make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement based on its FY 2023 cost report.

We are also proposing to modify the methodology used to calculate Factor 3 for new hospitals. Specifically, we propose to determine Factor 3 for new hospitals using a denominator based solely on uncompensated care costs from cost reports for the most recent fiscal year for which audits have been conducted. For example, if a new hospital is ultimately determined to be eligible for Medicare DSH payments for FY 2023, the hospital will receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2023 cost report, and the denominator is the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2019 cost reports for all DSH-eligible hospitals. In addition, we are proposing to apply a scaling factor, as discussed previously, to the Factor 3 calculation for a new hospital. We believe applying the scaling factor is appropriate for purposes of calculating Factor 3 for all hospitals, including new hospitals and hospitals that are treated as new

hospitals, in order to improve consistency and predictability across all hospitals.

• Proposed Modifications to the Newly Merged Hospital Policy

We will continue to treat hospitals that merge after the development of the final rule for the applicable fiscal year similar to new hospitals. As explained in the FY 2015 IPPS/LTCH PPS final rule, for these newly merged hospitals, we do not have data currently available to calculate a Factor 3 amount that accounts for the merged hospital's uncompensated care burden (79 FR 50021). In the FY 2015 IPPS/LTCH PPS final rule, we finalized a policy under which Factor 3 for hospitals that we do not identify as undergoing a merger until after the public comment period and additional review period following the publication of the final rule or that undergo a merger during the fiscal year will be recalculated similar to new hospitals (79 FR 50021 and 50022). Consistent with the policy adopted in the FY 2015 IPPS/LTCH PPS final rule, we will continue to treat newly merged hospitals in a similar manner to new hospitals, such that the newly merged hospital's final uncompensated care payment will be determined at cost report settlement where the numerator of the newly merged hospital's Factor 3 will be based on the cost report of only the surviving hospital (that is, the newly merged hospital's cost report) for the current fiscal year. However, if the hospital's cost reporting period includes less than 12 months of data, the data from the newly merged hospital's cost report will be annualized for purposes of the Factor 3 calculation. Consistent with the proposed modification to the methodology used to determine Factor 3 for new hospitals described previously, we are proposing to determine Factor 3 for newly merged hospitals using a denominator that is the sum of the uncompensated care costs for all DSH-eligible hospitals, as reported on Worksheet S–10 of their cost reports for the most recent fiscal year for which audits have been conducted. In addition, we would apply a scaling factor, as discussed previously, to the Factor 3 calculation for a newly merged hospital. We believe applying the scaling factor is appropriate for purposes of calculating Factor 3 for all hospitals, including new hospitals and hospitals that are treated as new hospitals, in order to improve consistency and predictability across all hospitals.

Consistent with past policy, interim uncompensated care payments for the newly merged hospital will be based only on the data for the surviving hospital's CCN available at the time of the development of the final rule. In other words, for FY 2023, the eligibility of a newly merged hospital to receive interim uncompensated care payments and the amount of any interim uncompensated care payments, will be based on the uncompensated care costs from the FY 2018 and FY 2019 cost reports available for the surviving CCN at the time the final rule is developed. However, at cost report settlement, we will determine the newly merged hospital's final uncompensated care payment based on the uncompensated care costs reported on its FY 2023 cost report. That is, we will revise the numerator of Factor 3 for the newly merged hospital to reflect the uncompensated care costs reported on the newly merged hospital's FY 2023 cost report. The denominator would be the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2019 cost reports for all DSH-eligible hospitals, which is the most recent fiscal year for which audits have been conducted.

• CCR Trim Methodology

The calculation of a hospital's total uncompensated care costs on Worksheet S–10 requires the use of the hospital's cost to charge ratio (CCR). Consistent with the process for trimming CCRs used in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58831 and 58832), we will apply the following steps to determine the applicable CCR for FY 2018 reports and FY 2019 reports separately:

Step 1: Remove Maryland hospitals. In addition, we will remove all-inclusive rate providers because their CCRs are not comparable to the CCRs calculated for other IPPS hospitals.

Step 2: Calculate a CCR ''ceiling'' for the applicable fiscal year with the following data: For each IPPS hospital that was not removed in Step 1 (including non-DSH eligible hospitals), we use cost report data to calculate a CCR by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. (Combining data from multiple cost reports from the same fiscal year is not necessary, as the longer cost report will be selected.) The ceiling is calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. This approach is consistent with the methodology for calculating the CCR ceiling used for high-cost outliers. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR.

Step 3: Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for the applicable fiscal year for hospitals within each State (including non-DSH eligible hospitals), weighted by the sum of total hospital discharges from Worksheet S–3, Part I, Line 14, Column 15.

Step 4: Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals, excluding all-inclusive rate providers, with a CCR for the applicable fiscal year greater than 3 standard deviations above the national geometric mean for that fiscal year (that is, the CCR ''ceiling''). For this proposed rule, the statewide average CCR was applied to 8 hospitals' FY 2018 reports, of which 3 hospitals had FY 2018 Worksheet S–10 data. The statewide average CCR was applied to 14 hospitals' FY 2019 reports, of which 6 hospitals had FY 2019 Worksheet S–10 data.

Step 5: For hospitals that did not report a CCR on Worksheet S–10, Line 1, we assign them the statewide average CCR for the applicable fiscal year as determined in step 3.

After completing the previously described steps, we re-calculate the hospital's uncompensated care costs (Line 30) for the applicable fiscal year using the trimmed CCR (the statewide average CCR (urban or rural, as applicable)).

• Proposed Modifications to the Uncompensated Care Data Trim Methodology

After applying the CCR trim methodology, there are rare situations where a hospital has potentially aberrant uncompensated care data for a fiscal year that are unrelated to its CCR. Therefore, under the trim methodology for potentially aberrant UCC that was included as part of the methodology for purposes of determining Factor 3 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58832), if the hospital's uncompensated care costs for FY 2018 or FY 2019 are an extremely high ratio (greater than 50 percent) of its total operating costs in the applicable fiscal year, we will determine the ratio of uncompensated care costs to the hospital's total operating costs from another available cost report, and apply that ratio to the total operating expenses for the potentially aberrant fiscal year to determine an adjusted amount of uncompensated care costs for the applicable fiscal year. Specifically, if a hospital's FY 2018 cost report is determined to include potentially

aberrant data, data from the FY 2019 cost report will be used for the ratio calculation. Thus, the hospital's uncompensated care costs for FY 2018 will be trimmed by multiplying its FY 2018 total operating costs by the ratio of uncompensated care costs to total operating costs from the hospital's FY 2019 cost report to calculate an estimate of the hospital's uncompensated care costs for FY 2018 for purposes of determining Factor 3 for FY 2023. Because we are proposing to use multiple years of cost reports in the Factor 3 calculation for FY 2023, we would apply this same approach to address potentially aberrant data in the FY 2019 cost report, by trimming based on the hospital's FY 2020 cost report.

We note that we have audited the FY 2018 and the FY 2019 Worksheet S–10 data for a number of hospitals. Because the UCC data for these hospitals have been subject to audit, we believe there is increased confidence that if high uncompensated care costs are reported by these audited hospitals, the information is accurate. Therefore, consistent with the policy that was adopted in the FY 2021 IPPS/LTCH PPS final rule, it is unnecessary to apply the trim methodology for a fiscal year for which a hospital's UCC data have been audited.

In addition to the UCC trim methodology, we will continue to apply a trim specific to certain hospitals that do not have audited FY 2018 Worksheet S–10 data and/or audited FY 2019 Worksheet S–10 data. We note that in rare cases, hospitals that are not currently projected to be DSH eligible and that do not have audited Worksheet S–10 data may have a potentially aberrant amount of insured patients' charity care costs (line 23 column 2). Similar to the approach initially adopted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45245 and 45246), we are proposing to continue to use a threshold of three standard deviations from the mean ratio of insured patients' charity care costs to total uncompensated care costs (line 23 column 2 divided by line 30) and a dollar threshold that is the median total uncompensated care cost reported on most recent audited cost reports for hospitals that were projected to be DSH-eligible. We continue to believe these thresholds are appropriate, in order to address potentially aberrant data. However, we are proposing to modify the calculation to include Worksheet S–10 data from IHS/Tribal hospitals and Puerto Rico hospitals consistent with our proposal in this proposed rule to begin using Worksheet S–10 data to determine Factor 3 for these hospitals. We also propose to apply the same thresholds to identify potentially aberrant charity care costs data for all cost reporting years that are used in determining Factor 3. We note that based on calculations from the FY 2019 reports, the threshold amounts were similar to FY 2018 reports; therefore, we believe it is reasonable to use the same thresholds to identify aberrant data for both years. Thus, under this proposal, in FY 2023 we would use the same thresholds to identify potentially aberrant data for both FY 2018 and FY 2019 reports. In addition, we are proposing to apply the same threshold amounts originally calculated for the FY 2018 reports to identify potentially aberrant data for subsequent fiscal years, which we believe will facilitate transparency and predictability. Therefore, for FY 2023 and subsequent fiscal years, we are proposing that in the rare case that a hospital's insured patients' charity care costs are greater than $7 million and the ratio of the hospital's cost of insured patient charity care (line 23 column 2) to total uncompensated care costs (line 30) is greater than 60 percent, we would exclude the hospital from the prospective Factor 3 calculation. This trim would only impact hospitals that are not currently projected to be DSH-eligible; and therefore, are not part of the calculation of the denominator of Factor 3, which includes only uncompensated care costs for projected DSH-eligible hospitals. Consistent with the approach adopted in the FY 2022 IPPS/LTCH PPS final rule, if a hospital would be trimmed under both the UCC trim methodology and this alternative trim, we would apply this trim in place of the existing UCC trim methodology. We continue to believe this alternative trim more appropriately addresses potentially aberrant insured patient charity care costs compared to the UCC trim methodology, because the UCC trim is based solely on the ratio of total uncompensated care costs to total operating costs and does not consider the level of insured patients' charity care costs.

In addition, we propose to continue to apply the policy adopted in the FY 2022 IPPS/LTCH PPS final rule, for the hospitals that would be subject to this alternative trim and are ultimately determined to be DSH-eligible at cost report settlement. We believe if a hospital subject to this trim is ultimately determined to be DSH-eligible at cost report settlement, its uncompensated care payment should be calculated only after the hospital's reporting of insured charity care costs on its FY 2023 Worksheet S–10 has been reviewed. Accordingly, the MAC would calculate a Factor 3 for the hospital only after reviewing the uncompensated care information reported on Worksheet S–10 of the hospital's FY 2023 cost report. We would then calculate Factor 3 for a hospital subject to this alternative trim using the same methodology used to determine Factor 3 for new hospitals. Specifically, the numerator would reflect the uncompensated care costs reported on the hospital's FY 2023 cost report, while the denominator would reflect the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2019 costs reports of all DSH-eligible hospitals. In addition, consistent with our proposed approach for new hospitals, we would apply a scaling factor, as discussed previously, to the Factor 3 calculation for these hospitals. We believe applying the scaling factor is appropriate for purposes of calculating Factor 3 for all hospitals, including new hospitals and hospitals that are treated as new hospitals, in order to improve consistency and predictability across all hospitals.

- Summary of Methodology

In summary, for FY 2023, we propose to compute Factor 3 for each hospital using the following steps:

Step 1: Select the hospital's longest cost report from its Federal fiscal year (FY) 2018 cost reports and the longest cost report from its FY 2019 cost reports. (Alternatively, in the rare case when the hospital has no cost report for a particular year because the cost report for the previous Federal fiscal year spanned the more recent Federal fiscal yeartime period, the previous Federal fiscal year cost report would be used in this step. In the rare case, that using a previous Federal fiscal year cost report results in a period without a report, then we propose to use the prior year report, if that cost report spanned the applicable period. (For example, if a hospital does not have a FY 2019 cost report because the hospital's FY 2018 cost report spanned the FY 2019 time period, then we would use the FY 2018 cost report that spanned the FY 2019 time period for this step. Using the same example, where the hospital's FY 2018 report is used for the FY 2019 time period, then we would use the hospital's FY 2017 report if it spans some of the FY 2018 time period. In other words, we would not use the same cost report for both the FY 2019 and the FY 2018 time periods.) In general, we note that, for purposes of the Factor 3 methodology, references to a fiscal year cost report are to the cost report that

spans the relevant Federal fiscal year period.

Step 2: Annualize the uncompensated care costs (UCC) from Worksheet S–10 Line 30, if a cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combine adjusted and/or annualized uncompensated care costs for hospitals that merged using the merger policy.

Step 4: Calculate Factor 3 for the all DSH eligible hospitals using annualized uncompensated care costs (Worksheet S–10 Line 30) based on FY 2018 cost report data and FY 2019 cost report (from Step 1, 2 or 3). New hospitals and other hospitals that are treated as if they are new hospitals for purposes of Factor 3 are excluded from this calculation.

Step 5: Average the Factor 3 values from Step 4; that is, add the Factor 3 values for FY 2018 and FY 2019 for each hospital, and divide that amount by the number of cost reporting periods with data to compute an average Factor 3 for the hospital. Multiply by a scaling factor.

For FY 2024 and subsequent fiscal years, these steps would be calculated using the most recent three years of audited cost reports. (For example, in FY 2024, the FY 2018, FY 2019, and FY 2020 reports would be used.)

We are proposing to make a conforming change to the existing regulation at § 412.106(g)(1)(iii)(C)(*8*) and to add a new regulation at § 412.106(g)(1)(iii)(C)(*10*) to reflect our proposal to calculate Factor 3 based on the most recent two years of audited data on uncompensated care costs in FY 2023. We are also proposing to add § 412.106(g)(1)(iii)(C)(*11*) to reflect our proposal to calculate Factor 3 for FY 2024 and subsequent fiscal years based on a 3-year average of the most recent available audited data on uncompensated care costs.

(d) Proposal Related to the per Discharge Amount of Interim Uncompensated Care Payments

Since FY 2014, we have made interim uncompensated care payments during the fiscal year on a per discharge basis. We have used a 3-year average of the number of discharges for a hospital to produce an estimate of the amount of the hospital's uncompensated care payment per discharge. Specifically, the hospital's total uncompensated care payment amount for the applicable fiscal year, is divided by the hospital's historical 3-year average of discharges computed using the most recent available data to determine the uncompensated care payment per discharge for that fiscal year.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45247 and 45248), we modified this calculation for FY 2022 to be based on an average of FY 2018 and FY 2019 historical discharge data, rather than a 3-year average that included data from FY 2018, FY 2019, and FY 2020. We explained our belief that computing a 3-year average with the FY 2020 discharge data would underestimate discharges, due to the decrease in discharges during the COVID–19 pandemic. For the same reason, we are now proposing to modify this calculation for FY 2023 to be based on the average of FY 2018, FY 2019, and FY 2021 historical discharge data, rather than a 3-year average of the most recent three years of discharge data from FY 2019, FY 2020, and FY 2021. We believe that computing a 3-year average using the most recent three years would potentially underestimate the number of discharges for FY 2023, due to the effects of the COVID–19 pandemic in FY 2020, which was the first year of the COVID–19 pandemic. Therefore, we believe the proposed modification may result in a better estimate of the number of discharges during FY 2023, for purposes of the interim uncompensated care payment calculation. In addition, we note that our proposal to include discharge data from FY 2021 to compute this 3-year average is consistent with the proposed use of FY 2021 Medicare claims in the IPPS ratesetting, as discussed in section I.F. of the preamble of this proposed rule. Under this proposal, the resulting 3-year average of the number of discharges would be used to calculate a per discharge payment amount that will be used to make interim uncompensated care payments to each projected DSH-eligible hospital during FY 2023. The interim uncompensated care payments made to a hospital during the fiscal year will be reconciled following the end of the year to ensure that the final payment amount is consistent with the hospital's prospectively determined uncompensated care payment for the FY 2023.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58833 and 58834), we finalized a voluntary process through which a hospital may submit a request to its MAC for a lower per discharge interim uncompensated care payment amount, including a reduction to zero, once before the beginning of the Federal fiscal year and/or once during the Federal fiscal year. In conjunction with this request, the hospital must provide supporting documentation demonstrating there would likely be a significant recoupment (for example, 10 percent or more of the hospital's total uncompensated care payment or at least $100,000) at cost report settlement if the per discharge amount is not lowered. For example, a hospital might submit documentation showing a large projected increase in discharges during the fiscal year to support reduction of its per discharge uncompensated care payment amount. As another example, a hospital might request that its per discharge uncompensated care payment amount be reduced to zero midyear if the hospital's interim uncompensated care payments during the year have already surpassed the total uncompensated care payment calculated for the hospital.

Under the policy we finalized in the FY 2021 IPPS/LTCH PPS final rule, the hospital's MAC would evaluate these requests and the supporting documentation before the beginning of the Federal fiscal year and/or with midyear requests when the historical average number of discharges is lower than the hospital's projected FY 2023 discharges. If following review of the request and the supporting documentation, the MAC agrees that there likely would be significant recoupment of the hospital's interim Medicare uncompensated care payments at cost report settlement, the only change that will be made is to lower the per discharge amount either to the amount requested by the hospital or another amount determined by the MAC to be appropriate to reduce the likelihood of a substantial recoupment at cost report settlement. If the MAC determines it would be appropriate to reduce the interim Medicare uncompensated care payment per discharge amount, that updated amount will be used for purposes of the outlier payment calculation for the remainder of the Federal fiscal year. We refer readers to the Addendum to this proposed rule for a more detailed discussion of the steps for determining the operating and capital Federal payment rate and the outlier payment calculation. No change would be made to the total uncompensated care payment amount determined for the hospital on the basis of its Factor 3. In other words, any change to the per discharge uncompensated care payment amount will not change how the total uncompensated care payment amount will be reconciled at cost report settlement.

(e) Process for Notifying CMS of Merger Updates and To Report Upload Issues

As we have done for every proposed and final rule beginning in FY 2014, in

conjunction with this proposed rule, we will publish on the CMS website a table listing Factor 3 for all hospitals that we estimate will receive empirically justified Medicare DSH payments in FY 2023 (that is, those hospitals that will receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving an uncompensated care payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. However, we note that a Factor 3 will not be published for new hospitals and hospitals that are subject to the alternative trim for hospitals with potentially aberrant data that are not projected to be DSH-eligible.

We also will publish a supplemental data file containing a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital. In the DSH uncompensated care supplemental data file, we list new hospitals and the 11 hospitals that would be subject to the alternative trim for hospitals with potentially aberrant data that are not projected to be DSH-eligible, with a N/A in the Factor 3 column.

Hospitals have 60 days from the date of public display of this FY 2023 IPPS/LTCH PPS proposed rule in the **Federal Register** to review the table and supplemental data file published on the CMS website in conjunction with this proposed rule and to notify CMS in writing of issues related to mergers and/or to report potential upload discrepancies due to MAC mishandling of Worksheet S–10 data during the report submission process (for example, report not reflecting audit results due to MAC mishandling or most recent report differs from previously accepted amended report due to MAC mishandling). Stakeholders may submit issues or concerns that are specific to the information included in the table and supplemental data file by email to the CMS inbox at *Section3133DSH@cms.hhs.gov*. We will address issues related to mergers and/or reporting upload discrepancies submitted to the CMS DSH inbox as appropriate in the table and the supplemental data file that we publish on the CMS website in conjunction with the publication of the FY 2023 IPPS/LTCH PPS final rule. All other comments submitted in response to our proposed policies for determining uncompensated care payments for FY 2023 must be submitted in one of three ways found in the **ADDRESSES** section of this proposed rule before the close of the comment period in order to be assured consideration. In addition, this CMS DSH inbox is not intended for Worksheet S–10 audit process related emails, which should be directed to the MACs.

For FY 2023, we are again proposing that hospitals will have 15 business days from the date of public display of the FY 2023 IPPS/LTCH PPS final rule in the **Federal Register** to review and submit comments on the accuracy of the table and supplemental data file published in conjunction with the final rule. Any changes to Factor 3 would be posted on the CMS website and would be effective beginning October 1, 2022. We continue to believe that hospitals have sufficient opportunity during the comment period for the proposed rule to provide information about recent and/or pending mergers and/or to report upload discrepancies. Hospitals do not enter into mergers without advanced planning. A hospital can inform CMS during the comment period for the proposed rule regarding any merger activity not reflected in supplemental file published in conjunction with the proposed rule. As discussed in an earlier section, we currently expect to use data from the March 2022 HCRIS extract for the FY 2023 final rule, which contributes to our increased confidence that hospitals would be able to comment on mergers and report any upload discrepancies during the comment period for this proposed rule. However, as previously indicated, we may consider using more recent data that may become available after March 2022, but before the final rule for the purpose of calculating the final Factor 3s for the FY 2023 IPPS/LTCH PPS final rule. In the event that there are any remaining merger updates and/or upload discrepancies after the final rule, the 15 business days from the date of public display of the FY 2023 IPPS/LTCH PPS final rule deadline should allow for the time necessary to prepare and make any corrections to Factor 3 calculations before the beginning of the Federal fiscal year.

We are inviting public comments on our proposed methodology for calculating Factor 3 for FY 2023 and subsequent fiscal years, including, but not limited to, our proposal to use the most recent audited Worksheet S–10 data from FY 2018 and FY 2019 cost reports to determine Factor 3 for FY 2023, and our proposal to begin using the three most recent years of audited Worksheet S–10 data starting in FY 2024.

E. Proposed Supplemental Payment for Indian Health Service and Tribal Hospitals and Puerto Rico Hospitals for FY 2023 and Subsequent Fiscal Years

In the IPPS/LTCH PPS rulemaking for several previous fiscal years, Indian Health Service (IHS) and Tribal hospitals and hospitals located in Puerto Rico have commented about the unique challenges they face with respect to uncompensated care due to structural differences in health care delivery and financing in these areas compared to the rest of the country. We refer the readers to FY 2022 IPPS/LTCH PPS final rule (86 FR 45242 and 45243) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58824 and 58825) for a discussion of these comments. We appreciate the concerns raised and the input offered by commenters regarding the methodology for calculating uncompensated care payments for IHS/Tribal hospitals and the Puerto Rico hospitals. As discussed in greater detail in this section, after taking into consideration stakeholders' longstanding concerns and their input on potential approaches to address these concerns, CMS is proposing to establish a new permanent supplemental payment under the IPPS for IHS/Tribal hospitals and hospitals located in Puerto Rico. As discussed in greater detail in this section, we believe this proposed new supplemental payment would mitigate the anticipated impact on IHS/Tribal hospitals and hospitals located in Puerto Rico from our proposal to discontinue the use of low-income insured days as a proxy for their uncompensated care costs for purposes of determining Factor 3 of the uncompensated care payment methodology by providing for an additional payment to these hospitals that would be determined based upon the difference between the amount of the uncompensated care payment determined for the hospital using Worksheet S–10 data and an approximation of the amount the hospital would have received if we had continued to use low-income days as a proxy for uncompensated care.

As background, beginning in the FY 2018 IPPS/LTCH PPS final rule when we first included Worksheet S–10 data in the calculation of Factor 3, and continuing through the FY 2022 IPPS/LTCH PPS final rule, we relied on the authority under section 1886(r)(2)(C)(i) of the Act to use alternative data that is a better proxy for the costs of hospitals for treating the uninsured in order to determine Factor 3 for IHS/Tribal and Puerto Rico hospitals using low-income insured days as a proxy for uncompensated care costs. Since FY

2019, Factor 3 for these hospitals has been determined using FY 2013 Medicaid days and the most recent available data on SSI days. We have explained our belief that this approach was appropriate as the FY 2013 Medicaid days data reflect the most recent available information regarding these hospitals' low-income insured days before any expansion of Medicaid. In addition, because we continued to use low-income insured patient days as a proxy for uncompensated care for Puerto Rico hospitals and residents of Puerto Rico are not eligible for SSI benefits, we continued to use a proxy for SSI days for Puerto Rico hospitals consisting of 14 percent of the hospital's Medicaid days, as initially adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956). For FY 2023 and subsequent fiscal years, as discussed in the previous section, we are proposing to discontinue the use of low-income insured days as a proxy for uncompensated care costs. We recognize that this proposal would result in a significant financial disruption to the IHS/Tribal hospitals and hospitals located in Puerto Rico. For the vast majority of these hospitals, the proposal to use uncompensated care data reported on Worksheet S–10 to determine Factor 3 of the uncompensated care payment methodology is expected to result in an approximately 90 to 100 percent reduction in uncompensated care payments for FY 2023 compared to FY 2022. For a discussion of the anticipated impact of the proposal to use uncompensated care costs from Worksheet S–10 to determine uncompensated care payments for IHS/Tribal hospitals and Puerto Rico hospitals and the proposal to establish a new supplemental payment for these hospitals, we refer the readers to section I.H. of the Appendix A of this proposed rule.

In consideration of the unique circumstances faced by the hospitals and the comments received from IHS/Tribal hospitals and Puerto Rico hospitals in response to prior rulemaking, raising concerns regarding financial stability in the event of a change in the data used to determine Factor 3, we are proposing to use our exceptions and adjustments authority under section 1886(d)(5)(I) of the Act to establish a new permanent supplemental payment under the IPPS for IHS/Tribal hospitals and hospitals located in Puerto Rico, beginning in FY 2023. Section 1886(d)(5)(I) of the Act authorizes the Secretary to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate. We have determined, after taking into consideration stakeholders' comments from prior rulemakings, that the supplemental payment is necessary so as not to cause undue long-term financial disruption to these hospitals as a result of our proposal to discontinue the use of low-income insured days as a proxy for uncompensated care in determining Factor 3 for IHS/Tribal hospitals and Puerto Rico hospitals beginning in FY 2023. We believe the proposed supplemental payment would help to mitigate the anticipated impact of the proposed changes to the uncompensated care payment methodology for these hospitals and therefore prevent undue long-term financial disruption for these providers.

This proposed new supplemental payment would not change in any way the DSH payment methodology under section 1886(d)(5)(F) or the uncompensated care payment methodology under section 1886(r). Therefore, the total uncompensated care payment amount discussed in the previous section of the preamble of this proposed rule, would not be affected by this proposal to establish a supplemental payment for IHS/Tribal and hospitals located in Puerto Rico nor would there be any impact on the amount of the uncompensated care payment determined for each DSH-eligible hospital under § 412.106(g)(1) of the regulations.

For IHS and Tribal hospitals and hospitals located in Puerto Rico for which Factor 3 of the uncompensated care payment methodology was determined using the low-income insured days proxy in FY 2022, we propose to calculate a supplemental payment as follows. We would use the hospital's FY 2022 uncompensated care payment as the starting point for this calculation. We believe using the FY 2022 uncompensated care payment is an appropriate starting point because FY 2022 is the most recent year for which we used low-income insured days data in the determination of uncompensated care payments for IHS/Tribal hospitals and Puerto Rico hospitals and the purpose of the supplemental payment is to avoid undue long-term financial disruption to these hospitals as a result of our proposal to discontinue the use of low-income insured days as a proxy for uncompensated care beginning in FY 2023. The base year amount would be calculated as the hospital's FY 2022 uncompensated care payment adjusted by one plus the percent change in the total uncompensated care amount between the applicable year (for example, FY 2023 for purposes of this rulemaking) and FY 2022, where the total uncompensated care amount for a year is determined as the product of Factor 1 and Factor 2 for the applicable year. For the hospitals that were not projected to be DSH eligible in FY 2022, we propose to use the uncompensated care payment that the hospital would receive, if the hospital were to be determined to be DSH eligible in FY 2022 at cost report settlement. For purposes of this proposed rule, the percent change between the proposed FY 2023 uncompensated care amount and final FY 2022 uncompensated care amount is projected to be negative 9.1 percent. (This negative 9.1 percent change is calculated based on the difference between the proposed FY 2023 uncompensated care amount of approximately $6.537 billion and the final FY 2022 uncompensated care amount of approximately $7.192 billion, divided by the final FY 2022 uncompensated care amount). Therefore, we propose to calculate each hospital's base year amount for FY 2023 by multiplying its FY 2022 uncompensated care amount by 0.909 (1–0.091). The hospital's supplemental payment for a fiscal year would then be determined as the difference between the hospital's base year amount and its uncompensated care payment for the applicable fiscal year as determined under § 412.106(g). If the base year amount is equal to or lower than the hospital's uncompensated care payment for the current fiscal year, then the hospital would not receive a supplemental payment because the hospital would not be experiencing financial disruption in that year as a result of the use of uncompensated care data from the Worksheet S–10 in determining Factor 3 of the uncompensated care payment methodology.

We propose to align the eligibility and payment processes for the new supplemental payment with the processes used to make uncompensated care payments. Consistent with the process for determining eligibility to receive interim uncompensated care payments adopted in the FY 2014 IPPS/LTCH final rule, for the supplemental payment, we propose to base eligibility to receive interim supplemental payments on a projection of DSH eligibility for the applicable fiscal year. In addition, consistent with the approach that is used to calculate interim uncompensated care payments on a per discharge basis, for the supplemental payment, we propose to

use an average of historical discharges to calculate a per discharge amount for interim supplemental payments. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for additional background and discussion of uncompensated care payment processes (78 FR 50643 through 50647). Consistent with our proposal to use 3-years of historical discharges to determine interim uncompensated care payments for a fiscal year, the amount of a hospital's supplemental payment calculated for a fiscal year would be divided by the hospital's historical 3-year average of discharges computed using the most recent available data to determine an estimated per discharge payment amount.

For FY 2023, we propose to use FY 2018, FY 2019, and FY 2021 discharge data to determine a hospital's historical 3-year average of discharges, because we continue to believe the FY 2020 discharge data would underestimate discharges, due to the effects of the COVID–19 pandemic in FY 2020. In addition, consistent with the policy of including per-discharge uncompensated care payment amounts in the outlier calculation, which was initially adopted in the FY 2014 IPPS/LTCH PPS final rule, we are proposing to use our authority under section 1886(d)(5)(I) to include the per-discharge supplemental payment in the outlier payment determination under section 1886(d)(5)(A) of the Act. We refer readers to the Addendum for further discussion of the outlier payment calculation.

Consistent with the process used to reconcile interim uncompensated care payments, we propose that the MAC would reconcile the interim supplemental payments at cost report settlement to ensure that the hospital receives the full amount of the supplemental payment that was determined prior to the start of the fiscal year. Consistent with the process used for cost reporting periods that span multiple Federal fiscal years, we propose that a pro rata supplemental payment calculation may be made if the hospital's cost reporting period differs from the Federal fiscal year. Thus, the final supplemental payment amounts that would be included on a cost report spanning two Federal fiscal years would be the pro rata share of the supplemental payment associated with each Federal fiscal year. This pro rata share would be determined based on the proportion of the applicable Federal fiscal year that is included in that cost reporting period. We refer readers to the FY 2014 interim final rule for additional background and discussion of the processes for determining pro rata uncompensated care payments (78 FR 61191 through 61196).

We propose that the MAC would make a final determination with respect to a hospital's eligibility to receive the supplemental payment for a fiscal year, in conjunction with its final determination of the hospital's eligibility for DSH payments and uncompensated care payments for that fiscal year. We note that if a hospital is determined not to be DSH eligible for a fiscal year then the hospital would not be eligible to receive a supplemental payment for that fiscal year. We believe linking eligibility for the supplemental payment to eligibility for DSH payments and the uncompensated care payment is appropriate because a hospital that is not eligible to receive an uncompensated care payment for a fiscal year would not experience any financial disruption due to the discontinuation of the low-income insured days proxy and the use of Worksheet S–10 data in determining Factor 3 for that fiscal year.

In addition, we propose that IHS/Tribal hospitals and Puerto Rico hospitals that do not have a FY 2022 Factor 3 amount determined under § 412.106(g)(1)(iii)(C)(9) using the low-income insured days proxy or that are new hospitals that begin participating in the Medicare program on or after October 1, 2022, would not be eligible to receive the supplemental payment. These hospitals will not experience any reduction to their uncompensated care payments due to the proposed discontinuation of the low-income insured days proxy because they are not currently receiving uncompensated care payments determined using the proxy.

We propose to redesignate the existing provision at § 412.106(h) as § 412.106(i) and to add a new provision at § 412.106(h) to reflect the methodology for calculating the supplemental payment for FY 2023 and subsequent fiscal years.

We are seeking comments on our proposal to establish a new supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals. As discussed in section IV.D.3. of the preamble of this proposed rule, which includes our proposed changes to the methodology for determining Factor 3 of the uncompensated care payment methodology for FY 2023 and subsequent fiscal years, we also are seeking comments on alternatives both to our proposal to use data on uncompensated care costs from the Worksheet S–10 to determine Factor 3 for IHS/Tribal hospitals and Puerto Rico hospitals and to the continued use of low-income insured days as a proxy for the uncompensated care costs of these hospitals. In addition, we are also seeking comments on how to best measure and define the uncompensated care costs associated with these hospitals that might not otherwise be captured in Factor 3 calculations based on Worksheet S–10 data.

F. Medicare Disproportionate Share Hospital (DSH) Payments: Counting Days Associated With Section 1115 Demonstrations in the Medicaid Fraction (§ 412.106)

States use section 1115(a) demonstrations to test changes to their Medicaid programs that generally cannot be made using other Medicaid authorities, including to provide health insurance to groups that generally could not or have not been made eligible for ''medical assistance under a State plan approved under title XIX'' (Medicaid benefits). These groups, commonly referred to as expansion populations or expansion waiver groups, are specific, finite groups defined in the demonstration approval letter and special terms and conditions for each demonstration. (We note in the discussion that follows, we use the term ''demonstration'' rather than ''project'' and/or ''waiver'' and the term ''groups'' instead of ''populations,'' as this terminology is generally more consistent with the implementation of the provisions of section 1115 of the Social Security Act.)

On January 20, 2000, we issued an interim final rule with comment period (65 FR 3136) (hereinafter, January 2000 interim final rule), followed by a final rule issued on August 1, 2000 (65 FR 47086 through 47087), that changed the Secretary's policy on how to treat the patient days of certain patients that receive Medicaid benefits under a section 1115 demonstration in calculating the Medicare DSH adjustment. Previously, hospitals could include only the days for those patients receiving Medicaid benefits under a section 1115 demonstration who were, or could have been made, eligible for Medicaid under the State plan. Patient days of those demonstration expansion groups that were not and could not be made eligible for Medicaid under the State plan were not to be included for purposes of determining Medicaid patient days in calculating the Medicare DSH patient percentage.

Under the policy adopted in the January 2000 interim final rule (65 FR 3136), hospitals could include in the numerator of the Medicaid fraction all patient days of groups made eligible for Title XIX matching payments through a

section 1115 demonstration, whether or not those individuals were, or could be made, eligible for Medicaid under a State plan (assuming they were not also entitled to benefits under Medicare Part A). This policy was effective for discharges occurring on or after January 20, 2000. In the January 2000 interim final rule (65 FR 3137), we explained that allowing hospitals to include patient days for section 1115 demonstration expansion groups in the Medicare DSH calculation is fully consistent with the Congressional goals of the Medicare DSH adjustment to recognize the higher costs to hospitals of treating low-income individuals covered under Medicaid.

In the FY 2004 IPPS final rule (68 FR 45420 and 45421), we further revised our regulations to limit the types of section 1115 demonstrations for which patient days could be counted in the numerator of the Medicaid fraction. We explained that in allowing hospitals to include patient days of section 1115 demonstration expansion groups, our intention was to include patient days of those groups who under a demonstration receive benefits, including inpatient benefits, that are similar to the benefits provided to Medicaid beneficiaries under a State plan. We had become aware, however, that certain section 1115 demonstrations provide expansion groups with benefit packages so limited that the benefits are unlike the relatively expansive health insurance (including insurance for inpatient hospital services) provided under a Medicaid State plan. We explained that these limited section 1115 demonstrations extend benefits only for specific services and do not include similarly expansive benefits.

In the FY 2004 IPPS final rule, we specifically discussed family planning benefits offered through a section 1115 demonstration as an example of the kind of demonstration days that should not be counted in the Medicaid fraction because the benefits granted to the expansion group are too limited. Our intention in discussing family planning benefits under a section 1115 demonstration was to provide a concrete example of how the changes being made in the FY 2004 IPPS final rule would refine the Secretary's policy (set forth in the January 2000 interim final rule (65 FR 3136)) to allow only the days of those demonstration expansion groups who are provided Medicaid benefits, and specifically inpatient hospital benefits, like the health care insurance that Medicaid beneficiaries receive under a State plan, to be included in the numerator of the Medicaid fraction of the Medicare DSH calculation. Moreover, this example was intended to illustrate the kind of benefits offered through a section 1115 demonstration that are so limited that the patients receiving them should not be considered eligible for Medicaid for purposes of the DSH calculation.

Because of the limited nature of the Medicaid benefits provided to expansion groups under some demonstrations, as compared to the benefits provided to the Medicaid population under a State plan, we determined it was appropriate to exclude the patient days of patients provided limited benefits under a section 1115 demonstration from the determination of Medicaid days for purposes of the DSH calculation. Therefore, in the FY 2004 IPPS final rule (68 FR 45420 and 45421), we revised the language of § 412.106(b)(4)(i) to provide that for purposes of determining the Medicaid fraction, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a section 1115 demonstration. Thus, under our current regulations, hospitals are allowed to count patient days in the numerator of the Medicaid fraction only if they are days of patients made eligible for inpatient hospital services under either a State Medicaid plan or a section 1115 demonstration, who are not also entitled to benefits under Medicare Part A.

In 2005, the Ninth Circuit held that demonstration expansion groups receive care ''under the State plan'' and that, accordingly, our pre-2000 practice of excluding them from the numerator of the Medicaid fraction was contrary to the plain language of the Act.[603] Subsequently, the District Court for the District of Columbia reached the same conclusion, reasoning that if our policy of counting the days of demonstration expansion groups after 2000 was correct, then patients in demonstration expansion groups were necessarily ''eligible for medical assistance under a State plan'' (that is, Medicaid) and the Act had always required inclusion of their days.[604]

Shortly after these court decisions, Congress, in early 2006, enacted the Deficit Reduction Act of 2005 (the DRA). Section 5002 of the DRA amended section 1886(d)(5)(F)(vi) of the Act to clarify our authority to include or exclude days of expansion groups from the DSH calculation. First, section 5002(a) of the DRA clarified that groups that receive Medicaid benefits through a section 1115 demonstration are not ''eligible for medical assistance under a State plan'' by referring to them as ''not so eligible.'' This provision effectively overruled the earlier court decisions that held that expansion groups were, in fact, made eligible for Medicaid. Second, the statute made explicit that the Secretary nevertheless has the discretion to include in the Medicaid fraction days of patients who are not eligible for Medicaid if they ''are regarded as'' being eligible for Medicaid ''because they receive benefits under a demonstration project approved under title XI.'' This statutory language endorsed and codified the Secretary's view that it is appropriate to include in the DSH calculation days of patients who are treated as if they were eligible for Medicaid under the authority of section 1115(a)(2). Third, the DRA granted the Secretary the discretion to include or exclude the days of patients who are regarded as being eligible for Medicaid in the numerator of the Medicaid fraction ''to the extent and for the period the Secretary determines appropriate.'' Finally, section 5002(b) of the DRA expressly ratified our policy on counting demonstration days in the Medicaid fraction. Our pre-2000 policy was not to include days of section 1115 demonstration expansion groups in the numerator of the Medicaid fraction unless they could have been made eligible for Medicaid under a State plan. As discussed previously, we changed our policy in 2000 to permit inclusion in the Medicaid fraction of all patient days of groups made eligible for matching payments under Title XIX through a section 1115 demonstration. By the time the DRA was enacted, CMS had further refined this policy, and we included in the Medicaid fraction the days of only a small subset of demonstration expansion groups regarded as eligible for Medicaid: Those that were eligible to receive inpatient hospital insurance benefits under the terms of a section 1115 demonstration.

Considering this history, and the text of the DRA, we understand the Secretary's authority to include the days of patients who receive benefits through a section1115 demonstration in the numerator of the Medicaid fraction of the DSH calculation as requiring two determinations. First, we must determine whether the patients at issue ''are regarded as'' being eligible for Medicaid. Second, if they are, the Secretary then has the discretion to determine whether to count those

[603] *Portland Adventist Med. Ctr.* v. *Thompson*, 399 F.3d 1091, 1096 (9th Cir. 2005).

[604] *Cookeville Reg'l Med. Ctr.* v. *Thompson*, No. 04–1053, 2005 WL 3276219, at *4–6 (D.D.C. Oct. 28, 2005).

patients in the DSH calculation and for what period.

We do not believe that the DRA gave the Secretary blanket authority to count in the Medicaid fraction any patient who is in any way related to a section 1115 demonstration. Rather, our authority under section 1886(d)(5)(F)(vi) of the Act remains limited to including the days of expansion groups—those for whom a state seeks Federal Medicaid matching funds in order to provide health insurance to individuals through a demonstration that is comparable to Medicaid state plan benefits—that is, patients who ''are regarded as'' ''eligible for medical assistance under a State plan approved under title XIX.'' Because the existing language of regulations already addressed the treatment of section 1115 days, we did not believe it was necessary to update our regulations after the DRA explicitly granted us the discretion to include or exclude section 1115 days.

More recently, section 1115 demonstrations have been used to authorize the funding of uncompensated care pools that help to offset hospitals' costs for treating uninsured and underinsured individuals. These pools do not extend health insurance directly to such individuals. Rather, such funding pools benefit patients less directly by helping hospitals treat the uninsured and underinsured and stay financially viable to treat patients eligible for Medicaid under a state plan. Unlike demonstrations that expand the group of people who receive Medicaid benefits beyond those groups eligible under the State plan, uncompensated care pools do not provide inpatient health insurance to patients or, like insurance, make payments on behalf of specific, covered individuals. These uncompensated care pools serve essentially the same function as Medicaid DSH payments under sections 1902(a)(13)(A)(iv) and 1923 of the Act by indirectly subsidizing the cost of treating the uninsured and underinsured.

We also note that demonstrations can simultaneously authorize different programs within a single demonstration, thereby creating a group regarded as Medicaid eligible because they receive health insurance through the demonstration while also creating a separate uncompensated/undercompensated care pool for providers that does not directly extend health insurance to individuals.

Recently, courts have decided a series of cases (*Bethesda Health, Inc.* v. *Azar*, 980 F.3d 121 (D.C. Cir. 2020); *Forrest General Hospital* v. *Azar*, 926 F.3d 221 (5th Cir. 2019); *HealthAlliance Hospitals, Inc.* v. *Azar*, 346 F. Supp. 3d 43 (D.D.C. 2018)) interpreting the current language of the regulation at § 412.106(b)(4) to require CMS to count in the numerator of the Medicaid fraction patient days for which hospitals have received payment from an uncompensated care pool authorized by a section 1115 demonstration and the days of patients who receive premium assistance under a section 1115 demonstration. Interpreting the regulatory language that was adopted before the DRA was enacted, these courts have concluded that if a hospital received payment for otherwise uncompensated inpatient hospital treatment of a patient, that patient is ''eligible for inpatient hospital services'' within the meaning of the current regulation. Likewise, a court has concluded that patients who receive premium assistance to pay for private insurance that covers inpatient hospital services are ''eligible for inpatient hospital services'' within the meaning of the current regulation.

As discussed previously, that was not our intent when we adopted the current language of the regulation, and in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25459), we stated that we continued to believe that it is not appropriate to include patient days associated with funding pools and premium assistance authorized by section 1115 demonstrations in the Medicaid fraction of the Medicare DSH calculation because the benefits offered under these demonstrations are not similar to Medicaid benefits under a State plan and may offset costs that hospitals incur when treating uninsured and underinsured individuals. In the FY 2022 IPPS/LTCH PPS proposed rule, we proposed a revision to our regulations to more clearly state that in order for an inpatient day to be counted in the Medicaid fraction of the Medicare DSH calculation, the section 1115 demonstration must provide inpatient hospital insurance benefits directly to the individual whose day is being considered for inclusion, and we proposed to revise our regulations to reflect this requirement. We specifically discussed that, under the proposed change, days of patients who receive premium assistance through a section 1115 demonstration and the days of patients for which hospitals receive payments from an uncompensated/undercompensated care pool created by a section 1115 demonstration would not be included in the calculation of the Medicaid fraction of the Medicare DSH calculation because neither premium assistance nor uncompensated/undercompensated care pools are inpatient hospital insurance benefits directly provided to individuals, nor are they comparable to the level of benefits available under a Medicaid State plan such that the individuals should be ''regarded as'' ''eligible for medical assistance under a State plan.''

Commenters generally disagreed with our proposal, arguing that both premium assistance programs and uncompensated/undercompensated care pools are used to provide individuals with inpatient hospital services, either by reimbursing hospitals for the same services as the Medicaid program in the case of uncompensated/undercompensated care pools or by allowing individuals to purchase insurance with benefits similar to Medicaid benefits offered under a State plan in the case of premium assistance, and thus should be included in calculating the Medicaid fraction. Following review of these comments, in the final rule with comment period published in the **Federal Register** on December 27, 2021, which finalized certain provisions of the FY 2022 IPPS/LTCH PPS proposed rule related to Medicare graduate medical education payments for teaching and Medicare organ acquisition payment, we stated that after further consideration of the issue, we had determined not to move forward with our proposal and planned to revisit the issue of section 1115 demonstration days in future rulemaking (86 FR 73418).

After considering the comments we received in response to the FY 2022 IPPS/LTCH PPS proposed rule, we continue to believe that, in order for days associated with section 1115 demonstrations to be counted in the numerator of the Medicaid fraction, the statute requires those days to be of patients who can be ''regarded as'' eligible for Medicaid. Accordingly, we propose to modify our regulations to explicitly state our view that ''regarded as eligible'' for Medicaid only includes patients who receive health insurance through a section 1115 demonstration where state expenditures to provide the insurance may be matched with funds from Title XIX. Furthermore, we believe that it is appropriate, and therefore propose, to use our discretion under the Act to include only the days of patients ''regarded as'' eligible for Medicaid who receive health insurance through a section 1115 demonstration that provides essential health benefits (EHB) as set forth in 42 CFR part 440, subpart C, for an Alternative Benefit Plan, which is a uniform benchmark and a standard that is broadly used. This would be a change from the current regulation that

requires a demonstration only provide inpatient hospital benefits for days to be counted in the DSH calculation. We believe that by applying the standard of EHB to identify which section 1115 days may be included in the DSH calculation, both providers and CMS contractors will be able to distinguish between section 1115 demonstrations, or parts of demonstrations, that provide benefits to individuals whose patient days are properly counted in the Medicaid fraction from those demonstrations or parts of demonstrations (like uncompensated/undercompensated care pools) that are not properly included.

Consistent with our interpretation of the Medicare DSH statute, the evolution of our policy on counting section 1115 demonstration days in the Medicaid fraction of the Medicare DSH calculation as set forth in our regulations, and considering the series of adverse cases interpreting the current regulation, we are proposing to amend the regulation to preclude counting days of patients associated with uncompensated/undercompensated care pools in the numerator of the Medicaid fraction. While these pools may result in hospitals receiving some payment for inpatient hospital services they provide to uninsured or underinsured individuals, such payments are not a form of health insurance and do not entitle any particular individual to any specific benefit. Rather, payments from uncompensated/undercompensated care pools essentially function as supplemental Medicaid DSH payments. As we have consistently stated, individuals eligible for benefits under Title XIX are eligible for specific benefits related to the provision of inpatient hospital services (in the form of inpatient hospital insurance). Because funding pool payments to hospitals do not inure to any specific individual, nor do uncompensated/undercompensated care pools provide any health insurance to any patient, it cannot reasonably be argued that patients associated with uncompensated care for which hospitals are reimbursed through section 1115 demonstration-authorized funding pools may be ''regarded as'' eligible for Medicaid. Individuals who receive health insurance through a section 1115 demonstration are being treated as if they were eligible for Medicaid. In contrast, uninsured or underinsured individuals, whether or not they benefit from uncompensated care pool payments to hospitals, do not have health insurance provided by the Medicaid program. Thus, we continue to believe that days associated with uncompensated/undercompensated care pools must be excluded from the Medicaid fraction of the Medicare DSH calculation.

Even if the statute could be read to permit patient groups whose uncompensated care is paid for from a section 1115 demonstration-authorized funding pool to be ''regarded as'' eligible for Medicaid (which the Secretary does not agree the statute permits), those groups may be quite distinct from the groups who are eligible for Medicaid under a State plan, and therefore we are proposing to use our discretion under section 1886(d)(5)(F)(vi) of the Act to exclude from the Medicaid fraction the days of patients whose care costs may be reimbursed to the hospitals through uncompensated/undercompensated care pools.

However, in further considering the comments regarding the treatment of the days of patients provided premium assistance through a section 1115 demonstration, we have concluded that patients receiving premium assistance through a section 1115 demonstration to purchase health insurance can be ''regarded as'' eligible for Medicaid under section 1886(d)(5)(F)(vi). Indeed, it may be difficult to distinguish between a patient who receives 100 percent, or nearly 100 percent (''all or substantially all,'' as defined below), in premium assistance under a section 1115 demonstration to purchase health insurance from a patient who is eligible for medical assistance under the State plan and may be enrolled in a Medicaid managed care plan. Both patients receive health insurance funded through a program of cooperative federalism and paid for with Title XIX funds. Therefore, upon further review we propose, for purposes of the DSH calculation, to ''regard as'' eligible for Medicaid those patients who use premium assistance they obtain through a section 1115 demonstration to buy and pay for all or substantially all (as defined below) of the cost of the health insurance.

Additionally, using the discretion granted to the Secretary under section 1886(d)(5)(F)(vi) of the Act to determine the extent to which patient days of patients ''regarded as'' eligible for Medicaid will be included in the Medicaid fraction, we further propose to include in the Medicaid fraction only those days of patients who have bought health insurance that provides EHB using premium assistance obtained through a section 1115 demonstration that is equal to at least 90 percent of the cost of the health insurance. As some commenters pointed out, some section 1115 demonstrations that provide premium assistance to enrollees require the insurance bought to be offered through the State's Health Insurance Exchange, and as a result the insurance that is available under these demonstrations is individual health insurance that is required to provide EHB, including inpatient hospital benefits. Further, we believe ''all or substantially all'' in the context of purchasing hospital insurance with premium assistance requires the premium assistance be equal to at least 90 percent of the cost of the insurance. We picked people who receive premium assistance of at least 90 percent of the cost of the hospital insurance that provides EHB because this level of benefit is similar to the benefits received by individuals who are eligible for Title XIX programs, and as such, it would be appropriate to include the days of these individuals in the numerator of the Medicaid fraction, if the individual is also not entitled to benefits under Medicare Part A. Individuals who receive less premium assistance are not receiving benefits similar to the benefits received by individuals eligible for Medicaid under a State plan. Therefore, we believe it is appropriate to exclude from the Medicaid fraction days of individuals who use premium assistance to buy health insurance that does not provide EHB or for whom the premium assistance provided by the demonstration accounts for less than 90 percent of the cost of the health insurance. Individual health insurance that is not grandfathered coverage, which is required to identify itself as grandfathered, is generally required to provide EHB. Additionally, depending on the state, information on health insurance that provides EHB may be available directly from individual states (for example, through a state's Insurance Commissioner).

Accordingly, in this proposed rule, we are proposing to revise our regulations at § 412.106(b)(4) to explicitly reflect our interpretation of the language ''regarded as'' ''eligible for medical assistance under a State plan approved under title XIX'' in section 1886(d)(5)(F)(vi) of the Act, to mean patients who receive health insurance through a section 1115 demonstration itself or purchase such insurance with the use of premium assistance provided by a section 1115 demonstration. Moreover, of the groups we ''regard'' as Medicaid eligible, we propose that only the days of those individuals that obtain health insurance that provides EHB (defined as meeting the EHB requirements set forth in 42 CFR part

440, subpart C, for an Alternative Benefit Plan), and if bought with premium assistance, for which the premium assistance is equal to or greater than 90 percent of the cost of the health insurance, are included in the Medicaid fraction of the DSH calculation, provided the patient is not also entitled to Medicare Part A.

As discussed previously, uncompensated/undercompensated care pools serve essentially the same function as Medicaid DSH by indirectly subsidizing the cost of treating the uninsured and underinsured, while not extending health insurance to additional groups. Accordingly, we do not interpret the statute as authorizing the Secretary to ''regard as'' Medicaid eligible patients with uncompensated care costs for which a hospital is reimbursed by a section 1115 demonstration-authorized uncompensated care funding pool. Additionally, even if section 1886(d)(5)(F)(vi) of the Act could be interpreted to permit patients with uncompensated care costs for which a hospital is reimbursed by a demonstration funding pool to be ''regarded as'' Medicaid eligible, we invoke our discretion to exclude such patient days from being counted in the Medicaid fraction of the DSH payment calculation because uncompensated/undercompensated care pools do not provide health insurance to individuals.

We propose that these changes would be effective for discharges occurring on or after October 1, 2022.

V. Other Decisions and Changes to the IPPS for Operating Costs

A. Proposed Changes in the Inpatient Hospital Update for FY 2022 (§ 412.64(d))

1. Proposed FY 2023 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' For FY 2023, we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2022. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.) Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS for FY 2023 is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to all of the following:

- A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act.
- A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act.
- An adjustment based on changes in economy-wide multifactor productivity (MFP) (the productivity adjustment).

Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

We note, in compliance with section 404 of the MMA, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45204), we replaced the 2014-based IPPS operating and capital market baskets with the rebased and revised 2018-based IPPS operating and capital market baskets beginning in FY 2022.

We are proposing to base the FY 2023 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Inc.'s (IGI's) fourth quarter 2021 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through third quarter 2021, which is estimated to be 3.1 percent. We also are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket update), we would use such data, if appropriate, to determine the FY 2023 market basket update in the final rule.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the productivity adjustment. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term multifactor productivity (MFP) with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) is now published by BLS as private nonfarm business total factor productivity. However, as mentioned, the data and methods are unchanged. Please see *www.bls.gov* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch*. In addition, we note that beginning with the FY 2022 final rule, we refer to this adjustment as the productivity adjustment rather than the MFP adjustment to more closely track the statutory language in section 1886(b)(3)(B)(xi)(II) of the Act. We note that the adjustment continues to rely on the same underlying data and methodology.

For FY 2023, we are proposing a productivity adjustment of 0.4 percent. Similar to the market basket update, for this proposed rule, the estimate of the proposed FY 2023 productivity adjustment is based on IGI's fourth quarter 2021 forecast As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2023 productivity adjustment for the final rule.

Based on these data, we have determined four proposed applicable percentage increases to the standardized amount for FY 2023, as specified in the following table:

PROPOSED FY 2023 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2023	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	3.1	3.1	3.1	3.1
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.775	-0.775
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.325	0	-2.325
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.4	-0.4	-0.4	-0.4
Proposed **Applicable Percentage Increase Applied to Standardized Amount**	**2.7**	**0.375**	**1.925**	**-0.4**

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42344), we revised our regulations at 42 CFR 412.64(d) to reflect the current law for the update for FY 2020 and subsequent fiscal years. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we added paragraph (d)(1)(viii) to § 412.64 to set forth the applicable percentage increase to the operating standardized amount for FY 2020 and subsequent fiscal years as the percentage increase in the market basket index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, less a productivity adjustment. (As previously noted, section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.)

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs also is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act.

Under current law, the MDH program is effective for discharges on or before September 30, 2022, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429 through 41430). Therefore, under current law, the MDH program will expire at the end of FY 2022. We refer readers to section V.D. of the preamble of this proposed rule for further discussion of the expiration of the MDH program.

For FY 2023, we are proposing the following updates to the hospital-specific rates applicable to SCHs: A proposed update of 2.7 percent for a hospital that submits quality data and is a meaningful EHR user; a proposed update of 0.375 percent for a hospital that submits quality data and is not a meaningful EHR user; a proposed update of 1.925 percent for a hospital that fails to submit quality data and is a meaningful EHR user; and a proposed update of −0.4 percent for a hospital that fails to submit quality data and is not an meaningful EHR user. As noted previously, for this proposed rule, the FY 2023 market basket update is based on IGI's fourth quarter 2021 forecast of the 2018-based IPPS market basket with historical data through third quarter 2021. Similarly, for this proposed rule, the FY 2023 productivity adjustment is based on IGI's fourth quarter 2021 forecast. We are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket update and the productivity adjustment), we would use such data, if appropriate, to determine the update in the final rule.

2. Proposed FY 2023 Puerto Rico Hospital Update

Section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have ''three-quarters'' of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket rate-of-increase, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users increases to 66⅔ percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. (We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.) The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2022 and subsequent fiscal years. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674).

For FY 2023, consistent with section 1886(b)(3)(B) of the Act, as amended by section 602 of Public Law 114–113, we

are setting the applicable percentage increase for Puerto Rico hospitals by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS for Puerto Rico hospitals will be equal to the rate of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a 66⅔ percent reduction to three-fourths of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for Puerto Rico hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to the productivity adjustment at section 1886(b)(3)(B)(xi) of the Act. As noted previously, section 1886(b)(3)(B)(xi) of the Act states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

Based on IGI's fourth quarter 2021 forecast of the 2018-based IPPS market basket update with historical data through third quarter 2021, for this FY 2023 proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as discussed previously, for Puerto Rico hospitals we are proposing a market basket update of 3.1 percent and a productivity adjustment of 0.4 percent. Therefore, for FY 2023, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we have determined the following proposed applicable percentage increases to the standardized amount for FY 2023 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we are proposing an applicable percentage increase to the FY 2023 operating standardized amount of 2.7 percent (that is, the FY 2023 estimate of the proposed market basket rate-of-increase of 3.1 percent less an adjustment of 0.4 percentage point for the proposed productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, we are proposing an applicable percentage increase to the operating standardized amount of 1.15 percent (that is, the FY 2023 estimate of the proposed market basket rate-of-increase of 3.1 percent, less an adjustment of 1.55 percentage point (the proposed market basket rate-of-increase of 3.1 percent $\times$ 0.75 $\times$ (⅔) for failure to be a meaningful EHR user), and less an adjustment of 0.4 percentage point for the proposed productivity adjustment).

As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2023 market basket update and the productivity adjustment for the FY 2023 IPPS/LTCH PPS final rule.

B. Rural Referral Centers (RRCs) Proposed Annual Updates to Case-Mix Index (CMI) and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997, IPPS final rule with comment period (62 FR 45999), we reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, we did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (5) and the September 30, 1988, **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if the hospital's—

- CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- Number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.

In the FY 2022 final rule (86 FR 45217), in light of the COVID–19 PHE, we amended the regulations at § 412.96(h)(1) to provide for the use of the best available data rather than the latest available data in calculating the national and regional CMI criteria. We also amended the regulations at § 412.96(c)(1) to indicate that the individual hospital's CMI value for discharges during the same Federal fiscal year used to compute the national and regional CMI values is used for purposes of determining whether a hospital qualifies for RRC classification. We also amended the regulations § 412.96(i)(1) and (2), which describe the methodology for calculating the number of discharges criteria, to provide for the use of the best available data rather than the latest available or most recent data when calculating the regional discharges for RRC classification.

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The proposed national median CMI value for FY 2023 is based on the CMI values of all urban hospitals nationwide, and the proposed regional

median CMI values for FY 2023 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). These proposed values are based on discharges occurring during FY 2021 (October 1, 2020 through September 30, 2021), and include bills posted to CMS' records through December 2021. We believe that this is the best available data for use in calculating the proposed national and regional median CMI values and is consistent with our proposal to use the FY 2021 MedPAR claims data for FY 2023 ratesetting. We refer the reader to section I.F. of the preamble of this proposed rule for a complete discussion regarding our proposal to use the latest available data (that is, the FY 2021 MedPAR data) as the best available data for purposes of this FY 2023 rulemaking.

In this FY 2023 IPPS/LTCH PPS proposed rule, we are proposing that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2022, they must have a CMI value for FY 2021 that is at least—

- 1.8251 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region are set forth in the table in this section of this rule. We intend to update the proposed CMI values in the FY 2023 final rule to reflect the updated FY 2021 MedPAR file, which will contain data from additional bills received through March 2022.

Region	Proposed Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.4962
2. Middle Atlantic (PA, NJ, NY)	1.607
3. East North Central (IL, IN, MI, OH, WI)	1.7053
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.7672
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.68955
6. East South Central (AL, KY, MS, TN)	1.67705
7. West South Central (AR, LA, OK, TX)	1.88435
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.8961
9. Pacific (AK, CA, HI, OR, WA)	1.85605

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

3. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. For FY 2023, we are proposing to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2020 (that is, October 1, 2019 through September 30, 2020), which are the latest cost report data available at the time this proposed rule was developed. We believe that this is the best available data for use in calculating the proposed median number of discharges by region and is consistent with our data proposal to use cost report data from cost reporting periods beginning during FY 2020 for FY 2023 ratesetting. We refer the reader to section I.F. of the preamble of this proposed rule for a complete discussion regarding our proposal to use the latest available data (that is, cost reports beginning during FY 2020) as the best available data for purposes of this FY 2023 rulemaking. Therefore, we are proposing that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2022, must have, as the number of discharges for its cost reporting period that began during FY 2020, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- If less, the median number of discharges for urban hospitals in the census region in which the hospital is located. We refer readers to the proposed number of discharges as set forth in this table. We intend to update these numbers in the FY 2023 final rule based on the latest available cost report data.

Region	Proposed Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,713
2. Middle Atlantic (PA, NJ, NY)	8,968
3. East North Central (IL, IN, MI, OH, WI)	7,573
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,786
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	9,718
6. East South Central (AL, KY, MS, TN)	8,007
7. West South Central (AR, LA, OK, TX)	5,794
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	7,730
9. Pacific (AK, CA, HI, OR, WA)	8,096

We note that because the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges, under this proposed rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

C. Proposed Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Expiration of Temporary Changes to Low-Volume Hospital Payment Policy

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41399), section 50204 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals under section 1886(d)(12) of the Act for FYs 2019 through 2022. Beginning with FY 2023, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011, and the preexisting low-volume hospital payment adjustment methodology and qualifying criteria, as implemented in FY 2005 and discussed later in this section, will resume. (For additional information on the temporary changes to the low-volume hospital payment policy, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41401). We also note, in that same final rule, we amended the regulations at 42 CFR 412.101 to reflect the provisions of section 50204 of the Bipartisan Budget Act of 2018.) We discuss the proposed payment policies for FY 2023 in section V.C.3. of the preamble of this proposed rule.

2. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital under the IPPS beginning in FY 2005. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is in addition to any payment calculated under section 1886 of the Act. Therefore, the additional payment adjustment is based on the per discharge amount paid to the qualifying hospital under section 1886 of the Act. In other words, the low-volume hospital payment adjustment is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outlier payments. For SCHs and MDHs, the low-volume hospital payment adjustment is based in part on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment.

As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45219 through 45221), section 50204 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 through 2022. Specifically, the qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act were amended to specify that, for FYs 2019 through 2022, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. Section 1886(d)(12)(D) of the Act was also amended to provide that, for discharges occurring in FYs 2019 through 2022, the Secretary determines the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year. Consistent with the requirements of section 1886(d)(12)(C)(ii) of the Act, the term ''discharge'' for purposes of these provisions refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges).

Beginning with FY 2023, the low volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011. Section 1886(d)(12)(C)(i) of the Act defines a low-volume hospital, for FYs 2005 through 2010 and FY 2023 and subsequent years, as a subsection (d) hospital that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and that has less than 800 discharges during the fiscal year. Section 1886(d)(12)(C)(ii) of the Act further stipulates that the term ''discharge'' means an inpatient acute care discharge of an individual, regardless of whether the individual is entitled to benefits under Medicare Part A (except with respect to FYs 2011 through 2018). Therefore, for FYs 2005 through 2010 and FY 2019 and subsequent years, the term ''discharge'' refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges), and as such the term discharge continues to refer to total discharges for FY 2023 and subsequent years. Furthermore, section 1886(d)(12)(B) of the Act requires, for discharges occurring in FYs 2005 through 2010 and FY 2023 and subsequent years, that the Secretary determine an applicable percentage increase for these low-volume hospitals based on the ''empirical relationship'' between the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges. The statute thus mandates that the Secretary develop an empirically justifiable adjustment based on the relationship

between costs and discharges for these low-volume hospitals. Section 1886(d)(12)(B)(iii) of the Act limits the applicable percentage increase adjustment to no more than 25 percent.

Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25-percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. In the FY 2006 IPPS final rule (70 FR 47432 through 47434), we stated that multivariate analyses supported the existing low-volume adjustment implemented in FY 2005. Accordingly, under the existing regulations, in order for a hospital to continue to qualify as a low-volume hospital on or after October 1, 2022, it must have fewer than 200 total discharges during the fiscal year and be located more than 25 road miles from the nearest ''subsection (d)'' hospital (see § 412.101(b)(2)(i)). (For additional information on the low-volume hospital payment adjustment prior to FY 2018, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56941 through 56943). For additional information on the low-volume hospital payment adjustment for FY 2018, we refer readers to the FY 2018 IPPS notice (CMS–1677–N) that appeared in the April 26, 2018, **Federal Register** (83 FR 18301 through 18308). For additional information on the low-volume hospital payment adjustment for FY 2019 through FY 2022, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41399).)

3. Proposed Payment Adjustment for FY 2023 and Subsequent Fiscal Years

In accordance with section 1886(d)(12) of the Act, beginning with FY 2023, the low-volume hospital definition and payment adjustment methodology will revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act and subsequent legislation. Therefore, effective for FY 2023 and subsequent years, under current policy at § 412.101(b), in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year. For FY 2023 and subsequent years, the statute specifies that a low-volume hospital must have less than 800 discharges during the fiscal year. However, as required by section 1886(d)(12)(B)(i) of the Act and as discussed earlier, the Secretary has developed an empirically justifiable payment adjustment based on the relationship, for IPPS hospitals with less than 800 discharges, between the additional incremental costs (if any) that are associated with a particular number of discharges. Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25-percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief for low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. (Under the policy we established in that same final rule, hospitals with between 200 and 799 discharges do not receive a low-volume hospital adjustment.)

For FYs 2005 through 2010 and FY 2018 and subsequent years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges. The hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year (§ 412.101(b)(2)(i)). We use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. We note that, for FYs 2011 through 2018, we used the most recently available MedPAR data to determine the hospital's Medicare discharges because only Medicare discharges were used to determine if a hospital met the discharge criterion for those years.

In addition to the discharge criterion, a hospital must also meet the mileage criterion to qualify for the low-volume payment adjustment. As specified by section 1886(d)(12)(C)(i) of the Act, a low-volume hospital must be more than 25 road miles (or 15 road miles for FYs 2011 through 2022) from another subsection (d) hospital. Accordingly, for FY 2023 and for subsequent fiscal years, in addition to the discharge criterion, the eligibility for the low-volume payment adjustment is also dependent upon the hospital meeting the mileage criterion at § 412.101(b)(2)(i), which specifies that a hospital must be located more than 25 road miles from the nearest subsection (d) hospital, consistent with section 1886(d)(12)(C)(i) of the Act. We define, at § 412.101(a), the term ''road miles'' to mean ''miles'' as defined at § 412.92(c)(1) (75 FR 50238 through 50275 and 50414).

4. Process for Requesting and Obtaining the Low-Volume Hospital Payment Adjustment

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414) and subsequent rulemaking, most recently in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45219 through 45221), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment.

Under this previously established process, a hospital makes a written request for the low-volume payment adjustment under § 412.101 to its MAC. This request must contain sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. The MAC will determine if the hospital qualifies as a low-volume hospital by reviewing the data the hospital submits with its request for low-volume hospital status in addition to other available data. Under this approach, a hospital will know in advance whether or not it will receive a payment adjustment under the low-volume hospital policy. The MAC and CMS may review available data such as the number of discharges, in addition to the data the hospital submits with its request for low-volume hospital status, to determine whether or not the hospital meets the qualifying criteria. (For additional information on our existing process for requesting the low-volume hospital payment adjustment, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401).)

As explained earlier, for FY 2019 and subsequent fiscal years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges, as was the case for FYs 2005 through 2010. Under § 412.101(b)(2)(i) and (iii), a hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 and 41400), we use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. (For FYs 2011 through 2018, the most recently available MedPAR data were used to determine the hospital's Medicare discharges because non-Medicare

discharges were not used to determine if a hospital met the discharge criterion for those years.) Therefore, a hospital must refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare) to decide whether or not to apply for low-volume hospital status for a particular fiscal year.

As also discussed in the FY 2019 IPPS/LTCH PPS final rule, in addition to the discharge criterion, for FY 2019 and for subsequent fiscal years, eligibility for the low-volume hospital payment adjustment is also dependent upon the hospital meeting the applicable mileage criterion specified in § 412.101(b)(2)(i) or (iii) for the fiscal year. Specifically, to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for FY 2023, a hospital must be located more than 25 road miles from the nearest subsection (d) hospital. (We define in § 412.101(a) the term ''road miles'' to mean ''miles'' as defined in § 412.92(c)(1) (75 FR 50238 through 50275 and 50414).) For establishing that the hospital meets the mileage criterion, the use of a web-based mapping tool as part of the documentation is acceptable. The MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospitals, location on a map, and distance from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the applicable mileage criterion.

In accordance with our previously established process, a hospital must make a written request for low-volume hospital status that is received by its MAC by September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the applicable low-volume hospital payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year). For a hospital whose request for low volume hospital status is received after September 1, if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the MAC's low-volume status determination.

Consistent with this previously established process, for FY 2023, we are proposing that a hospital must submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria (as described earlier). Specifically, for FY 2023, a hospital must make a written request for low-volume hospital status that is received by its MAC no later than September 1, 2022, in order for the 25-percent, low-volume, add-on payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2022. If a hospital's written request for low-volume hospital status for FY 2023 is received after September 1, 2022, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2023 discharges, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

Under this process, a hospital that qualified for the low-volume hospital payment adjustment for FY 2022 may continue to receive a low-volume hospital payment adjustment for FY 2023 without reapplying if it meets both the discharge criterion and the mileage criterion applicable for FY 2023. As discussed previously, for FY 2023 the discharge and the mileage criteria are reverting to the statutory requirements that were in effect prior to FY 2011, and to the preexisting low-volume hospital qualifying criteria, as implemented in FY 2005 and specified in the existing regulations at § 412.101(b)(2)(i). As in previous years, we are proposing that such a hospital must send written verification that is received by its MAC no later than September 1, 2022, stating that it meets the mileage criterion applicable for FY 2023 (that is, is located more than 25 road miles from the nearest ''subsection (d)'' hospital). For FY 2023, we are further proposing that this written verification must also state, based upon the most recently submitted cost report, that the hospital meets the discharge criterion applicable for FY 2023 (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges). If a hospital's request for low-volume hospital status for FY 2023 is received after September 1, 2022, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the 25-percent, low-volume, add-on payment adjustment to determine the payment for the hospital's FY 2023 discharges, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41401 and 41702), in accordance with the provisions of section 50204 of the Bipartisan Budget Act of 2018, for FY 2023 and subsequent fiscal years, we made conforming changes to the regulations at 42 CFR 412.101 to reflect that the low-volume payment adjustment policy in effect for these years is the same low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010. Under these revisions, beginning with FY 2023, consistent with current law, the low-volume hospital qualifying criteria and payment adjustment methodology will return to the criteria and methodology that were in effect prior to the amendments made by the Affordable Care Act (that is, the low-volume hospital payment policy in effect for FYs 2005 through 2010). Therefore, no further revisions to the policy or to the regulations at § 412.101 are required to conform them to the statutory requirement that the low-volume hospital policy in effect prior to the Affordable Care Act will again be in effect for FY 2023 and subsequent years.

D. Proposed Changes in the Medicare-Dependent, Small Rural Hospital (MDH) Program (§ 412.108)

1. Background for the MDH Program

Section 1886(d)(5)(G) of the Act provides special payment protections, under the IPPS, to a Medicare-dependent, small rural hospital (MDH). (For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684).) As discussed in section VB of the preamble of this proposed rule, the MDH program provisions at section 1886(d)(5)(G) of the Act will expire at the end of FY 2022. Beginning with discharges occurring on or after October 1, 2022, all hospitals that previously qualified for MDH status will be paid based on the Federal rate.

Since the extension of the MDH program through FY 2012 provided by section 3124 of the Affordable Care Act, the MDH program had been extended by subsequent legislation as follows: Section 606 of the ATRA (Pub. L. 112–240) extended the MDH program through FY 2013 (that is, for discharges occurring before October 1, 2013). Section 1106 of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) extended the MDH program through the

first half of FY 2014 (that is, for discharges occurring before April 1, 2014). Section 106 of the PAMA (Pub. L. 113–93) extended the MDH program through the first half of FY 2015 (that is, for discharges occurring before April 1, 2015). Section 205 of the MACRA (Pub. L. 114–10) extended the MDH program through FY 2017 (that is, for discharges occurring before October 1, 2017). Section 50205 of the Bipartisan Budget Act (Pub. L. 115– 123) extended the MDH program through FY 2022 (that is for discharges occurring before October 1, 2022). For additional information on the extensions of the MDH program after FY 2012, we refer readers to the following **Federal Register** documents: The FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405 and 53413 through 53414); the FY 2013 IPPS notification (78 FR 14689); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50647 through 50649); the FY 2014 interim final rule with comment period (79 FR 15025 through 15027); the FY 2014 notification (79 FR 34446 through 34449); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50022 through 50024); the August 2015 interim final rule with comment period (80 FR 49596); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57054 through 57057); the FY 2018 notice (83 FR 18303 through 18305); and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429).

2. Expiration of the MDH Program

Because section 50205 of the Bipartisan Budget Act extended the MDH program through FY 2022 only, beginning October 1, 2022, the MDH program will no longer be in effect. Because the MDH program is not authorized by statute beyond September 30, 2022, beginning October 1, 2022, all hospitals that previously qualified for MDH status under section 1886(d)(5)(G) of the Act will no longer have MDH status and will be paid based on the IPPS Federal rate.

When the MDH program was set to expire at the end of FY 2012, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405), we revised our sole community hospital (SCH) policies to allow MDHs to apply for SCH status in advance of the expiration of the MDH program and be paid as such under certain conditions. We codified these changes in the regulations at § 412.92(b)(2)(i) and (v). Specifically, the existing regulations at § 412.92(b)(2)(i) and (v) allow for an effective date of an approval of SCH status that is the day following the expiration date of the MDH program. We note that these same conditions apply to MDHs that intend to apply for SCH status with the expiration of the MDH program on September 30, 2022. Therefore, in order for an MDH to receive SCH status effective October 1, 2022, the MDH must apply for SCH status at least 30 days before the expiration of the MDH program; that is, the MDH must apply for SCH status by September 1, 2022. The MDH also must request that, if approved as an SCH, the SCH status be effective with the expiration of the MDH program; that is, the MDH must request that the SCH status, if approved, be effective October 1, 2022, immediately after its MDH status expires with the expiration of the MDH program on September 30, 2022. We emphasize that an MDH that applies for SCH status in anticipation of the expiration of the MDH program would not qualify for the October 1, 2022, effective date for SCH status if it does not apply by the September 1, 2022, deadline. If the MDH does not apply by the September 1, 2022, deadline, the hospital would instead be subject to the usual effective date for SCH classification; that is, as of the date the MAC receives the complete application as specified at § 412.92(b)(2)(i).

We note that the regulations governing the MDH program are found at § 412.108 and the MDH program is also cited in the general payment rules in the regulations at § 412.90. As stated earlier, under current law, the MDH program will expire at the end of FY 2022, which is already reflected in §§ 412.108 and 412.90(j). As such, we are not proposing specific amendments to the regulations at § 412.108 or § 412.90 to reflect the expiration of the MDH program. However, we are proposing that if the MDH program were to be extended by law, similar to how it was extended through FY 2013, by the ATRA (Pub. L. 112–240); through March 31, 2014, by the Pathway for SGR Reform Act of 2013 (Pub. L. 113–167); through March 31, 2015, by the PAMA (Pub. L. 113–93); through FY 2017, by the MACRA (Pub. L. 114–10); and most recently through FY 2022, by the Bipartisan Budget Act of 2018 (Pub. L. 115–123), we would make conforming changes to the regulations governing the MDH program at § 412.108(a)(1) and (c)(2)(iii) and the general payment rules at § 412.90(j) to reflect such an extension of the MDH program. These conforming changes would only be made if the MDH program were to be extended by statute beyond September 30, 2022.

E. Proposed Indirect Medical Education (IME) Payment Adjustment Factor (§ 412.105)

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2023, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2023 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10 percent increase in the hospital's resident-to-bed ratio.

F. Payment for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 Through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the

hospital's Medicare share of total inpatient days.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the IPPS for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital (and, for discharges occurring on or after October 1, 1997, at non-provider sites, when applicable) to the number of inpatient hospital beds.

The calculation of both direct GME payments and the IME payment adjustment is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress, through the Balanced Budget Act of 1997 (Pub. L. 105–33), established a limit on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied, effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

a. Direct GME Payment Formula

As mentioned previously, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days. Section 1886(h)(4) of the Act specifies the methodology for determining the amount of FTE residents to be included in a hospital's direct GME payment formula. That is, the number of FTE residents training at a hospital (or in non-provider sites as applicable) would not necessarily equal the sum of those FTE residents used in the hospital's direct GME payment formula, since certain rules and factors are applied to adjust the count of FTE residents for direct GME payment purposes. First, section 1886(h)(4)(C) of the Act requires that a ''weighting factor'' of either 1.0 or 0.5 be applied to each FTE resident, as follows: In calculating the number of FTE residents in an approved residency program on or after July 1, 1987, for a resident who is not in the resident's initial residency period, the weighting factor is 0.50. Section 1886(h)(5)(F) of the Act defines the term ''initial residency period'' as the ''period of board eligibility,'' with certain exceptions. Finally, section 1886(h)(4)(G) of the Act states that the term ''period of board eligibility'' means, for a resident, the minimum number of years of formal training necessary to satisfy the requirements for initial board eligibility in the particular specialty for which the resident is training. The direct GME calculation and our policy on applying the weighting factors to each FTE resident based on the FTE resident's status within or beyond the initial residency period (IRP) was established in the September 29, 1989, **Federal Register** (54 FR 40287, 40292, 40305–6), and implemented in the regulations at 42 CFR 413.86(f) (now 42 CFR 413.79(a) and (b)).

Thus, the FTE count used in the direct GME payment formula must be a weighted FTE count when a hospital is training residents beyond their IRPs. However, the direct GME FTE cap is an unweighted number. That is, under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's *unweighted* FTE count of residents for purposes of direct GME may not exceed the hospital's *unweighted* FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996 (that is the hospital's unweighted 1996 FTE cap or FTE cap). Regulations regarding the FTE caps and unweighted FTE counts were first published in the August 29, 1997, **Federal Register**. To address situations where a hospital's weighted FTE count exceeds its unweighted 1996 FTE cap, we established a policy effective for cost reporting periods beginning on or after October 1, 1997, to bring the weighted FTE count within the unweighted FTE cap using the following ratio on the Medicare cost report: ((1996 unweighted FTE cap/current year unweighted FTE count) × (current year total weighted FTE count)) (see 62 FR 46005 and 63 FR 26,330 (May 12, 1998)). In the August 1, 2001, **Federal Register** (66 FR 39893 through 39896), we modified this ratio effective for cost reporting periods beginning on or after October 1, 2001, to separately account for a hospital's current year weighted primary care and obstetrics/gynecology (OB/GYN) FTE count and primary care and OB/GYN PRA, and current year weighted other FTE count and other PRA, as follows: (FTE cap/unweighted total FTEs in the cost reporting period) × (weighted primary care and OB/GYN FTEs in the cost reporting period) plus (FTE cap/unweighted total FTEs in the cost reporting period) × (weighted nonprimary care FTEs in the cost reporting period). The sum of the products is the current year allowable weighted FTE count. In addition, effective for cost reporting periods beginning on or after October 1, 2001, the direct GME payment is calculated using two separate rolling averages, one for primary care and OB/GYN FTE residents, and one for nonprimary care FTE residents. These calculations were implemented at 42 CFR 413.86(g)(4) and (5) respectively, currently 42 CFR 413.79(c)(2)(iii) and (d)(3).

2. Milton S. Hershey Medical Center, et al. v. Becerra Litigation

On May 17, 2021, the U.S. District Court for the District of Columbia ruled against CMS's method of calculating direct GME payments to teaching hospitals when those hospitals' weighted FTE counts exceed their direct GME FTE cap. In *Milton S. Hershey Medical Center, et al.* v. *Becerra* (Slip. Op., 2021 WL 1966572, May 17, 2021), the court ordered CMS to recalculate reimbursement owed, holding that CMS's regulation impermissibly modified the statutory weighting factors discussed previously. The plaintiffs in these consolidated cases alleged that as far back as 2005, the proportional reduction that CMS applied to the weighted FTE count when the weighted FTE count exceeded the FTE cap conflicted with the Medicare statute, and it was an arbitrary and capricious exercise of agency discretion under the Administrative Procedure Act. The Court held that the proportional reduction methodology improperly modified the weighting factors statutorily assigned to residents and fellows. The court ordered CMS to pay

the plaintiffs according to a more favorable method.

For example, a hospital has a direct GME cap of 100, trains 90 FTE residents weighted at 1.0 and 10 FTE fellows weighted at 0.5, for a total unweighted count of 100, and a total weighted FTE count of 95. Under current methodology, the proportional reduction is:

(100 cap/100 current year unweighted count) × 95 (current year weighted count) = 95.

If that hospital adds 10 more fellows and exceeds the cap with an unweighted total of 110 (90 residents and 20 fellows), its weighted FTE count of 100 is reduced as follows:

(100 cap/110 current year unweighted count) × 100 (current year weighted count) = 90.91.

The plaintiffs argued that CMS's proportional reduction method unlawfully reduced the weighting factor of 0.5 to an amount less than that, thereby reducing the capped unweighted FTE amount (100 reduced to 90.91 in the example) to which they were entitled for direct GME payment purposes. The court granted the plaintiffs' motion for summary judgment, denied defendant's, and remanded to the Agency so that it could recalculate plaintiffs' reimbursement payments consistent with the court's opinion. The court held that CMS's proportional reduction methodology, enacted at 42 CFR 413.79(c)(2)(iii), was inconsistent with the statutory weighting factors. In response to the court's decision, we are proposing to implement a modified policy applicable to all teaching hospitals, effective as of October 1, 2001, which would replace the existing policy at 42 CFR 413.79(c)(2)(iii). While the proportional reduction method struck down in *Hershey* was first effective for cost reports beginning on or after October 1, 1997, we are unaware of any open or reopenable NPRs for the 1997–2001 period where the proportional reduction method caused a provider's payments to be lower than they would be under our proposed new policy, but we welcome comments alerting us of such NPRs. The proportional reduction method was amended to its present form effective for cost reporting periods beginning on or after October 2001. *See* current 42 CFR 413.79(c)(2)(ii), (iii). We are therefore proposing to modify the policy embodied in 42 CFR 413.79(c)(2)(iii), which the Court found unlawful in *Hershey.*

Because the *Hershey* court concluded that § 413.79(c)(2)(iii) was inconsistent with the statute, and the Secretary did not appeal, the Secretary ''has no promulgated rule governing'' DGME payments to teaching hospitals over the cap for cost reporting periods beginning on or after October 1, 2001. (See *Allina Health Servs.* v. *Price,* 863 F.3d 937, 939 (D.C. Cir. 2017).) The Secretary is required to ''establish rules consistent with this paragraph for the computation of the number of full-time-equivalent residents in an approved medical residency training program'' (42 U.S.C. 1395ww(h)(4)). We believe that, in order to comply with the statutory requirement to make rules governing the computation of FTEs, it is necessary to engage in a retroactive rulemaking to establish the statutorily-required rule effective for cost reporting periods beginning on or after October 1, 2001. Doing so via notice-and-comment rulemaking is in the public interest because it will permit interested stakeholders to comment on the proposed approach and allow the agency to have the benefit of those comments in the development of a final rule. This is particularly true in this situation, where the existing policy was promulgated via an interim final rule with comment period, and the agency received no comments on the policy the court held unlawful and finalized it as originally proposed.

Because we are proposing to establish this policy retroactively, it would cover cost reporting periods for which many NPRs have already been final settled. Consistent with § 405.1885(c)(2), any final rule retroactively adopting the proposed new policy would not be the basis for reopening final settled NPRs.

a. Change to Direct GME Calculation in Response to Decision in Milton S. Hershey Medical Center et al. v. Becerra

After reviewing the statutory language regarding the direct GME FTE cap and the court's opinion, we have decided to propose a modified policy to be applied for cost reporting periods beginning on October 1, 2001, as described previously. The proposed modified policy would address situations for applying the FTE cap when a hospital's weighted FTE count is greater than its FTE cap, but would not reduce the weighting factor of residents that are beyond their IRP to an amount less than 0.5. Section 1886(h)(4)(F) of the Act states that for purposes of a cost reporting period beginning on or after October 1, 1997, the total number of FTE residents before application of weighting factors may not exceed the number of such FTEs for the hospital's most recent cost reporting period ending on or before December 31, 1996. Under current policy, we interpreted this to mean that only a hospital's unweighted (before application of weighting factors) allopathic and osteopathic FTE count was compared to its FTE cap, and if the unweighted allopathic and osteopathic FTE count exceeded the FTE cap, then the proportional reduction is made to the weighted FTE counts. Under this modified proposed policy, in the instance where a hospital's unweighted allopathic and osteopathic FTE count exceeds its FTE cap, we propose to add a step to also compare the total *weighted* allopathic and osteopathic FTE count to the FTE cap. If the total weighted allopathic and osteopathic FTE count is equal to or less than the FTE cap, then no adjustments would be made to the respective primary care & OB/GYN weighted FTE counts or the other weighted FTE counts. If the total weighted allopathic and osteopathic FTE count exceeds the FTE cap, then we would adjust the respective primary care & OB/GYN weighted FTE counts or the other weighted FTE counts to make the total weighted FTE count *equal* the FTE cap, as follows:

((primary care & OB/GYN weighted FTEs/total weighted FTEs) × FTE cap)) + ((other weighted FTEs/total weighted FTEs) × FTE cap)).

The sum would be the current year total allowable weighted FTE count, which would be reported on Worksheet E–4, line 9, column 3.

More specific to the Medicare cost report, we propose to revise the instructions to Worksheet E–4, line 9 to state: If line 6 is less than or equal to line 5, enter the amounts from line 8, columns 1 and 2, in columns 1 and 2, of this line. Otherwise, *if the total weighted FTE count from line 8, column 3 is greater than the amount on line 5, then enter in column 1 the result of ((primary care & OBGYN weighted FTEs/total weighted FTEs) × FTE cap)). Enter in column 2 the result of ((other weighted FTEs/total weighted FTEs) × FTE cap)). Enter in column 3 the sum of*

((primary care & OBGYN weighted FTEs/total weighted FTEs) × FTE cap)) + ((other weighted FTEs/total weighted FTEs) × FTE cap)).

Example 1: Hospital with a FTE cap of 100 trains 120 FTEs with a weight of 1.0, and 105 FTEs with a weight of 0.5, consisting of 70 weighted primary care & OBGYN FTEs and 35 weighted other FTEs. Since the total weighted count of 105 (Worksheet E–4, line 8, column 3) exceeds the FTE cap of 100 (Worksheet E–4, line 5), the Hospital reports the following adjusted weighted FTE counts on Worksheet E–4:

Line 9, column 1: ((70 weighted primary care & OBGYN FTEs/105 total weighted FTEs) × 100 cap)) = 66.67.
Line 9, column 2: ((35 weighted other FTEs/105 total weighted FTEs) × 100 cap)) = 33.33.
Line 9, column 3: 66.67 FTEs + 33.33 FTEs = 100.

Example 2: Hospital with a FTE cap of 100 trains 102 unweighted FTEs, equating to 96 weighted FTEs. This 96-weighted count consists of 30 weighted primary care & OBGYN FTEs, and 66 weighted other FTEs. Since the total weighted count of 96 (Worksheet E–4, line 8, column 3) is less than the FTE cap of 100 (Worksheet E–4, line 5), then no further adjustment is needed; enter the amounts from line 8, columns 1 and 2, in columns 1 and 2, of line 9.

Example 3: Hospital with a cap of 100 FTEs trains 90 FTEs with a weight of 1.0, and 20 FTEs with a weight of 0.5. Since the total weighted count is 100 (90 + (20 × 0.5)), then no further adjustment is needed. Enter the amounts from line 8, columns 1 and 2, in columns 1 and 2 of line 9.

Under section 1886(h)(4)(G)(i) and 42 CFR 413.79(d)(3), a hospital's weighted FTE count for payment purposes is the 3-year average of its current year weighted FTEs, prior year weighted FTEs, and penultimate year FTEs (for primary care & OBGYN FTEs and other FTEs respectively). Effective for cost reporting periods beginning on or after October 1, 2001, we are proposing to implement this modified methodology for the purpose of determining the prior year weighted FTE count on line 12 of Worksheet E–4, and for the purpose of determining the penultimate year's weighted FTE count on line 13 of Worksheet E–4, even though the prior and penultimate years' FTE counts would be from cost reporting periods prior to October 1, 2001. In this manner, the modified methodology would be fully applied to determining the direct GME payment for cost reporting periods beginning on or after October 1, 2001. Therefore, we are proposing to modify the cost report instructions on Worksheet E–4, lines 12 and 13, respectively to state that effective for cost reporting periods beginning on or after October 1, 2001, if subject to the cap in the prior year or penultimate year respectively, *if the prior/penultimate year total weighted FTE count from line 8, column 3 is greater than the amount on line 5 from the prior/penultimate year, then enter in column 1 the result of ((primary care & OBGYN weighted FTEs/total weighted FTEs) × FTE cap)). Enter in column 2 the result of ((other weighted FTEs/total weighted FTEs) × FTE cap)) plus the amount on line 10, column 2.* These instructions do not in any way modify or reopen final-settled prior and penultimate year NPRs.

We are proposing to amend the regulations text at 42 CFR 413.79(c)(2)(iii) to state that, effective for cost reporting periods beginning on or after October 1, 2001, if the hospital's unweighted number of FTE residents exceeds the limit described in this section, and the number of weighted FTE residents in accordance with § 413.79(b) also exceeds that limit, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the limit. If the number of FTE residents weighted in accordance with § 413.79(b) does not exceed that limit, then the allowable weighted FTE count is the actual weighted FTE count.

3. Reasonable Cost Payment for Nursing and Allied Health Education Programs

a. General

Under section 1861(v) of the Act, Medicare has historically paid providers for Medicare's share of the costs that providers incur in connection with approved educational activities. Approved nursing and allied health (NAH) education programs are those that are, in part, operated by a provider, and meet State licensure requirements, or are recognized by a national accrediting body. The costs of these programs are excluded from the definition of inpatient hospital operating costs and are not included in the calculation of payment rates for hospitals or hospital units paid under the IPPS, IRF PPS, or IPF PPS, and are excluded from the rate-of-increase ceiling for certain facilities not paid on a PPS. These costs are separately identified and ''passed through'' (that is, paid separately on a reasonable cost basis). Existing regulations on NAH education program costs are located at § 413.85. The most recent rulemakings on these regulations were in the January 12, 2001 final rule (66 FR 3358 through 3374), and in the August 1, 2003, final rule (68 FR 45423 and 45434).

b. Medicare+Choice Nursing and Allied Health Education Payments

Section 541 of the Balanced Budget Refinement Act (BBRA) of 1999 provides for additional payments to hospitals for costs of nursing and allied health education associated with services to Medicare+Choice (now called Medicare Advantage (MA)) enrollees. Hospitals that operate approved nursing or allied health education programs and receive Medicare reasonable cost reimbursement for these programs would receive additional payments from Medicare Advantage organizations. Section 541 of the nBBRA limits total spending under the provision to no more than $60 million in any calendar year (CY). (In this document, we refer to the total amount of $60 million or less as the payment ''pool''.) Section 541 of the BBRA also provides that direct Graduate Medical Education (GME) payments for Medicare+Choice utilization are reduced to the extent that these additional payments are made for nursing and allied health education programs. This provision was effective for portions of cost reporting periods occurring in a CY, on or after January 1, 2000.

Section 512 of the Benefits Improvement and Protection Act (BIPA) of 2000 changed the formula for determining the additional amounts to be paid to hospitals for MA nursing and allied health costs. Under section 541 of the BBRA, the additional payment amount was determined based on the proportion of each individual hospital's nursing and allied health education payment to total nursing and allied health education payments made to all hospitals. However, this formula did not account for a hospital's specific MA utilization. Section 512 of the BIPA revised this payment formula to specifically account for each hospital's MA utilization. This provision was effective for portions of cost reporting periods occurring in a CY, beginning with CY 2001, and was implemented in the August 1, 2001 IPPS final rule (66 FR 39909 and 39910).

The regulations at 42 CFR 413.87 codified both of these statutory provisions. We first implemented the BBRA NAH MA provision in the August 1, 2000 IPPS interim final rule with comment period (IFC) (65 FR 47036 through 47039). In that IFC, we outlined the qualifying conditions for a hospital to receive the NAH MA payment, how we would calculate the NAH MA payment pool, and how a qualifying hospital would calculate its ''share'' of payment from that pool. Determining a hospital's NAH MA payment essentially involves applying a ratio of the hospital-specific NAH Part A payments, total inpatient days, and MA inpatient days, to national totals of those same amounts, from cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year. The formula is as follows:

(((Hospital NAH pass-through payment / Hospital Part A Inpatient Days) *

Hospital MA Inpatient Days) / ((National NAH pass-through payment / National Part A Inpatient Days) * National MA Inpatient Days)) * Current Year Payment Pool.

With regard to determining the total national amounts for NAH pass-through payment, Part A inpatient days, and MA inpatient days, we note that section 1886(l) of the Act, as added by section 541 of the BBRA, gives the Secretary the discretion to ''estimate'' the national components of the formula noted previously. For example, section 1886(l)(2)(A) states that the Secretary would estimate the ratio of payments for all hospitals for portions of cost reporting periods occurring in the year under subsection (h)(3)(D) to total direct graduate medical education payments estimated for the same portions of periods under subsection (h)(3). Accordingly, we made the following statements in the August 1, 2000 IFC:

- Each year, we would determine and publish in a proposed rule and a final rule the total amount of nursing and allied health education payments made across all hospitals during the fiscal year that is 2 years prior to the current calendar year (65 FR 47038). We would use the best available cost reporting data for the applicable hospitals from the Hospital Cost Report Information System (HCRIS) for cost reporting periods in the fiscal year that is 2 years prior to the current calendar year (65 FR 47038).
- To calculate the pool, in accordance with section 1886(l) of the Act, we would ''estimate'' a total amount for each calendar year, not to exceed $60 million (65 FR 47038).
- To calculate the proportional reduction to Medicare+Choice (now MA) Direct GME payments, we stated that the percentage is estimated by calculating the ratio of the Medicare+Choice nursing and allied health payment ''pool'' for the current calendar year to the projected total Medicare+Choice direct GME payments made across all hospitals for the current calendar year. We stated that the projections of Medicare+Choice direct GME and Part A direct GME are based on the best available cost report data from the HCRIS (for example, for calendar year 2000, the projections are based on the best available cost report data from HCRIS 1998), and these payment amounts were increased using the increases allowed by section 1886(h) of the Act for these services (using the percentage applicable for the current calendar year for Medicare+Choice direct GME and the Consumer Price Index (CPI) increases for Part A direct GME). We also stated that we would publish the applicable percentage reduction each year in the IPPS proposed and final rules (65 FR 47038).

Thus, in the August 1, 2000, IFC, we described our policy regarding the timing and source of the national data components for the NAH MA add-on payment and the percent reduction to the direct GME MA payments, and we stated that we would publish the rates for each calendar year in the IPPS proposed and final rules. While the rates for CY 2000 were published in the August 1, 2000, IFC (see 65 FR 47038 and 47039), the rates for subsequent CYs were only issued through Change Requests (CRs) (CR 2692, CR 11642, CR 12407). After recent issuance of the CY 2019 rates in CR 12407 on August 19, 2021, we reviewed our update procedures, and were reminded that the August 1, 2000 IFC states that we would publish the NAH MA rates and direct GME percent reduction every year in the IPPS rules. Accordingly, for CY 2020 and forward, the NAH MA add-on rates will be proposed and included in the IPPS proposed and final rules, and we are also reiterating the data sources we would use.

In this FY 2023 IPPS proposed rule, we are proposing the NAH MA add-on rates as well as the direct GME MA percent reductions for CYs 2020 and 2021. In this proposed rule, we are proposing to issue the rates for CYs 2020 and 2021 because we believe we have sufficient HCRIS data to develop the rates for these years, and these rate years are most needed to ensure accurate and timely cost report settlements of cost reports with portions overlapping with CYs 2020 and 2021. We expect to propose to issue the rates for CY 2022 in the FY 2024 IPPS proposed rule, and the rates for CY 2023 in the FY 2025 IPPS proposed rule, and so forth.

Consistent with the use of HCRIS data for past CYs, for CY 2020, we propose to use data from cost reports ending in FY 2018 HCRIS (the fiscal year that is 2 years prior to the calendar year of 2020) to compile these national amounts: NAH pass-through payment, Part A Inpatient Days, MA Inpatient Days. We propose to use data from cost reports ending in FY 2019 HCRIS (the fiscal year that is 2 years prior to the calendar year of 2021) to compile the same national amounts for CY 2021. However, to calculate the ''pool'' and the direct GME MA percent reduction, we ''project'' Part A direct GME payments and MA direct GME payments for the current calendar years, which in this proposed rule, are CYs 2020 and 2021, based on the ''best available cost report data from the HCRIS'' (65 FR 47038). Next, consistent with the method we described previously from the August 1, 2000 IFC, we increase these payment amounts from midpoint to midpoint of the appropriate calendar year using the increases allowed by section 1886(h) of the Act for these services (using the percentage applicable for the current calendar year for MA direct GME, and the Consumer Price Index–Urban (CPI–U) increases for Part A direct GME. For CY 2020, the direct GME projections are based on FY 2019 HCRIS. For CY 2021, the direct GME projections are based on FY 2019 HCRIS. For calendar years 2020 and 2021, the proposed national rates and percentages, and their data sources are set forth in this table. We intend to update these numbers in the FY 2023 final rule based on the latest available cost report data.

	CY 2020	SOURCE	CY 2021	SOURCE
NAH Pass-Through	$272,775,476	Cost reports ending in FY 2018 HCRIS	$277,240,471	Cost reports ending in FY 2019 HCRIS
Part A Inpatient Days	64,510,859	Cost reports ending in FY 2018 HCRIS	66,521,096	Cost reports ending in FY 2019 HCRIS
MA Inpatient Days	9,481,755	Cost reports ending in FY 2018 HCRIS	10,705,665	Cost reports ending in FY 2019 HCRIS
Part A Direct GME	$2,770,987,049	CY 2019 HCRIS + CPI-U	$2,749,561,756	CY 2019 HCRIS + CPI-U
MA Direct GME	$1,617,557,770	CY 2019 HCRIS + CPI-U	$1,862,798,849	CY 2019 HCRIS + CPI-U
Pool (not to exceed $60 million)	$60,000,000	((Part A DGME/MA DGME) * (NAH Pass-through))	$60,000,000	((Part A DGME/MA DGME) * (NAH Pass-through))
Percent Reduction to MA DGME Payments	3.71%	(Pool/MA direct GME)	3.22%	(Pool/MA direct GME)

We are not proposing any changes to the regulations text at 42 CFR 413.87 at this time, as our proposal to include the nursing and allied health MA rates in the IPPS rulemaking is consistent with current regulations.

4. Proposal To Allow Medicare GME Affiliation Agreements Within Certain Rural Track FTE Limitations

Sections 1886(h)(4)(F) and 1886(d)(5)(B)(v) of the Act established limits on the number of allopathic and osteopathic residents that hospitals may count for purposes of calculating direct GME payments and the IME adjustment, respectively, thereby establishing hospital-specific direct GME and IME full-time equivalent (FTE) resident caps. However, under the authority granted by section 1886(h)(4)(H)(ii) of the Act, the Secretary may issue rules to allow institutions that are members of the same affiliated group to apply their direct GME and IME FTE resident caps on an aggregate basis through a Medicare GME affiliation agreement. The Secretary's regulations permit hospitals, through a Medicare GME affiliation agreement, to increase or decrease their IME and direct GME FTE resident caps to reflect the rotation of residents among affiliated hospitals for agreed-upon academic years. Consistent with the broad authority conferred by the statute, we established criteria for defining an ''affiliated group'' and an ''affiliation agreement'' in both the August 29, 1997, final rule (62 FR 45966, 46006) and the May 12, 1998, final rule (63 FR 26318). In the August 1, 2002, IPPS final rule (67 FR 49982, 50069), we amended our regulations to require that each Medicare GME affiliation agreement must have a shared rotational arrangement. The term ''Medicare GME affiliation agreement'' is defined at 42 CFR 413.75(b) as a written, signed, and dated agreement by responsible representatives of each respective hospital in a Medicare GME affiliated group, as defined in § 413.75(b), that specifies—

- The term of the Medicare GME affiliation agreement (which, at a minimum is 1 year), beginning on July 1 of a year;
- Each participating hospital's direct and indirect GME FTE caps in effect prior to the Medicare GME affiliation;
- The total adjustment to each hospital's FTE caps in each year that the Medicare GME affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to one hospital's direct and indirect FTE caps that is offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect FTE caps of at least the same amount;
- The adjustment to each participating hospital's FTE counts resulting from the FTE resident's (or residents') participation in a shared rotational arrangement at each hospital participating in the Medicare GME affiliated group for each year the Medicare GME affiliation agreement is in effect. This adjustment to each participating hospital's FTE count is also reflected in the total adjustment to each hospital's FTE caps (in accordance with criteria 3); and
- The names of the participating hospitals and their Medicare provider numbers.

We also define the term ''Shared Rotational Arrangement'' in that section of our rules as a residency training program under which a resident(s) participates in training at two or more hospitals in that program.

To encourage the training of residents in rural areas, section 407(c) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113) (BBRA) amended section 1886(h)(4)(H) of the Act to add a provision (subsection (iv)) stating that, in the case of a hospital that is not located in a rural area (an urban hospital) that establishes separately accredited approved medical residency training programs (or rural tracks) in a rural area, or has an accredited training program with an integrated rural track, the Secretary shall adjust the urban hospital's cap on the number of FTE residents under subsection 1886(h)(4)(F), in an appropriate manner in order to encourage training of physicians in rural areas. Historically, the Accreditation Council for Graduate Medical Education (ACGME) has separately accredited family medicine programs in the ''1–2 format'' (meaning, residents in the 1–2 format receive their first year experience at a core family medicine program, and their second and third year experiences at another site, which may or may not be rural). Section 407(c) of Public Law 106–113 was effective for direct GME payments to hospitals for cost reporting periods beginning on or after April 1, 2000, and for IME payments applicable to discharges occurring on or after April 1, 2000. We refer readers to the August 1, 2000, interim final rule with comment period (65 FR 47025, 47033 through 47037) and the FY 2002 IPPS final rule (66 FR 39828, 39902 through 39909) where we implemented section 407(c) of Public Law 106–113. The regulations for establishing rural track FTE limitations are located at 42 CFR 413.79(k) for direct GME and at 42 CFR 412.105(f)(1)(x) for IME. (We note that additional legislative and regulatory changes were made to Rural Track Programs in the December 27, 2021 final rule, 86 FR 73445.) When we first implemented the rural track regulations in the August 1, 2000 IFC, we specified that the caps associated with rural tracks are separate and distinct from a hospital's general FTE caps. Specifically, we defined Rural track FTE limitation at 42 CFR 413.75(b) as the maximum number of residents training

in a rural track residency program that an urban hospital may include in its FTE count and that is in addition to the number of FTE residents already included in the hospital's FTE cap (emphasis added). As a result, the rural track FTE limitations are not part of the regular FTE caps that hospitals may aggregate in Medicare GME affiliation agreements.

The rural track FTE limitations are calculated in the same manner as the adjustments to any allowable new program, in accordance with 42 CFR 413.79(e)(1). That is, at the end of the 5-year cap building window for the rural track program, the urban hospital's and rural hospital respective IME and direct GME rural track FTE limitations are calculated as the product of three factors (limited to the number of accredited slots for each program):

- The highest total number of FTE residents trained in any program year during the fifth year of the first new program's existence at all of the hospitals to which the residents in the program rotate;
- The number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program.
- The ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period.

Thus, while the calculated rural track FTE limitations calculated at the end of the 5-year window may reflect the division of the rotations between the urban and rural hospitals over the 5 initial years of the program, the future rotations amounts may change somewhat (albeit adhering to greater than 50 percent of the duration of the training occurring in the rural hospital/rural area). As rotations shift to meet patient care needs, the respective rural track FTE limitations may not quite match the amount of FTEs actually training in the urban and rural hospitals. We have been asked that the same flexibility with cap sharing afforded to teaching hospitals to share general FTE cap slots via Medicare GME affiliation agreements also be afforded to urban and rural teaching hospitals that together train residents in a rural track program. This flexibility would allow the urban and rural hospitals to share their rural track FTE limitations in a manner that best matches the rotations occurring in the urban and rural hospitals. Stakeholders representing urban-rural training partnerships specifically raised this request with regard to separately accredited 1–2 family medicine programs that have existed for a number of years, and either already have established their rural track FTE limitations, or have just recently reached or will reach the end of their 5-year cap building windows.

We have considered this request and agree it would be equitable to allow an urban and rural hospital jointly training residents in a 1–2 separately accredited family medicine program to aggregate their respective IME and direct GME rural track FTE limitations and enter into a ''Rural Track Medicare GME Affiliation Agreement'' to share those cap slots, and facilitate the cross-training of residents. We are proposing to allow urban and rural hospitals that participate in the same separately accredited 1–2 family medicine rural track program and have rural track FTE limitations to enter into ''Rural Track Medicare GME Affiliation Agreements.'' We propose that programs that are not separately accredited in the 1–2 format and are not in family medicine would not be permitted to enter into ''Rural Track Medicare GME Affiliation Agreements'' under this proposal. These Rural Track Medicare GME Affiliation Agreements, which we propose to define in this proposed rule, will be structured similarly to regular Medicare GME affiliation agreements, but we propose two distinct requirements.

First, in an effort to ensure that regular FTE caps and FTE residents in non-rural track programs are not commingled with the rural track FTE residents, and that rural track FTE limitations are not being used to provide additional cap slots for non-rural track FTE residents, we propose that the responsible representatives of each urban and rural hospital entering into the Rural Track Medicare GME Affiliation Agreement must attest in that written agreement that each participating hospital's FTE counts and rural track FTE limitations in the agreement do not reflect FTE residents nor FTE caps associated with programs other than the rural track program. We note this attestation is important for both the urban and rural hospital, as both urban and rural hospitals may have regular FTE caps that could be part of regular Medicare GME affiliation agreements (see 42 CFR 413.79(e)(1)(iv) and (v) and 413.79(f)). Second, we propose to only allow urban and rural hospitals to participate in Rural Track Medicare GME Affiliated Groups if they are separately accredited 1–2 family medicine programs that have rural track FTE limitations in place prior to October 1, 2022. We are proposing to choose these criteria and this date of October 1, 2022, as the date by which eligible hospitals must have rural track FTE limitations in place because the effective date of section 127 of the Consolidated Appropriations Act (CAA) is cost reporting periods beginning on or after October 1, 2022, and we are proposing to limit this proposal to only rural track FTE limitations established under the BBRA of 1999 that are unaffected by section 127 of the CAA. In this proposed rule, we are distinguishing between rural track programs with rural track FTE limitations associated with the BBRA of 1999 in effect prior to October 1, 2022, and Rural Track Programs (RTPs, defined at 42 CFR 413.75(b)) started or expanded to new participating sites under the authority of section 127 of the CAA. We explain this distinction later in this section. First, we refer readers to the December 27, 2021, final rule (86 FR 73445) for details about section 127 of the CAA. Generally, that provision removes the requirement that rural track programs be separately accredited by the ACGME, places in statute (previously in regulation) the requirement that rural track residents must spend greater than 50 percent of their training time in a rural area, and allows urban and rural hospitals to receive adjustments to their rural track FTE limitations for adding new rural training sites to an existing rural track program. In that December 27, 2021, final rule, we addressed a comment (86 FR 73456) asking whether multiple rural hospital training sites added under the new section 127 authority may share their rural track FTE limitations via a Medicare GME affiliation agreement. We responded that effective October 1, 2022, we are not permitting the formation of Medicare GME affiliated groups for the purpose of aggregating and cross-training RTP FTE limitations. First, we explained that we believe Medicare GME affiliated groups for RTPs would be premature, as only starting October 1, 2022, would hospitals have the first opportunity to add additional participating sites. Subsequently, there would be the 5-year cap building period in which Medicare GME affiliations are not permitted, even under existing Medicare GME affiliation agreement rules (42 CFR 413.79(f)). Second, we stated that before we create Medicare GME affiliation agreements unique to RTPs, we believe it would be best to first modify the Medicare cost report form to add spaces for the hospitals to indicate the number of any additional RTP FTEs, and the caps applicable to those FTEs. We also stated that we wish to assess flexibility within

a hospital's own total RTP FTE limitation, before sharing those slots with other hospitals. We would need to be vigilant to ensure that the RTP FTE limitations are not comingled with regular FTE cap adjustments currently used in Medicare GME affiliation agreements. Therefore, we concluded with our belief that it is best to reassess allowing Medicare GME affiliation agreements for RTP FTE limitations at some point in the future. For these same reasons, at this time, we believe it is appropriate to only propose to allow rural track Medicare GME affiliation agreements with urban and rural hospitals that have a rural track FTE limitation in place prior to October 1, 2022. We will assess allowing these agreements with RTP FTE limitations established after October 1, 2022, in the future.

We are proposing the following new definitions at 42 CFR 413.75(b) and requirements:

- Rural track Medicare GME affiliated group is an urban hospital and a rural hospital that participates in a rural track program defined in 42 CFR 413.75(b), and that have rural track FTE limitations in effect prior to October 1, 2022, and that comply with 42 CFR 413.79(f)(1) through (6) for Medicare GME affiliated groups.
- Rural track Medicare GME affiliation agreement is a written, signed, and dated agreement by responsible representatives of each respective hospital in a rural track Medicare GME affiliated group, as defined in 42 CFR 413.75(b), that specifies—

++ A statement attesting that each participating hospital's FTE counts and rural track FTE limitations in the agreement do not reflect FTE residents nor FTE caps associated with programs other than the rural track program.

++ The term of the rural track Medicare GME affiliation agreement (which, at a minimum is 1 year), beginning on July 1 of a year;

++ Each participating hospital's direct and indirect GME rural track FTE limitations in effect prior to the rural track Medicare GME affiliation;

++ The total adjustment to each hospital's rural track FTE limitations in each year that the rural track Medicare GME affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to one hospital's direct and indirect rural track FTE limitations that is offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect rural track FTE limitations of at least the same amount;

++ The adjustment to each participating hospital's FTE counts resulting from the FTE resident's (or residents') participation in a shared rotational arrangement at each hospital participating in the rural track Medicare GME affiliated group for each year the Medicare GME affiliation agreement is in effect. This adjustment to each participating hospital's FTE count is also reflected in the total adjustment to each hospital's rural track FTE limitations (in accordance with criteria 3); and

++ The names of the participating hospitals and their Medicare provider numbers.

In addition, we are proposing to require that no later than July 1 of the residency year during which the rural track Medicare GME affiliation agreement will be in effect, the urban and rural hospital must submit the signed agreement to the CMS contractor or MAC servicing the hospital and send a copy to the CMS Central Office. The hospitals may submit amendments to the adjustments to their respective rural track FTE limitations to the MAC with a copy to CMS by June 30 of the residency year that the agreement is in effect. We propose that eligible urban and rural hospitals may enter into rural track Medicare GME affiliation agreements effective with the July 1, 2023, academic year.

With regard to how the rural track Medicare GME affiliation adjustments would be reported on the Medicare cost report, first, for background, we note that on the previous Medicare cost report CMS–Form–2552–96, the rural track FTE limitation was combined, together with the ''cap'' add-on for new (non-rural track) programs on Worksheet E, Part A, line 3.05, and on Worksheet E–3, Part IV, line 3.02. On the current cost report CMS–Form–2552–10, the rural track FTE limitation is, likewise, combined together with the ''cap'' add-on for new (non-rural track) programs on Worksheet E, Part A, line 6, and on Worksheet E–4, line 2. Going forward, we intend to add lines to the cost report to accommodate separate reporting of urban or rural hospital rural track FTE limitations, and the positive or negative adjustments made to the rural track FTE limitations, including those applicable to the affiliated agreements.

In summary, we are proposing to allow urban and rural hospitals that participate in the same separately accredited 1–2 family medicine rural track program and have rural track FTE limitations to enter into ''Rural Track Medicare GME Affiliation Agreements''. We propose that programs that are not separately accredited in the 1–2 format and are not in family medicine would not be permitted to enter into ''Rural Track Medicare GME Affiliation Agreements'' under this proposal. We are proposing to add new definitions at 42 CFR 413.75(b) of rural track Medicare GME affiliated group and rural track Medicare GME affiliation agreement. We are also proposing to require that the responsible representatives of each urban and rural hospital entering into the rural track Medicare GME affiliation agreement must attest in that agreement that each participating hospital's FTE counts and rural track FTE limitations in the agreement do not reflect FTE residents nor FTE caps associated with programs other than the rural track program. In addition, we propose to only allow urban and rural hospitals to participate in rural track Medicare GME affiliated groups if they have rural track FTE limitations in place prior to October 1, 2022. We propose that eligible urban and rural hospitals may enter into rural track Medicare GME affiliation agreements effective with the July 1, 2023, academic year.

G. Proposed Payment Adjustment for Certain Clinical Trial and Expanded Access Use Immunotherapy Cases (§§ 412.85 and 412.312)

Effective for FY 2021, we created MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, which were reported using ICD–10–PCS procedure codes XW033C3 or XW043C3 (85 FR 58599 through 58600). Effective for FY 2022, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106). We refer the reader to section II.D.17. of the preamble of this proposed rule for discussion of the agenda items for the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting relating to new procedure codes to describe the administration of a CAR T-cell or another type of gene or cellular therapy product, as well as our established process for determining the MS–DRG assignment for codes approved at the March meeting.

Effective for FY 2021, we modified our relative weight methodology for MS–DRG 018 in order to develop a relative weight that is reflective of the typical costs of providing CAR T-cell therapies relative to other IPPS services. Specifically, under our finalized policy we do not include claims determined to be clinical trial claims that group to MS–DRG 018 when calculating the average cost for MS–DRG 018 that is

used to calculate the relative weight for this MS–DRG, with the additional refinements that: (a) When the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for MS DRG 018 to the extent such claims can be identified in the historical data; and (b) when there is expanded access use of immunotherapy, these cases will not be included when calculating the average cost for MS–DRG 018 to the extent such claims can be identified in the historical data (85 FR 58600). The term ''expanded access'' (sometimes called ''compassionate use'') is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.[605]

Effective FY 2021, we also finalized an adjustment to the payment amount for applicable clinical trial and expanded access immunotherapy cases that group to MS–DRG 018 using the same methodology that we used to adjust the case count for purposes of the relative weight calculations (85 FR 58842 through 58844). (As previously noted, effective beginning FY 2022, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106).) Specifically, under our finalized policy we apply a payment adjustment to claims that group to MS–DRG 018 and include ICD–10–CM diagnosis code Z00.6, with the modification that when the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the payment adjustment will not be applied in calculating the payment for the case. We also finalized that when there is expanded access use of immunotherapy, the payment adjustment will be applied in calculating the payment for the case. This payment adjustment is codified at 42 CFR 412.85 (for operating IPPS payments) and 42 CFR 412.312 (for capital IPPS payments), for claims appropriately containing Z00.6, as described previously, and reflects that the adjustment is also applied for cases involving expanded access use immunotherapy, and that the payment adjustment only applies to applicable clinical trial cases; that is, the adjustment is not applicable to cases where the CAR T-cell, non CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product. The regulations at 42 CFR 412.85(c) also specify that the adjustment factor will reflect the average cost for cases to be assigned to MS–DRG 018 that involve expanded access use of immunotherapy or are part of an applicable clinical trial to the average cost for cases to be assigned to MS–DRG 018 that do not involve expanded access use of immunotherapy and are not part of a clinical trial (85 FR 58844).

For FY 2023, we are proposing to continue to apply an adjustment to the payment amount for expanded access use of immunotherapy and applicable clinical trial cases that would group to MS–DRG 018 using the same methodology adopted in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58842), which is the same methodology we are proposing to use to adjust the case count for purposes of the relative weight calculations:

- Calculate the average cost for cases to be assigned to MS–DRG 018 that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000.
- Calculate the average cost for all other cases to be assigned to MS–DRG 018.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply this adjustor when calculating payments for expanded access use of immunotherapy and applicable clinical trial cases that group to MS–DRG 018 by multiplying the relative weight for MS–DRG 018 by the adjustor.

Additionally, we are proposing to continue to use our finalized methodology for calculating this payment adjustment, such that: (a) When the CAR T-cell, non CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for cases not determined to be clinical trial cases; and (b) when there is expanded access use of immunotherapy, these cases will be included when calculating the average cost for cases determined to be clinical trial cases. However, we continue to believe to the best of our knowledge there are no claims in the historical data (FY 2021 MedPAR) used in the calculation of the adjustment for cases involving a clinical trial of a different product, and to the extent the historical data contain claims for cases involving expanded access use of immunotherapy we believe those claims would have drug charges less than $373,000. We note that we are in the process of making modifications to the MedPAR files to include information for claims with the payer-only condition code ''ZC'' in the future. Payer-only condition code ''ZC'' is used by the IPPS Pricer to identify a case where the CAR T-cell, non CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product so that the payment adjustment is not applied in calculating the payment for the case (for example, see Change Request 11879, available at *https://www.cms.gov/files/document/r10571cp.pdf*).

Consistent with our calculation of the proposed adjustor for the relative weight calculations, and our proposal to use the FY 2021 data for the FY 2023 ratesetting, for this proposed rule we are proposing to calculate this adjustor based on the December 2021 update of the FY 2021 MedPAR file for purposes of establishing the FY 2023 payment amount. Specifically, in accordance with 42 CFR 412.85 (for operating IPPS payments) and 42 CFR 412.312 (for capital IPPS payments), we are proposing to multiply the FY 2023 relative weight for MS–DRG 018 by a proposed adjustor of 0.20 as part of the calculation of the payment for claims determined to be applicable clinical trial or expanded use access immunotherapy claims that group to MS–DRG 018, which includes CAR T-cell and non-CAR T-cell therapies and other immunotherapies. We are also proposing to update the value of the adjustor based on more recent data for the final rule.

H. Hospital Readmissions Reduction Program: Proposed Updates and Changes (§§ 412.150 Through 412.154)

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, establishes the Hospital Readmissions Reduction Program. Under the Hospital Readmissions Reduction Program, Medicare payments under the acute inpatient prospective payment system (IPPS) for discharges from an applicable hospital, as defined under section 1886(d) of the Act, may be reduced to

[605] *https://www.fda.gov/news-events/expanded-access/expanded-access-keywords-definitions-and-resources.*

account for certain excess readmissions. Section 15002 of the 21st Century Cures Act requires the Secretary to compare hospitals with respect to the proportion of beneficiaries who are dually eligible for Medicare and full-benefit Medicaid (also known as ''dually-eligible beneficiaries'') in determining the extent of excess readmissions. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49531) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240) for a detailed discussion of and additional information on the statutory history of the Hospital Readmissions Reduction Program.

2. Regulatory Background

We refer readers to the following final rules for detailed discussions of the regulatory background and descriptions of the current policies for the Hospital Readmissions Reduction Program:

- FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676).
- FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401).
- FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676).
- FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048).
- FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543).
- FY 2017 IPPS/LTCH PPS final rule (81 FR 56973 through 56979).
- FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240).
- FY 2019 IPPS/LTCH PPS final rule (83 FR 41431 through 41439).
- FY 2020 IPPS/LTCH PPS final rule (84 FR 42380 through 42390).
- FY 2021 IPPS/LTCH PPS final rule (85 FR 58844 through 58847.
- FY 2022 IPPS/LTCH PPS final rule (86 FR 45249 through 45266).

We have also codified certain requirements of the Hospital Readmissions Reduction Program at 42 CFR 412.152 through 412.154.

3. Current Measures

The Hospital Readmissions Reduction Program currently includes six applicable conditions/procedures: Acute myocardial infarction (AMI); heart failure (HF); pneumonia (PN); elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass graft (CABG) surgery.

We continue to believe the measures we have adopted adequately meet the goals of the Hospital Readmissions Reduction Program. In the FY 2022 IPPS/LTCH PPS final rule, we finalized suppression of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the FY 2023 program year due to the impact of the COVID–19 PHE (86 FR 45254 through 45256). In this proposed rule, we propose to resume use of this measure in the Hospital Readmissions Reduction Program beginning with the FY 2024 program year, with an exclusion of patients with principal or secondary COVID–19 diagnoses from both the cohort and the outcome. We are also providing information on technical specification updates for all of the condition/procedure-specific readmission measures in the Hospital Readmissions Reduction Program to include a covariate adjustment for patients with a clinical history of COVID–19 in the 12 months prior to the index admission.

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41431 through 41439) for more information about how the Hospital Readmissions Reduction Program supports CMS' goal of bringing quality measurement, transparency, and improvement together with value-based purchasing to the hospital inpatient care setting through the Meaningful Measures Framework.

4. Flexibility for Changes That Affect Quality Measures During a Performance Period in the Hospital Readmissions Reduction Program

In the FY 2022 IPPS/LTCH PPS final rule, we adopted a policy for the duration of the COVID–19 PHE that has allowed us to suppress the use of quality measures via adjustment to the Hospital Readmissions Reduction Program's program calculations if we determine that circumstances caused by the COVID–19 PHE significantly affected those measures and the associated ''excess readmissions'' calculations (86 FR 45250 through 45253). As described under that finalized policy, if we were to determine that the suppression of a Hospital Readmissions Reduction Program measure was warranted for an applicable period, we would calculate the measure's rates for that program year but then suppress the use of those rates to make changes to hospitals' Medicare payments. In the Hospital Readmissions Reduction Program, this policy would have the effect of temporarily weighting the affected measure at zero percent in the program's scoring methodology until adjustments were made, the affected portion of the performance period for the measure was made no longer applicable to program calculations, or the measure was removed entirely through rulemaking. We also explained that we would provide feedback reports to hospitals as part of program activities, including to inform their quality improvement activities, and to ensure that they were made aware of the changes in performance rates that we observed (86 FR 45251). We stated that we would publicly report a suppressed measure's data with appropriate caveats noting the limitations of the data due to the COVID–19 PHE (86 FR 45251). To provide stakeholders an opportunity to review this proposed rule prior to release of the Hospital Specific Reports (HSRs) that incorporate updates to the CMS 30-Day Pneumonia Readmission Measure (NQF #0506), we are postponing incorporation of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506), which would typically be included in the July update of the Compare website hosted by HHS (*https://www.medicare.gov/care-compare/*).

In the FY 2022 IPPS/LTCH PPS final rule, we also adopted Measure Suppression Factors to guide our determination of whether to suppress a Hospital Readmissions Reduction Program measure for one or more program years that include discharges during the COVID–19 PHE (86 FR 45251). We adopted these Measure Suppression Factors for use in the Hospital Readmissions Reduction Program, and for consistency, the following other value-based purchasing programs: Hospital Value-Based Purchasing, HAC Reduction Program, Skilled Nursing Facility Value-Based Purchasing Program, and End-Stage Renal Disease Quality Incentive Program. We stated our belief that these Measure Suppression Factors will help us evaluate the Hospital Readmissions Reduction Program's measures and that their adoption in the other value-based purchasing programs, as previously noted, would help ensure consistency in our measure evaluations across programs. The previously adopted Measure Suppression Factors are as follows:

- Significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
- Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the PHE for COVID–19.
- Rapid or unprecedented changes in—

++ Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or

++ The generally accepted scientific understanding of the nature or

biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

- Significant national shortages or rapid or unprecedented changes in—
  - ++ Healthcare personnel;
  - ++ Medical supplies, equipment, or diagnostic tools or materials; or
  - ++ Patient case volumes or facility-level case mix.

We stated our belief that we view this measure suppression policy as necessary to ensure that the Hospital Readmissions Reduction Program did not penalize hospitals based on factors that the program's measures were not designed to accommodate (86 FR 45252).

In this proposed rule, we are not proposing any changes to this policy.

5. Provisions That Address the Impact of COVID–19 on Current Hospital Readmissions Reduction Program Measures

a. Background

As described in V.H.4 of the preamble of this proposed rule, in the FY 2022 IPPS/LTCH PPS final rule, we adopted a measure suppression policy and Measure Suppression Factors to ensure that the Hospital Readmissions Reduction Program did not penalize hospitals based on factors that the program's measures were not designed to accommodate (86 FR 45252).

Additionally, in the FY 2022 IPPS/LTCH PPS final rule, we finalized suppression of the CMS 30-Day Pneumonia Readmissions Measure (NQF #0506) for the FY 2023 program year (86 FR 45254 through 45256). We expressed the belief that the second Measure Suppression Factor (clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the COVID–19 PHE) applied to the CMS 30-Day Pneumonia Readmissions Measure (NQF #0506). In our analysis of the impacts of the COVID–19 PHE on the measures in the Hospital Readmissions Reduction Program, we observed that pneumonia has been identified as a typical characteristic of individuals infected with COVID–19 (86 FR 45254). Using data available during and subsequent to the preparation of the FY 2022 IPPS/LTCH PPS final rule, we found that a substantial portion of the CMS 30-Day Pneumonia Readmissions Measure (NQF #0506) cohort included admissions with a COVID–19 diagnosis, ranging from 13.3 percent in April 2020 to a high of 27.1 percent in December 2020.[606] Furthermore, we noted that at the beginning of the pandemic, the 30-day observed readmission rate for pneumonia patients with a secondary diagnosis of COVID–19 present on admission was lower than the observed readmissions rate for pneumonia patients without a diagnosis of COVID–19 (12.4 percent versus 15.8 percent) because patients with a secondary diagnosis of COVID–19 present on admission had a higher risk of mortality than patients without a COVID–19 diagnosis (86 FR 45254 through 45255).

Additionally, we provided information on technical specification updates for the remaining five condition/procedure-specific readmission measures to exclude patients with a principal or secondary COVID–19 diagnosis from the measures' numerators and denominators beginning in fiscal year (FY) 2023 (86 FR 45256 through 45258). In the FY 2015 IPPS/LTCH PPS final rule, we finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the Hospital Readmissions Reduction Program (79 FR 50039). In the FY 2022 IPPS/LTCH PPS final rule, we noted that to continue to account for readmissions as intended, we would use our subregulatory process to update the specifications to exclude patients with a principal or secondary diagnosis of COVID–19 from the denominators (cohorts) and the numerators (outcomes) of the following five condition/procedure-specific readmission measures: (1) Hospital 30-Day All-Cause RSRR Following AMI Hospitalization (NQF #0505); (2) the Hospital 30-Day, All-Cause, Unplanned, RSRR Following CABG Surgery (NQF #2515); (3) the Hospital 30-Day, All-Cause, RSRR Following COPD Hospitalization (NQF #1891); (4) the Hospital 30-Day, All-Cause RSRR Following Heart Failure Hospitalization (NQF #0330); and (5) the Hospital-Level 30-Day, RSRR Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551) beginning in FY 2023 (86 FR 45256).

b. Proposed Resumption of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the FY 2024 Program Year

Our measure suppression policy, described in section V.H.4 of the preamble of this proposed rule, focuses on a short-term, equitable approach during this unprecedented PHE, and was not intended for indefinite application. While we recognize that performance on some measures may not immediately return to levels seen prior to the PHE, we want to emphasize the long-term importance of value-based care and incentivizing quality care tied to payment. The Hospital Readmissions Reduction Program is an example of our long-standing effort to link payments to healthcare quality in the inpatient hospital setting. Our goal has been to resume the use of measure data for scoring and payment adjustment purposes. We note that in the FY 2022 IPPS/LTCH PPS final rule, we finalized the suppression of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the FY 2023 Program Year and stated that we would continue to monitor the claims that form the basis for this measure's calculations to evaluate the effect of the circumstances on quality measurement and to determine the appropriate policies in the future. Additionally, we recognized that it is important to continue tracking the impact of the COVID–19 PHE on the CMS 30-Day Pneumonia Readmission Measure (NQF #0506), as these data will inform our considerations regarding whether future measure suppression is necessary beyond FY 2023. We noted that the measure is important to improving patient safety and quality of care and stated that we would continue to monitor measure data to determine when it may be considered sufficiently reliable such that resuming full implementation of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) is appropriate (86 FR 45256).

Following publication of the FY 2022 IPPS/LTCH PPS final rule, we have continued to monitor the claims that form the basis for this measure's calculations. While pneumonia continues to be a typical characteristic of individuals infected with COVID–19, we believe that coding practices enhanced by the availability of COVID–19-related ICD–10–CM and ICD–10–PCS codes, effective since January 1, 2021, have enabled us to differentiate patients with COVID–19 from pneumonia patients without COVID–19 within certain data periods.

In this proposed rule, we are proposing that beginning in FY 2024, the Pneumonia Readmission Measure (NQF #0506) will no longer be suppressed under the Hospital Readmissions Reduction Program. We would resume the use of the pneumonia readmission measure for FY 2024 because of the following differences between the FY 2023 and FY 2024 performance periods: (1) The improved coding practices; (2) decreased

[606] While data prior to April 1, 2020 are available, these data used a different method to identify COVID–19 diagnoses. To improve consistency of analysis we began our analysis on April 1, 2020 with the introduction of the COVID–19 ICD–10 codes.

proportion of COVID–19 admissions in the pneumonia readmission measure for this performance period; and (3) sufficient available data to make technical updates to the measure specifications in order to further account for how patients with a COVID–19 diagnosis might impact the quality of care assessed by this measure. These differences lead us to believe that the clinical proximity of the measure's focus is no longer sufficiently close to the health impacts of the COVID–19 PHE for the suppression factor to continue to apply. Specifically, effective January 2021, the ICD–10 code J12.82, pneumonia due to coronavirus disease 2019, was added for use as a secondary diagnosis, along with a principal diagnosis of COVID–19 (U07.1), to identify patients with COVID–19 pneumonia. J12.82 is not included within the cohort of the pneumonia readmission measure, therefore readmission rates for patients with an index admission of COVID pneumonia (J12.82) are not captured by this measure as of January 1, 2021. Whenever new codes are introduced, changes in coding practices are difficult to predict. At the time of the FY 2022 IPPS final rule, we did not have sufficient data to determine the effects of these coding changes on the proportion of COVID–19 patients and readmission rates with pneumonia due to COVID–19 in the pneumonia readmission measure. As additional months of data have become available since early 2021, we have now seen increased use of these codes. Secondly, as these coding changes have occurred and as the COVID–19 PHE has evolved, more recent data show the proportion of COVID–19 admissions in the pneumonia readmission measure have decreased compared to 2020 data. Finally, with the availability of additional data and the decrease in the proportion of COVID–19 admissions in the pneumonia readmission measure, we are now able to make technical updates to the measure specifications in alignment with the technical updates we are making to the five other readmission measures. All of these factors have led us to conclude that the suppression factor no longer applies to the CMS 30-Day Pneumonia Readmissions Measure (NQF #0506) measure.

As previously discussed, we observed that in 2020 following the declaration of the COVID–19 PHE for COVID–19 a substantial proportion of the CMS 30-Day Pneumonia Readmissions Measure (NQF #0506) cohort included admissions with a COVID–19 diagnosis, ranging from 13.3 percent when the COVID–19 ICD–10 diagnosis code became available in April 2020 to a high of 27.1 percent in December 2020. After the J12.82 code was implemented in January 2021, the proportion of patients with COVID–19 diagnosis present on admission in the pneumonia measure dropped to 9.8 percent. Data on the proportion of patients with COVID–19 diagnosis present on admission from April 2020 through December 2020 are detailed in Table V.H.–01. The most recently available data on the proportion of patients with COVID–19 diagnosis present on admission for January through September 2021, which do not include patients with pneumonia due to coronavirus disease 2019 per ICD–10 code J12.82, are detailed in Table V.H–02.

TABLE V.H.-01: PERCENT OF PRINCIPAL OR SECONDARY COVID-19 DIAGNOSES IN READMISSION MEASURE COHORTS APRIL 2020 – DECEMBER 2020

Measure Cohort	April 2020	May 2020	June 2020	July 2020	August 2020	September 2020	October 2020	November 2020	December 2020
Pneumonia	13.3%	11.2%	6.7%	15.6%	14.5%	7.5%	9.5%	17.9%	27.1%
COPD	0.3%	0.2%	0.2%	0.4%	0.5%	0.4%	0.4%	0.9%	1.4%
AMI	0.5%	0.6%	0.5%	1.0%	1.1%	0.8%	0.9%	2.2%	3.6%
HF	0.4%	0.6%	0.6%	0.7%	0.8%	0.6%	0.7%	1.3%	2.1%
THA/TKA	0.3%	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%	0.3%	0.5%
CABG	0.1%	0.2%	0.2%	0.4%	0.4%	0.3%	0.3%	0.5%	1.5%

TABLE V.H.-02: PERCENT OF PRINCIPAL OR SECONDARY COVID-19 DIAGNOSES IN READMISSION MEASURE COHORTS JANUARY 2021 – SEPTEMBER 2021

Measure Cohort	January 2021	February 2021	March 2021	April 2021	May 2021	June 2021	July 2021	August 2021	September 2021
Pneumonia	9.8%	5.6%	2.5%	1.9%	1.2%	0.8%	0.7%	2.1%	3.5%
COPD	1.4%	0.9%	0.5%	0.3%	0.3%	0.2%	0.2%	0.6%	0.7%
AMI	3.7%	2.3%	1.2%	0.8%	0.6%	0.4%	0.3%	1.4%	2.0%
HF	2.4%	1.8%	1.0%	0.7%	0.6%	0.3%	0.3%	0.9%	1.1%
THA/TKA	0.6%	0.4%	0.2%	0.2%	0.1%	0.1%	0.1%	0.2%	0.2%
CABG	1.4%	1.1%	0.5%	0.4%	0.3%	0.2%	0.1%	0.5%	0.6%

We note that the surge of COVID–19-related hospitalizations had begun to subside with the rollout of the U.S. vaccination program in early 2021, although hospitalizations began increasing again during late summer 2021 with the COVID–19 Delta variant and increased over the fall and winter with the COVID–19 Omicron variant.

We also note that updated data show that the proportion of admissions with a COVID–19 diagnosis for the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) between April 2020 and December 2020 was 13.1 percent, whereas the proportion between January 2021 and September 2021 is substantially lower, at 3.1 percent.

Analyzing data available for the FY 2022 IPPS/LTCH PPS final rule (April 2020 through June 2020), we noted that the 30-day observed readmissions rate for patients with a secondary diagnosis of COVID–19 present on admission at the index admission were lower than the observed readmissions rates for patients without a diagnosis of COVID–19 (12.4 percent versus 15.8 percent). In more recent data, we have found that the observed readmission rate for admissions with a COVID–19 diagnosis are similar to observed readmission rates for admissions without a COVID–19 diagnosis (17.3 percent vs. 17.2 percent, respectively) as depicted in Table V.H.–03.

TABLE V.H.-03: OBSERVED READMISSION RATE FOR ADMISSIONS WITH/WITHOUT SECONDARY DIAGNOSIS OF COVID PRESENT ON ADMISSION*

	Number of Admissions	Number of Readmissions	Observed 30-Day Readmission Rate
Admissions with Secondary Diagnosis of COVID-19 present on admission	22,967	3,972	17.3%
Admissions without a Diagnosis of COVID-19	757,517	130,067	17.2%

*For the Pneumonia Readmission measure, based on data from July 1, 2018-February 28, 2021, excluding admissions from December 2, 2019-June 30, 2020 reflecting application of the nationwide ECE in response to the COVID-19 ECE.

Because updated data show that following the January 2021 coding update patients with a diagnosis of COVID–19 now make up a smaller proportion of the population of pneumonia admissions than in the analysis described in the FY 2022 IPPS/LTCH PPS final rule, and because observed 30-day readmission rates are similar between admissions with and without a COVID–19 diagnosis, we believe that resuming the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) with a modification to exclude patients with a primary or secondary diagnosis of COVID–19 beginning with the FY 2024 program year would be appropriate. As described in more detail in section V.H.5.c of the preamble of this proposed rule, we will also add a covariate to adjust for a history of COVID–19 diagnosis in the 12 months prior to the admission as a technical update to the measure specifications.

In our analysis, measure scores calculated with the cohort and denominator exclusions and addition of the covariate for a history of COVID–19 diagnosis in the 12 months prior resulted in mean measure scores that were closer to the prior non-COVID–19 affected period compared with the unchanged measure. We note that these measure-specific modifications are in addition to application of the nationwide ECE granted in response to the COVID–19 PHE, which precludes the use of data from January 1, 2020 through June 30, 2020 from measure score calculations. Because these updates are to minimize the effect of COVID–19 on the pneumonia measure, which was not developed to account for COVID–19 diagnosed patients, we believe that these changes do not fundamentally change the measure such that it is no longer the same measure that we originally adopted, and therefore we believe that these are non-substantive updates. We note that in the FY 2015 IPPS/LTCH PPS final rule, we finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the Hospital Readmissions Reduction Program (79 FR 50039). We reiterated this policy in the FY 2020 IPPS/LTCH PPS final rule, stating our continued belief that the subregulatory process is the most expeditious manner possible to ensure that quality measures remain fully up to date while preserving the public's ability to comment on updates that so fundamentally change a measure that it is no longer the same measure that we originally adopted (84 FR 42385). We believe that excluding COVID–19 patients from the measure denominator (cohort) and numerator (outcome) and adding a covariate to adjust for a history of a COVID–19 diagnosis in the 12 months prior to an admission (discussed in section V.H.5.c. of the preamble of this proposed rule), will ensure that this condition-specific readmission measure continues to account for readmissions as intended and meets the goals of the Hospital Readmissions Reduction Program. We note that the readmission measure uses three years of data. The performance period for the FY 2023 program year includes admissions from July 1, 2018 through June 30, 2021, exclusive of January 1, 2020 through June 30, 2020 data excluded due to the ECE waiver. Therefore, we continue to believe it is appropriate to suppress the currently implemented measure for use in payment calculations for FY 2023 as finalized in the FY 2022 IPPS/LTCH PPS final rule.

Additional resources about the current measure technical specifications and methodology for the hospital technical specification of the current readmission measures are provided at our website in the Measure Methodology Reports (when the readmission Measure Methodology reports for 2022 public reporting are available, they will be posted on the QualityNet website at *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*). Hospital Readmissions Reduction Program resources are located at the Resources web page of the QualityNet website (available at *https://qualitynet.cms.gov/inpatient/hrrp/resources*).

We welcome public comment on our proposal to resume use of the CMS 30-Day Pneumonia Readmissions Measure

(NQF #0506) beginning with the FY 2024 program year.

c. Technical Measure Specification Update To Include Covariate Adjustment for COVID–19 Beginning With FY 2023

As discussed in section V.H.5.b of the preamble of this proposed rule, we have previously finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the Hospital Readmissions Reduction Program (79 FR 50039) and reiterated this policy in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42385) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45256). As we continue to evaluate the effects of the COVID–19 PHE on our programs, and the effects of COVID–19 on our measures, we have observed that for some patients COVID–19 continues to have lasting effects, including fatigue, cough, palpitations, and others potentially related to organ damage, post-viral syndrome, post-critical care syndrome or other reasons.[607] These clinical conditions could affect a patient's risk factors for being readmitted following an index admission for any of the six conditions/procedures included in the Hospital Readmissions Reduction Program. Therefore, we are modifying the technical measure specifications of each of our six condition/procedure specific risk-standardized readmission measures to include a covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission beginning with the FY 2023 program year. This inclusion of the covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission will be effective beginning with the FY 2023 program year and for subsequent years for the five non-pneumonia condition- and procedure-specific readmission measures. As described in V.H.5.b, the pneumonia readmission measure remains suppressed from scoring and payment adjustments for the FY 2023 program year and will be resumed for the FY 2024 program year. However, this update will be reflected in the confidential and public reporting of the pneumonia readmission measure for FY 2023.[608] For more information on the application of covariate adjustments, please see the Measure Methodology Reports (when the readmission Measure Methodology reports for 2022 public reporting are available, they will be posted on the QualityNet website at *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*).

6. Definition of ''Applicable Period''

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53375) for discussion of our previously finalized policy for defining ''applicable period.'' The definition of ''applicable period'' is also specified at 42 CFR 412.152. The ''applicable period'' is the 3-year period from which data are being collected in order to calculate excess readmission ratios (ERRs) and payment adjustment factors for the fiscal year; this includes aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment. The ''applicable period'' for dually-eligible beneficiaries is the same as the ''applicable period'' that we otherwise adopt for purposes of the Hospital Readmissions Reduction Program.

In order to provide greater certainty around future ''applicable periods'' for the Hospital Readmissions Reduction Program, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58845 through 58846), we finalized the automatic adoption of ''applicable periods'' for FY 2023 and all subsequent program years for the Hospital Readmissions Reduction Program.

Beginning in FY 2023, the ''applicable period'' for the Hospital Readmissions Reduction Program will be the 3-year period beginning 1 year advanced from the previous program fiscal year's start of the ''applicable period.'' [609] Under this policy, for all subsequent years, we will advance this 3-year period by 1 year unless otherwise specified by the Secretary, which we would convey through notice and comment rulemaking. Similarly, the ''applicable period'' for dual eligibility will continue to correspond to the ''applicable period'' for the Hospital Readmissions Reduction Program, unless otherwise specified by the Secretary. We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58845 through 58846) for a more detailed discussion of this topic.

In this proposed rule, we are not proposing any updates to this policy.

7. Identification of Aggregate Payments for Each Condition/Procedure and All Discharges

When calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payment amount for an individual hospital for the applicable period for each condition/procedure using Medicare inpatient claims from the MedPAR file with discharge dates that are within the applicable period. Under our established methodology, we use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each Federal fiscal year within the applicable period, as our data source.

In identifying discharges for the applicable conditions/procedures to calculate the aggregate payments for excess readmissions, we apply the same exclusions to the claims in the MedPAR file as are applied in the measure methodology for each of the applicable conditions/procedures. For the FY 2023 applicable period, this includes the discharge diagnoses for each applicable condition/procedure based on a list of specific ICD–10–CM and ICD–10–PCS code sets, as applicable, for that condition/procedure.

We identify Medicare fee-for-service (FFS) claims that meet the criteria as previously described for each applicable condition/procedure to calculate the aggregate payments for excess readmissions. This means that services covered by Medicare Advantage are not included in this calculation. This policy is consistent with the methodology to calculate ERRs based solely on admissions and readmissions for Medicare FFS patients.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38232), we stated that we would determine the neutrality modifier using the most recently available full year of MedPAR data. For the purpose of modeling the estimated FY 2023 readmissions payment adjustment factors for this proposed rule, we would use the proportion of dually eligible beneficiaries, excess readmission ratios, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2023 Hospital Readmissions Reduction Program applicable period (July 1, 2018 through June 30, 2021).[610]

[607] Raveendran, A.V., Jayadevan, R. and Sashidharan, S., *Long COVID: An overview.* Available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8056514/.* Accessed on December 15, 2021.

[608] We note that the pneumonia readmission measure would typically be included in the July update of the Compare website. However, to provide stakeholders an opportunity to provide comment on these updates, we are postponing incorporation of the pneumonia readmission measure to the October refresh of the Compare website.

[609] Although the FY 2023 applicable period would be July 1, 2018 through June 30, 2021, we note that the first and second quarter data from CY 2020 is excluded from consideration for program calculation purposes due to nationwide ECE that was granted in response to the COVID–19 PHE.

[610] Although the FY 2023 applicable period is July 1, 2018, through June 30, 2021, we note that

For the FY 2023 program year, applicable hospitals will have the opportunity to review and correct calculations based on the FY 2023 applicable period of July 1, 2018 to June 30, 2021, before they are made public under our policy regarding reporting of hospital-specific information. Again, we reiterate that this period is intended to review the program calculations, and not the underlying data. For more information on the review and corrections process, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53401).

We are not proposing any changes to our policies for the identification of aggregate payments for each condition/procedure in this proposed rule.

8. Use of MedPAR Data Corresponding to the Applicable Period

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53387 through 53390) for discussion of our previously finalized policy for the use of MedPAR claims data as our data source for determining aggregate payments for each condition/procedure and aggregate payments for all discharges during applicable periods. Most recently, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45258), we finalized our policy on the continued use of the MedPAR data corresponding to the applicable period for the Hospital Readmissions Reduction Program calculations for the FY 2022 applicable period.

In addition, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45259), we expressed our continued belief that the use of MedPAR claims data is the appropriate source for identifying aggregate payments for each condition/procedure and all discharges during the corresponding applicable period for the Hospital Readmissions Reduction Program. Therefore, we finalized our proposal to automatically adopt the use of MedPAR data corresponding to the applicable period (the 3-year period beginning 1 year advanced from the previous program fiscal year's MedPAR data) [611] for Hospital Readmissions Reduction Program calculations for FY 2023 and all subsequent program years.

In this proposed rule, we are not proposing any changes to this policy.

9. Calculation and Application of Payment Adjustment Factors

As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226), section 1886(q)(3)(D) of the Act requires the Secretary to group hospitals and apply a methodology that allows for separate comparisons of hospitals within peer groups, based on the proportion of dually eligible beneficiaries served by each hospital, in determining a hospital's adjustment factor for payments applied to discharges beginning in FY 2019. Section 1886(q)(3)(D) of the Act also states that this methodology could be replaced through the application of subclause (E)(i), which states that the Secretary may take into account the studies conducted and the recommendations made by the reports required by section 2(d)(1) of the IMPACT Act of 2014 (Pub. L. 113–185; 42 U.S.C. 1395 note) with respect to risk adjustment methodologies.

Additionally, section 1886(q)(3)(A) of the Act defines the payment adjustment factor for an applicable hospital for a fiscal year as ''equal to the greater of: (i) The ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C).'' Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is equal to 1 minus the ratio of aggregate payments for excess readmissions to aggregate payments for all discharges, scaled by the neutrality modifier. The calculation of this ratio is codified at 42 CFR 412.154(c)(l) and the floor adjustment factor is codified at 42 CFR 412.154(c)(2). Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor at 0.97 for FY 2015 and subsequent fiscal years.

Consistent with section 1886(q)(3) of the Act, and codified in our regulations at 42 CFR 412.154(c)(2), for FY 2023, the payment adjustment factor will be either the greater of the ratio or the floor adjustment factor of 0.97. Under our established policy, the ratio is rounded to the fourth decimal place. In other words, for FY 2023, a hospital subject to the Hospital Readmissions Reduction Program would have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237) for a detailed discussion of the payment adjustment methodology. For additional information on Hospital Readmissions Reduction Program payment calculations, we refer readers to the Hospital Readmissions Reduction Program information and resources available on our QualityNet website.

We are not proposing any changes to our calculation of payment methodology in the proposed rule.

10. Extraordinary Circumstance Exception (ECE) Policy for the Hospital Readmissions Reduction Program

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49542 through 49543), we adopted an ECE policy for the Hospital Readmissions Reduction Program, which recognized that there may be periods of time during which a hospital is not able to submit data (from which readmission measures data are derived) in an accurate or timely fashion due to an extraordinary circumstance beyond its control. When adopting this policy, we noted that we considered the feasibility and implications of excluding data for certain measures for a limited period of time from the calculations for a hospital's excess readmission ratios for the applicable performance period. By minimizing the data excluded from the program, the policy enabled affected hospitals to continue to participate in the Hospital Readmissions Reduction Program for a given fiscal year if they otherwise continued to meet applicable measure minimum threshold requirements. We expressed the belief that this approach would help alleviate the burden for a hospital that might be adversely impacted by a natural disaster or other extraordinary circumstance beyond its control, while enabling the hospital to continue to participate in the Hospital Readmissions Reduction Program. We further observed that section 1886(q)(5)(D) of the Act permits the Secretary to determine the applicable period for readmissions data collection, and we interpreted the statute to allow us to determine that the period not include times when hospitals may encounter extraordinary circumstances. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38239 through 38240), we modified the requirements for the Hospital Readmissions Reduction Program ECE policy to further align with the processes used by other quality reporting and VBP programs for requesting an exception from program reporting due to an extraordinary

first and second quarter data from CY 2020 is excluded from consideration for program calculation purposes due to the nationwide ECE that was granted in response to the COVID–19 PHE.

[611] Although the FY 2023 applicable period is July 1, 2018, through June 30, 2021, we note that first and second quarter data from CY 2020 is excluded from consideration for program calculation purposes due to the nationwide ECE that was granted in response to the COVID–19 PHE. Taking into consideration the 30-day window to identify readmissions, the period for calculating DRG payments would be adjusted to July 1, 2018 through December 1, 2019 and July 1, 2020 through June 30, 2021. Further information will be found in the FY 2023 Hospital Specific Report (HSR) User Guide located on QualityNet website at *https://qualitynet.cms.gov/inpatient/hrrp/reports.*

circumstance not within a provider's control.

In response to COVID–19, we announced relief for clinicians, providers, hospitals, and facilities participating in Medicare quality reporting and value-based purchasing programs. On September 2, 2020, we published the interim final rule with comment period (IFC), ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 54820). The IFC updated the ECE we granted in response to the COVID–19 PHE, for the Hospital Readmissions Reduction Program and several other quality reporting programs (85 FR 54827 through 54837). In the IFC, we updated the previously announced application of our ECE policy for the Hospital Readmissions Reduction Program (85 FR 54832 through 54833) to the COVID–19 PHE to exclude any data submitted regarding care provided during the first and second quarters of CY 2020 from our calculation of performance for FY 2022, FY 2023, and FY 2024.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45260 through 45262), we clarified our ECE policy to highlight that an ECE granted under the Hospital Readmissions Reduction Program would exclude claims data during the corresponding ECE period. Although we have considered the feasibility and implications of excluding data under the ECE policy for the Hospital Readmissions Reduction Program, we have never specified the types of data that would be excluded under an ECE granted to an individual hospital. Considering that the Hospital Readmissions Reduction Program only uses claims data, we clarified our ECE policy to specify that claims data will be excluded from calculations of measure performance under an approved ECE for the Hospital Readmissions Reduction Program. We further clarified that although an approved ECE for the Hospital Readmissions Reduction Program would exclude excepted data from Hospital Readmissions Reduction Program payment reduction calculations, we did not waive the data submission requirements of a hospital for claims data (86 FR 45261 through 45262). For example, for claims data, we require a hospital to submit claims to receive payments for the services they provided to patients. Although an individual ECE approval under the Hospital Readmissions Reduction Program would except data submitted by a hospital from Hospital Readmissions Reduction Program calculations, a hospital would still need to submit its claims in order to receive payment outside the scope of the Hospital Readmissions Reduction Program for services provided.

Finally, in the FY 2022 IPPS/LTCH PPS final rule, we clarified that, although an approved ECE for the Hospital Readmissions Reduction Program would exclude excepted data from Hospital Readmissions Reduction Program payment reduction calculations, such an ECE does not exempt hospitals from payment reductions under the Hospital Readmissions Reduction Program (86 FR 45262).

We are not proposing any changes to our previously finalized ECE Policy in this proposed rule.

11. Request for Public Comment on Possible Future Inclusion of Health Equity Performance in the Hospital Readmissions Reduction Program

We are committed to achieving equity in healthcare outcomes for our beneficiaries by supporting providers' quality improvement activities to reduce health inequities, by enabling them to make more informed decisions, and by promoting provider accountability for healthcare disparities.[612] As described in section IX.B. of the preamble of this proposed rule, we discuss and seek comment on overarching principles for measuring health care quality disparities to provide more actionable and comprehensive information on health care disparities across multiple social risk factors and demographic variables. As part of this request for information, we also discuss different approaches for identifying meaningful performance differences and guiding principles for reporting disparity measures.

As previously discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226), section 1886(q)(3)(D) of the Act requires the Secretary to group hospitals and apply a methodology that allows for separate comparisons of hospitals with differing proportions of dually eligible beneficiaries in determining a hospital's adjustment factor for payments applied to discharges beginning in FY 2019. To implement this provision, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237), we finalized a number of changes to the payment reduction methodology, including our policy to stratify hospitals into quintiles, or peer groups, based on their proportion of dually eligible beneficiaries (82 FR 38229 through 38231) and our policy to use the median excess readmission ratio for the hospital's peer group in place of 1.0 in the payment reduction formula (82 FR 38231 through 38237). In this peer grouping methodology, dual-eligibility status is used as it is an indicator of beneficiaries' social risk. The peer grouping methodology mitigates against disproportionate payment reductions for hospitals serving socially at-risk populations. However, this peer grouping methodology does not directly measure or account for disparities in health care quality between beneficiary groups with heightened social risk and groups with less social risk.

In the FY 2018 IPPS/LTCH PPS final rule, we introduced confidential reporting of hospital quality measure data stratified by social risk factors (82 FR 38403 through 38409). We have created two complementary methods to calculate disparities in condition/procedure-specific readmission measures (the CMS Disparity Methods). The first method (the Within-Hospital disparity method) promotes quality improvement by calculating differences in outcome rates across beneficiary groups within a hospital while accounting for their clinical risk factors. This method also allows for comparison of those differences, or disparities, across hospitals, so hospitals could assess how well they are closing disparity gaps compared to other hospitals. The second methodological approach (the Across-Hospital method) assesses hospitals' outcome rates for subgroups of beneficiaries across hospitals, allowing for a comparison across hospitals on their performance serving beneficiaries with social risk factors. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38405 through 38407) and the Disparity Methods technical report and Updates and Specifications Report posted on the QualityNet website for additional details. The CMS Disparity Methods more directly measure disparities in health care quality between dually eligible and non-dually eligible beneficiary groups than the Hospital Readmissions Reduction Program's peer grouping methodology. For example, when considering the CMS Disparity Methods results calculated using data for the FY 2022 Hospital Readmissions Reduction Program performance period, measures showed not only a range between low and high disparity rates within hospitals, but also worse overall outcome rates for beneficiaries with

[612] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf.*

social risk using beneficiary dual eligibility status as the stratification variable. Of these measures, the most actionable for hospitals were measures that showed overall high readmission rates for dually eligible beneficiaries across hospitals, or a large difference in readmission rates between dually eligible and non-dually eligible beneficiaries. These gaps in care indicated that there is potential for improvement, or a reduction in disparity at poorly performing hospitals if they were able to emulate the performance of strongly performing hospitals.

The Hospital Readmissions Reduction Program currently groups hospitals into one of five peer groups based on their proportion of beneficiaries who are dually eligible for Medicare and full Medicaid benefits. Beneficiaries' dual eligibility for Medicare and Medicaid is a widely used proxy for a beneficiary's financial risk. Medicaid enrollees have incomes and overall wealth below a certain threshold and thus, Medicaid eligibility may be used as a proxy for low socioeconomic status. The use of beneficiaries' dual eligibility in social risk factor analyses was supported by ASPE's First Report to Congress.[613] This report found that in the context of value-based purchasing programs such as the Hospital Readmissions Reduction Program, dual eligibility, as an indicator of social risk, was among the most powerful predictors of poor health outcomes among those social risk factors that ASPE examined and tested. In alignment with the current program, we are considering the use of the beneficiary's dual eligibility status as a measure of beneficiaries' social risk that could be used to incorporate hospitals' performance for socially at-risk populations in the Hospital Readmissions Reduction Program.

As part of our broader goal of achieving equity in healthcare outcomes for our beneficiaries, we are interested in encouraging providers to improve health equity and reduce health care disparities through the Hospital Readmissions Reduction Program. We are seeking comment on approaches to updating the Hospital Readmissions Reduction Program to incorporate performance for socially at-risk populations. For example, we are considering approaches that would account for a hospital's performance on readmissions for socially at-risk beneficiaries compared to all other hospitals, or its performance in treating socially at-risk beneficiaries compared to other beneficiaries within the hospital, or combinations of these approaches. We acknowledge that updating the Hospital Readmissions Reduction Program to encourage improved performance for socially at-risk populations can take many forms, and we seek to explore different approaches so we can find an approach that satisfies our goals without unintended consequences.

In exploring approaches to incorporate performance for socially at risk populations in the Hospital Readmissions Reduction Program, our objective is to encourage providers to improve health equity and reduce health care disparities without disincentivizing hospitals to treat socially at-risk beneficiaries or disproportionately penalizing hospitals that treat a large proportion of socially at-risk beneficiaries. We are seeking comment on approaches that would achieve this objective.

As also discussed in our request for information on overarching principles for measuring health care quality disparities, as described in section IX.C of the preamble of this proposed rule, many non-clinical drivers of health are known to impact beneficiary outcomes, including social risk factors such as socioeconomic status, housing security and adequacy, and food security. The Hospital Readmissions Reduction Program currently uses beneficiaries' dual eligibility for Medicare and Medicaid as a proxy for a beneficiary's social risk and uses dual eligibility, as required by the statute, to divide hospitals into peer groups for comparison under the program. We are seeking comment on variables associated with or measures of social risk and beneficiary demographics that are already collected, as well as broader definitions of dual eligibility, such as those who are enrolled in a Medicare Savings Program or the Medicare Part D Low Income Subsidy, that could be included in the Hospital Readmissions Reduction Program in addition to dual eligibility. We note initially we would use such variables to stratify results within Hospital Specific Reports (HSRs) as confidential feedback to hospitals.

Measures of social risk could also include indices developed for the purpose of identifying socially at-risk populations and measuring the degree of risk. For example, as described in section IX.B, we are considering the University of Wisconsin School of Medicine and Public Health and Health Resources and Services Administration's Area Deprivation Index,[614] Agency for Healthcare Research and Quality Socioeconomic Status Index,[615] and the Centers for Disease Control and Prevention's Social Vulnerability Index.[616] For example, the Area Deprivation Index allows for rankings of neighborhoods by socioeconomic disadvantage in a region of interest (such as at the state or national level), and includes factors for income, education, employment, and housing quality and is used in our Everyone with Diabetes Counts program in order to target seniors in the most disadvantaged neighborhoods for diabetes education.[617] In addition to individual variables or sets of variables we are seeking comment on the addition of one or more of these indices or proposals for other indices or modified indices that capture multiple dimensions of social risk and that have demonstrated relations to health outcomes or access to health care resources, that can be added to the Program along with dual eligibility as factors for stratifying data. We ask commenters to include information on the availability of public data sources and documentation of the methods and testing that establish their applicability and provide supporting information about availability and methods when suggesting variables or indices to measure social risk. Support from a national-level assessment of the impact of social risk can be particularly useful to demonstrate the relevance of a proposed indicator.

Before any changes to the Hospital Readmissions Reduction Program are implemented, we plan to assess the extent to which they address our objective as well as their financial impact on the Hospital Readmissions Reduction Program. Any proposals to update the Hospital Readmissions

[613] Office of the Assistant Secretary for Planning and Evaluation. (2016). Social risk factors and performance under Medicare's value-based purchasing programs. Available at: *https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs.*

[614] Center for Health Disparities Research. About the Neighborhood Atlas. Available at: *https://www.neighborhoodatlas.medicine.wisc.edu/.*

[615] Bonito A., Bann C., Eicheldinger C., Carpenter L. (2008). Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare & Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality.

[616] Flanagan, B.E., Gregory, E.W., Hallisey, E.J., Heitgerd, J.L., Lewis, B. (2011). A social vulnerability index for disaster management. Journal of Homeland Security and Emergency Management, 8(1). Available at: *https://www.atsdr.cdc.gov/placeandhealth/svi/img/pdf/Flanagan_2011_SVIforDisasterManagement-508.pdf.*

[617] *https://www.neighborhoodatlas.medicine.wisc.edu/.*

Reduction Program to account for the extent to which a hospital is able to provide high quality and equitable care for beneficiaries with social risk factors, as previously described, would be made through future rulemaking.

We invite public comment on the following: (1) The benefit and potential risks, unintended consequences, and costs of incorporating hospital performance for beneficiaries with social risk factors in the Hospital Readmissions Reduction Program; (2) the approach of linking performance in caring for socially at-risk populations and payment reductions by calculating the reductions based on readmission outcomes for socially at-risk beneficiaries compared to other hospitals or compared to performance for other beneficiaries within the hospital; and (3) measures or indices of social risk, in addition to dual eligibility, that should be used to measure hospitals' performance in achieving equity in the Hospital Readmissions Reduction Program.

I. Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes

Section 1886(o) of the Act requires the Secretary to establish a hospital value-based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made in a fiscal year (FY) to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

For more of the statutory background and descriptions of our current policies for the Hospital VBP Program, we refer readers to our codified requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.168.

1. Flexibilities for the Hospital VBP Program in Response to the Public Health Emergency (PHE) Due to COVID–19

a. Measure Suppression Policy for the Duration of the COVID–19 PHE

In the FY 2022 IPPS/LTCH PPS final rule, we finalized a measure suppression policy and several Measure Suppression Factors for the duration of the COVID–19 PHE (86 FR 45266 through 45269). We stated that we had previously identified the need for flexibility in our quality programs to account for the impact of changing conditions that are beyond participating hospitals' control. We identified this need because we would like to ensure that participants in our programs are not affected negatively when their quality performance suffers not due to the care provided, but due to external factors, such as the COVID–19 PHE.

Specifically, we finalized a policy for the duration of the COVID–19 PHE that enables us to suppress the use of data for a number of measures if we determine that circumstances caused by the COVID–19 PHE have affected those measures and the resulting Total Performance Scores (TPSs) significantly. We also finalized the adoption of Measure Suppression Factors which will guide our determination of whether to suppress a Hospital VBP Program measure for one or more program years where the baseline or performance period of the measure overlaps with the COVID–19 PHE. The finalized Measure Suppression Factors are as follows:

- Measure Suppression Factor 1: Significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
- Measure Suppression Factor 2: Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the PHE for COVID–19.
- Measure Suppression Factor 3: Rapid or unprecedented changes in—
  - ++ Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or
  - ++ The generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.
- Measure Suppression Factor 4: Significant national shortages or rapid or unprecedented changes in—
  - ++ Healthcare personnel;
  - ++ Medical supplies, equipment, or diagnostic tools or materials; or
  - ++ Patient case volumes or facility-level case mix.

We also note that, as part of this measure suppression policy, we stated that we would still provide confidential feedback reports to hospitals on their measure rates on all measures to ensure that they are made aware of the changes in performance rates that we have observed. We also stated that we would publicly report suppressed data with appropriate caveats noting the limitations of the data due to the COVID–19 PHE. We continue to strongly believe that publicly reporting these data will balance our responsibility to provide transparency to consumers and uphold safety while ensuring that hospitals are not unfairly scored or penalized through payment under the Hospital VBP Program. We also note that, due to operational complications associated with the proposed changes to the scoring methodology, and in order to allow enough time for the appropriate notice and comment period process, we may not be able to provide hospitals with the feedback reports for FY 2023 until after August 1, 2022. We intend to provide hospitals with these feedback reports for FY 20223 as soon as possible and estimate that we will be able to provide reports before the end of 2022.

We are not proposing any changes to the measure suppression policy in this proposed rule.

b. Proposals To Suppress Specific Measures for the FY 2023 Program Year

(1) Background and Overview

COVID–19 has had significant negative health effects—on individuals, communities, nations, and globally. Consequences for individuals who have COVID–19 include morbidity, hospitalization, mortality, and post-COVID–19 related conditions (also known as long COVID). As of early-March 2022, over 78 million COVID–19 cases, 4.5 million new COVID–19 related hospitalizations, and 900,000 COVID–19 deaths have been reported in the U.S.[618] One analysis projected that COVID–19 would reduce life expectancy in 2020 by 1.13 years overall, with the estimated impact disproportionately affecting minority communities. According to this analysis, the estimated life expectancy reduction for Black and Latino populations is 3 to 4 times the estimate when comparing to the white population.[619] With a death toll surpassing that of the 1918 influenza pandemic, COVID–19 is the deadliest disease in American history.[620]

Additionally, impacts of the COVID–19 pandemic have continued to accelerate in 2021 as compared with 2020. The Delta variant of COVID–19 (B.1.617.2) surfaced in the United States in early-to-mid 2021. Studies have shown that the Delta variant is up to 60 percent more transmissible than the previously dominant Alpha variant in

[618] *https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/index.html.*

[619] Andrasfay, T., & Goldman, N. (2021). Reductions in 2020 US life expectancy due to COVID–19 and the disproportionate impact on the Black and Latino populations. Proceedings of the National Academy of Sciences of the United States of America, 118(5), e2014746118. *https://www.pnas.org/content/118/5/e2014746118.*

[620] Covid overtakes 1918 Spanish flu as deadliest disease in U.S. history (*statnews.com*).

2020.[621] Further, in November 2021, the number of COVID–19 deaths for 2021 surpassed the total deaths for 2020. According to CDC data, the total number of deaths involving COVID–19 reached 385,453 in 2020 and 451,475 in 2021.[622] With this increased transmissibility and morbidity associated with the Delta variant as well as new variants like Omicron which have impacted 2021 [623] [624] and worsening staffing shortages in Q3 and Q4 2021 associated with the ongoing PHE,[625] we remain concerned about using measure data that is significantly impacted by COVID–19 for scoring and payment purposes for the FY 2023 program year.

As noted in section V.H.1.a., in the FY 2022 IPPS/LTCH PPS final rule, we finalized a measure suppression policy and several Measure Suppression Factors for the duration of the COVID–19 PHE (86 FR 45266 through 45269). In addition, under this policy, we suppressed the following measures for the FY 2022 program year:

- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (NQF #0166)
- Medicare Spending per Beneficiary—Hospital (MSPB) (NQF #2158)
- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
- National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
- American College of Surgeons-Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753)
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcomes Measure (NQF #1716)
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717)

Since the publication of the FY 2022 IPPS/LTCH PPS final rule, we have conducted analyses on all Hospital VBP Program measures to determine whether and how COVID–19 has impacted the validity of the data used to calculate these measures for the FY 2023 program year. We discuss our findings from these analyses that follows. Based on those analyses, we are proposing to suppress the following measures for the FY 2023 program year:

- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (NQF #0166)
- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
- National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
- American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753)
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716)
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717)

We also note that in the FY 2022 IPPS/LTCH PPS final rule, we finalized our proposal to suppress the Hospital 30-Day, All Cause, Risk Standardized Mortality Rate Following Pneumonia (PN) Hospitalization measure (NQF #0468) (MORT–30–PN) for the FY 2023 program year (86 FR 45274 through 45276).

(2) Proposal To Suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Measure (NQF #0166) for the FY 2023 Hospital VBP Program Year

As noted in section V.H.1.b. of the preamble of this proposed rule, in the FY 2022 IPPS/LTCH PPS final rule, we finalized the suppression of the HCAHPS measure for the FY 2022 program year under Measure Suppression Factor 1, significant deviation in national performance on the measures, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. We refer readers to the FY 2022 IPPS/LTCH PPS final rule for additional details and a summary of public comments we received related to that finalized policy (86 FR 45270 through 45271).

We are proposing to suppress the HCAHPS measure for the FY 2023 program year under Measure Suppression Factor 1, significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse as compared to historical performance during the immediately preceding program years, and Measure Suppression Factor 4, significant national shortages or rapid or unprecedented changes in healthcare personnel. We would calculate hospitals' HCAHPS measure rates, but we would not use these measure rates to generate achievement, improvement, or consistency points for this measure. Additionally, because the HCAHPS measure is the only measure included in the Person and Family Engagement domain, we would not calculate hospitals' FY 2023 domain scores for the Person and Family Engagement domain. Participating hospitals would continue to report the measure data to CMS so that we can monitor the effect of the circumstances on quality measurement and consider appropriate policies in the future. We would continue to provide confidential feedback reports to hospitals as part of program activities to allow hospitals to track the changes in performance rates that we observe. We also intend to publicly report CY 2021 measure rate data where feasible and appropriately caveated. As noted in section V.I.1.a. of the preamble of this proposed rule, we believe that publicly reporting suppressed measure data is an important step in providing transparency and upholding the quality of care and safety for consumers.

Based on our analysis of HCAHPS data from Q1 2019 to Q3 2021, we continue to observe a sustained decline in hospital-level HCAHPS scores beginning in Q2 2020. This decline is associated with the COVID–19 PHE in 2020 and 2021. HCAHPS measure results are publicly reported as ''top-box'', ''bottom-box'', and ''middle-box'' scores, with ''top-box'' being the most positive response to HCAHPS Survey items.[626]

In order to determine whether the COVID–19 PHE impacted the HCAHPS

[621] Allen H., Vusirikala A., Flannagan J., et al. Increased Household Transmission of COVID–19 cases associated with SARS–CoV–2 Variant of Concern B.1.617.2: A national case-control study. Public Health England. 2021.

[622] *https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm.*

[623] *https://www.cdc.gov/coronavirus/2019-ncov/science/forecasting/mathematical-modeling-outbreak.html.*

[624] *https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html?s_cid=11734:omicron%20variant:sem.ga:p:RG:GM:gen:PTN:FY22.*

[625] Bloomberg, U.S. Hospital Staff Shortages Hit Most in a Year on Covid Surge, *https://www.bloomberg.com/news/articles/2022-01-05/one-in-five-u-s-hospitals-face-staffing-shortages-most-in-year* (citing HHS data).

[626] Summary Analyses (*hcahpsonline.org*): *https://www.hcahpsonline.org/en/summary-analyses/.*

measure for the FY 2023 program year and to what extent, we conducted an analysis that compared the Q1 2021, Q2 2021, and Q3 2021 HCAHPS data to the Q1 2019, Q2 2019, and Q3 2019 HCAHPS data.[627] This analysis was similar to the analysis we conducted last year when we compared Q1 2020 and Q2 2020 HCAHPS data to Q1 2019 and Q2 2019 HCAHPS data.[628] As reflected in Table V.I.–01, this analysis showed that HCAHPS measure top-box scores in Q1, Q2, and Q3 2021 compared to the same quarter in pre-COVID–19 2019 were almost always lower. The relatively steady decline in HCAHPS top-box scores that began in Q2 2020 became sharper in Q3 2021. Compared to Q3 2019, HCAHPS scores in Q3 2021 were lower by 1 to 4 top-box points. These changes were statistically significant for all HCAHPS measures in Q2 2021 and Q3 2021 at the $p < 0.0001$ level, meaning that changes were too large to occur by chance more than one time in 10,000.[629] These changes stand in sharp contrast to the pattern of generally small improvements prior to Q2 2020.

We believe that the analysis of Q1, Q2, and Q3 2021 HCAHPS scores indicates a pattern of significant negative changes in hospital performance from the immediately preceding pre-COVID–19 quarters where HCAHPS scores generally changed by less than 1 top-box point, sometimes increasing and sometimes decreasing, compared to the same quarter one year earlier.

TABLE V.I.-01: CHANGE IN HCAHPS TOP-BOX SCORES IN MATCHED QUARTERS FROM Q1 2020 VS. Q1 2019, TO Q3 2021 VS. Q3 2019

HCAHPS Measure used in the Hospital VBP Program	COVID-19 QUARTERS Change in HCAHPS Top-Box Points						
	Q1 2020 vs. Q1 2019	Q2 2020 vs. Q2 2019	Q3 2020 vs. Q3 2019	Q4 2020 vs. Q4 2019	Q1 2021 vs. Q1 2019	Q2 2021 vs. Q2 2019	Q3 2021 vs. Q3 2019
Communication with Nurses	-0.04	**-1.15****	**-1.40****	**-1.09****	**-1.41****	**-1.30****	**-2.04****
Communication with Doctors	0.00	**-0.91****	**-1.06****	**-0.78****	**-0.90****	**-1.02****	**-1.67****
Staff Responsiveness	**-0.82***	**-2.06****	**-2.54****	**-2.99****	**-2.79****	**-2.61****	**-4.39****
Communication About Medicine	**-1.23****	**-3.27****	**-3.05****	**-2.12****	**-2.68****	**-2.67****	**-3.84****
Cleanliness	**-0.63****	**-0.92****	**-2.44****	**-2.70****	**-2.02****	**-2.21****	**-3.70****
Quietness	**0.41****	**0.54****	**-0.20***	**0.46****	0.17	**-0.87****	**-1.34****
Discharge Information	**0.20****	**-0.79****	**-0.69****	**-0.76****	**-0.52****	**-0.59****	**-1.02****
Care Transition	**0.25****	**-2.00****	**-1.96****	**-1.63****	**-1.42****	**-1.26****	**-2.06****
Overall Rating	**0.77****	-0.19	**-1.41****	**-0.70****	**-0.80****	**-1.56****	**-2.64****
Number of hospitals in each pair of matched quarters	1606	1701	3074	3117	3129	3084	3084

*Significant at $p<0.05$; **Significant at $p<0.005$; ***Significant at $p<0.0001$. All bolded values are statistically significant.

Notes: Approximately 90% of hospitals in the Q3 2021 vs. Q3 2019 comparison are IPPS hospitals. Standard HCAHPS scoring, including survey mode and patient-mix adjustment, has been applied. Each column compares data from the named quarter (Q1 2020 to Q3 2021) to data from the same hospitals in the same quarter of 2019, thus accounting for seasonal effects and patient-mix adjustment.

We are also proposing to suppress the HCAHPS measure for the FY 2023 program year under Measure Suppression Factor 4, significant national shortage or rapid or unprecedented changes in healthcare personnel. During the course of the PHE, an unprecedented number of healthcare personnel have left the workforce or ended their employment in hospitals.[630] This healthcare personnel shortage worsened in 2021, with hospitals across the United States reporting 296,466 days of critical staffing shortages, an increase of 86 percent from the 159,320 days of critical staffing shortage hospitals reported in 2020.[631] Healthcare workers, especially those in areas with higher infection rates, have reported serious psychological symptoms, including anxiety, depression, and burnout.[632] [633]

Shortages in hospital healthcare personnel have been shown to affect quality of care and patient satisfaction. Studies have shown that hospitals with greater numbers of hospitalists treating general-medicine patients and greater availability of nursing unit support services have been associated with higher levels of patient satisfaction.[634] [635]

[627] We note that the COVID–19 PHE was declared on January 31, 2020: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx*.

[628] As described further in the FY 2022 IPPS/LTCH PPS final rule, in order to detect the possible impact of the COVID–19 PHE on patients' experience of hospital care, we previously conducted an ''apples-to-apples'' analysis in which we compared hospitals' HCAHPS measure top-box scores for each quarter between Q1 2019 and Q4 2020 to their top-box scores for each of the same quarters one year earlier (86 FR 45270 through 45271). We refer readers to the FY 2022 IPPS/LTCH PPS final rule for additional details on that analysis (86 FR 45270 through 45271).

[629] Comparisons for this analysis are based on hospitals with at least 25 completed surveys in each of the two matched quarters.

[630] Health Affairs, *COVID–19's Impact on Nursing Shortages, The Rise of Travel Nurses, and Price Gouging* (Jan. 28, 2022), *https://www.healthaffairs.org/do/10.1377/forefront.20220125.695159/*.

[631] *https://healthdata.gov/Hospital/COVID-19-Reported-Patient-Impact-and-Hospital-Capa/g62h-syeh*.

[632] Kriti Prasad, Colleen McLoughlin, Martin Stillman, Sara Poplau, Elizabeth Goelz, Sam Taylor, Nancy Nankivil, Roger Brown, Mark Linzer, Kyra Cappelucci, Michael Barbouche, Christine A. Sinsky. Prevalence and correlates of stress and burnout among U.S. healthcare workers during the COVID–19 pandemic: A national cross-sectional survey study. EClinicalMedicine, Volume 35. 2021. 100879. ISSN 2589–5370. *https://doi.org/10.1016/j.eclinm.2021.100879*.

[633] Vizheh, M., Qorbani, M., Arzaghi, S.M. *et al.* The mental health of healthcare workers in the COVID–19 pandemic: A systematic review. *J Diabetes Metab Disord* 19, 1967–1978 (2020). *https://doi.org/10.1007/s40200-020-00643-9*.

[634] Chen L, Birkmeyer J, Saint S, Jha A. 2013. Hospitalist Staffing and Patient Satisfaction in the National Medicare Population. Journal of Hospital Medicine, *https://doi.org/10.1002/jhm.2001*.

[635] Bacon, C.T., & Mark, B. (2009). Organizational effects on patient satisfaction in hospital medical-surgical units. The Journal of nursing administration, 39(5), 220–227. *https://doi.org/10.1097/NNA.0b013e3181a23d3f*.

Conversely, nurse burnout has been linked to lower nurse-assessed quality of care [636] and lower patient satisfaction.[637] Nursing shortages have also been linked with negative patient perceptions of care.[638] Therefore, we believe this significant national change in healthcare personnel due to the COVID–19 PHE has significantly impacted hospitals' scores on the HCAHPS measure, which measures patient experience of hospital care, including staff responsiveness, communication with hospital staff, and cleanliness of the hospital environment.

Additionally, reports of hospital staff shortages have varied widely geographically. In January 2021, half of the hospitals in New Mexico and over 40 percent of the hospitals in Vermont, Rhode Island, West Virginia, and Arizona reported staffing shortages.[639] Conversely, in that same week, less than 10 percent of hospitals in Washington, DC, Connecticut, Alaska, Illinois, New York, Maine, Montana, Idaho, Texas, South Dakota and Utah reported staffing shortages. Given the wide variance in reported staffing shortages, and the impact staffing shortages has had on HCAHPS scores, we believe our proposal to suppress the HCAHPS measure fairly addresses the geographic disparity in the impact of the COVID–19 PHE on participating hospitals.

Due to the emergence of COVID–19 variants, such as the Delta variant, which worsened staffing shortages in Q3 and Q4 2021,[640] we anticipate that Q4 2021 data will continue to demonstrate a deviation in national performance such that scoring this measure would not be representative of national or individual hospital quality of care. Additionally, we believe that suppressing the HCAHPS measure is appropriate because the impact of COVID–19 on the measure cannot be addressed through risk-adjustment for two reasons. First, we cannot risk adjust the measure to exclude patients whose admissions were related to COVID–19 because this measure does not capture patient-level diagnosis data. Second, even if we could exclude patients whose admissions were related to COVID–19 from the measure, we believe the HCAHPS calculations would still be impacted because hospital staffing and resource issues affect a hospital's entire patient population. Therefore, we believe that suppressing this measure for the FY 2023 program year will address concerns about the potential unintended consequences of penalizing hospitals that treated COVID–19 diagnosed patients.

For these reasons, we are proposing to suppress the HCAHPS measure for the FY 2023 Hospital VBP program year under Measure Suppression Factors 1 and 4.

We welcome public comment on this proposal.

(3) Proposal To Suppress the Five Healthcare-Associated Infection (HAI) Safety Measures for the FY 2023 Hospital VBP Program Year

As noted in section V.H.1.b. of the preamble of this proposed rule, in the FY 2022 IPPS/LTCH PPS final rule, we finalized the suppression of the five HAI Safety measures (CAUTI, CLABSI, Colon and Hysterectomy SSI, MRSA, and CDI) for the FY 2022 program year under Measure Suppression Factor 1, significant deviation in national performance on the measures, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. We refer readers to the FY 2022 IPPS/LTCH PPS final rule for additional details on that policy and a summary of public comments we received related to that finalized policy (86 FR 45272 through 45274).

In this proposed rule, we are proposing to suppress the five HAI Safety measures (CAUTI, CLABSI, Colon and Hysterectomy SSI, MRSA, and CDI) for the FY 2023 program year under Measure Suppression Factor 1, significant deviation in national performance on the measures, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years, Measure Suppression Factor 3, rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials, and Measure Suppression Factor 4, significant national shortages or rapid or unprecedented changes in healthcare personnel and patient case volumes. We are concerned that the COVID–19 PHE affected measure performance on the HAI measures in 2021 such that we will not be able to score hospitals fairly or reliably for national comparison and payment adjustment purposes. As part of this proposal, we would calculate hospitals' five HAI measure rates, but we would not use these measure rates to generate achievement or improvement points for these measures. Additionally, because these five measures make up the entirety of the Safety domain, we would not calculate hospitals' FY 2023 Safety domain score. Participating hospitals would continue to report the measure data to the CDC and CMS so that we can monitor the effect of the circumstances on quality measurement and consider appropriate policies for the future. We would continue to provide confidential feedback reports to hospitals as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. Though we are concerned that the COVID–19 PHE has affected measure performance on the HAI measures in 2021, patient safety remains a priority in our value-based purchasing programs. Therefore, we also intend to publicly report CY 2021 data where feasible and appropriately caveated. As noted in section V.I.1.a. of the preamble of this proposed rule, we believe that publicly reporting suppressed measure data is an important step in providing transparency and upholding quality of care and safety for consumers.

We are proposing to suppress three of the five CDC NHSN HAI measures (CLABSI, CAUTI, and MSRA bacteremia) under Measure Suppression Factor 1, significant deviation in national performance on the measures, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45272 through 45274) for previous analysis on the HAI Safety measures that showed that measure rates for the CLABSI, CAUTI, and MRSA measures increased during the CY 2020 pandemic year as compared to the pre-COVID–19 CY 2019 year immediately preceding the COVID–

[636] Aiken L, Clarke S, Sloane D. Hospital staffing, organization, and quality of care: Cross-national findings. International Journal for Quality in Health Care. Int J Qual Health Care. 2002.10.1093/intqhc/14.1.5.

[637] Jeannie P. Cimiotti, et al., Nurse staffing, burnout, and health care-associated infection, American Journal of Infection Control, Volume 40, Issue 6, 2012, Pages 486–490, *https://doi.org/10.1016/j.ajic.2012.02.029* (citing Vahey DC, et al., Nurse burnout and patient satisfaction. Med Care 2004;42:II–57–66 and Leiter MP, Harvie P, Frizzell C. The correspondence of patient satisfaction and nurse burnout. Soc Sci Med 1998;47:1611–7).

[638] Aiken LH, Sloane DM, Ball J, *et al,* Patient satisfaction with hospital care and nurses in England: an observational study, *https://bmjopen.bmj.com/content/8/1/e019189*.

[639] U.S. News, States With the Biggest Hospital Staffing Shortages (Jan. 13, 2022), *https://www.usnews.com/news/health-news/articles/2022-01-13/states-with-the-biggest-hospital-staffing-shortages* (citing data from the HHS, CDC, and Assistant Secretary for Preparedness and Response Community Profile Report, updated frequently and available here: *https://healthdata.gov/Health/COVID-19-Community-Profile-Report/gqxm-d9w9*).

[640] Bloomberg, U.S. Hospital Staff Shortages Hit Most in a Year on Covid Surge, *https://www.bloomberg.com/news/articles/2022-01-05/one-in-five-u-s-hospitals-face-staffing-shortages-most-in-year* (citing HHS data).

19 PHE. To determine whether the CLABSI, CAUTI, and MRSA measure rates would continue to show increases for CY 2021, the CDC analyzed changes in standardized infection ratios (SIRs) for Q1 and Q2 of CY 2021 as compared to the SIRs in Q1 and Q1 of CY 2019. This analysis found that the CLASBI, CAUTI, and MSRA measures had statistically significant measure rate increases during Q1 and Q2 of CY 2021 as compared to pre-pandemic levels in Q1 and Q2 of CY 2019. For Q1 2021, the national SIR increased by approximately 45 percent for the CLABSI measure, approximately 12 percent for the CAUTI measure, and approximately 39 percent for the MRSA measure as compared to Q1 2019. For Q2 2021, the national SIR increased by approximately 15 percent for the CLABSI measure and approximately 8 percent for the MRSA measure. The SIRs for the CAUTI measure showed no statistically significant difference for Q2 2021 as compared to Q2 2019.

TABLE V.I.-02: PERCENT CHANGES IN SIRS COMPARED TO RESPECTIVE 2019 QUARTERS

	2020 Q1	2020 Q2	2020 Q3	2020 Q4	2021 Q1	2021 Q2	Preliminary 2021 Q3*
CLABSI	-11.8	27.9	46.4	47.0	45.3	14.6	48.6
CAUTI	-21.3	No change	12.7	18.8	11.5	No change	13.3
SSI: Colon surgery	-9.1	No change	-6.9	-8.3	No change	No change	-6.6
SSI: Abdominal hysterectomy	-16.0	No change	No change	-13.1	No change	No change	No change
MRSA bacteremia	-7.2	12.2	22.5	33.8	39.2	8.3	44.5%
CDI	-17.5	-10.3	-8.8	-5.5	-15.6	-14.1	-14.5%

*This data is preliminary as of the time of the FY 2023 IPPS/LTCH PPS proposed rule publication. The Q3 2021 HAI measure data submission deadline was February 15, 2022 and the SIR for Q3 2021 has not yet been finalized.

For the CDI measure, the national SIR decreased by approximately 16 percent for Q1 2021 as compared to Q1 2019 and by approximately 14 percent for Q2 2021 as compared to Q2 2019. The SSI measure showed no significant increase or decrease during Q1 2021 and Q2 2021 as compared to Q1 2019 and Q2 2019. Though the changes in the national SIRs for SSI and CDI were not as large as compared to the other Safety domain measures, we are proposing to suppress these measures under Measure Suppression Factor 4, significant national shortages or rapid or unprecedented changes in patient case volumes and Measure Suppression Factor 3, rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials, respectively. Specifically, for the SSI measure, we are proposing to suppress the measure for FY 2023 under Measure Suppression Factor 4, rapid or unprecedented changes in patient case volumes. We note that the SSI measure has historically had a low procedure volume for many hospitals, which impacts our ability to produce SIRs for that measure. For CY 2019, 2,087 hospitals (61 percent) did not have sufficient procedure-level data needed to calculate SSI SIRs for abdominal hysterectomy, and 1,262 hospitals (37 percent) did not have sufficient data to calculate SIRs for colon surgery. However, nationally, procedure volumes declined even further during the COVID–19 PHE in 2020, compared to 2019, with decreases of up to 23 percent for colon procedures and 39 percent for abdominal hysterectomy procedures.[641] As of July 2021, abdominal hysterectomy procedures were still 6 percent below predicted levels.[642] These changes in patient volumes for the SSI measure limit our ability to calculate SSI SIRs for hospitals that do not have sufficient data in FY 2023, which may impact the accuracy and reliability of overall national comparison on performance for this measure.

For the CDI measure, we are proposing to suppress the measure under Measure Suppression Factor 3, rapid or unprecedented changes in clinical guidelines, care delivery or practice, related protocols, or equipment or diagnostic tools or materials. Pandemic-related improvements to typical CDI prevention practices such as hand hygiene, PPE practices, and environmental cleaning could have contributed to the declines seen in the CDI SIR in 2021 compared to 2019.[643] In addition, a decline in outpatient antibiotic prescribing was observed starting in 2020 as healthcare utilization decreased during the COVID–19 pandemic.[644] This, combined with the continued use of inpatient antibiotic stewardship programs in hospitals, may also have contributed to the decline in the national CDI SIRs, as reducing patient antibiotic exposure is a recommended strategy for CDI prevention. More information about CDI prevention strategies can be found at *https://www.cdc.gov/cdiff/clinicians/cdi-prevention-strategies.html.*

Additionally, because we cannot identify all potential elements that could be impacting the overall HAI experience at facilities during an unprecedented PHE as well as potential geographic disparities in the impact of the PHE that could cause uneven impact on facilities based on their location, and in order to reduce bias toward only those measures that are performing well at the national level, we believe all five CDC NHSN HAI measures should be suppressed. Therefore, we believe it is appropriate to suppress all five HAI measures in the Safety domain to ensure

[641] Weiner-Lastinger, L, et al,. The impact of coronavirus disease 2019 (COVID–19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. Infection Control & Hospital Epidemiology (2022), 43, 12–25. doi:10.1017/ice.2021.362.

[642] *https://epicresearch.org/articles/elective-surgeries-approach-pre-pandemic-volumes.*

[643] Weiner-Lastinger LM, et al. (2021). The impact of coronavirus disease 2019 (COVID–19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. Infection Control & Hospital Epidemiology, *https://doi.org/10.1017/ice.2021.362.*

[644] The intersection of antibiotic resistance (AR), antibiotic use (AU), and COVID–19. Department of Health and Human Services website. *https://www.hhs.gov/sites/default/files/antibiotic-resistance-antibiotic-use-covid-19-paccarb.pdf.* Published February 10, 2021. Accessed June 28, 2021.

an accurate and reliable national comparison of performance on hospital safety.

We are also proposing to suppress the five CDC NHSN HAI measures for the FY 2023 program year under Measure Suppression Factor 4, significant national shortage or rapid or unprecedented changes in healthcare personnel. As discussed in section V.I.1.b.(2). of the preamble of this proposed rule, during the course of the COVID–19 PHE, an unprecedented number of healthcare personnel have left the workforce or ended their employment in hospitals.[645] This healthcare personnel shortage worsened in 2021, with hospitals across the United States reporting 296,466 days of critical staffing shortages, an increase of 86 percent from the 159,320 days of critical staffing shortage hospitals reported in 2020.[646] Healthcare workers, especially those in areas with higher infection rates, have reported serious psychological symptoms, including anxiety, depression, and burnout.[647] [648]

Healthcare personnel staffing shortages and burnout has been shown to be significantly associated with hospital-associated infections, including urinary tract infections and surgical site infections.[649] [650] Along with being shown to impact quality of care,[651] healthcare staffing shortages impact a hospital's ability to investigate infections and take corrective action.[652] As discussed in section V.I.1.b.(2). of the preamble of this proposed rule, reports of hospital staff shortages have varied widely geographically, ranging from 10 to 50 percent of hospitals in any particular state reporting staffing shortages. Given the wide variance in reported staffing shortages, and the impact staffing shortages may have on CDC NHSN HAI scores, we believe our proposal to suppress the CDC NHSN HAI measures fairly addresses the geographic disparity in the impact of the COVID–19 PHE on participating hospitals.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45272 through 45274), we stated our belief that the distortion in measure performance may be due to circumstances unique to the effects of the pandemic such as staffing shortages and turnover, patients that are more susceptible to infections due to increased hospitalization stays, and longer indwelling catheters and central lines. We believe that the continued distortion in measure performance is impacted by similar circumstances unique to the effects of the COVID–19 PHE as hospitals and researchers have investigated the impact of COVID–19 on HAIs and found that COVID–19 is associated with increases in HAIs, with changes in the SIR varying geographically and over time.[653] [654] [655] [656] [657] Additionally, we believe that suppressing the HAI measures is appropriate because the impact of COVID–19 on the measure cannot be addressed through risk-adjustment. Under current collection requirements for the CDC NHSN HAI measures, the data used for risk-adjustment are collected at the ward or facility level, meaning that the hospital submits infection data for a given ward or the entire facility rather than at the individual patient level. Accordingly, we are not able to identify the number of patients with HAIs who also had COVID–19 and therefore cannot risk-adjust for or otherwise account for COVID–19 diagnoses. In order to address the impact of the ongoing COVID–19 PHE on HAI incidence, we are proposing to suppress the CY 2021 HAI measure data.

We welcome public comment on our proposal to suppress the five HAI Safety domain measures for the FY 2023 program year.

c. Proposed Scoring and Payment Methodology for the FY 2023 Program Year Due to the COVID–19 PHE

As described in section V.I.1.b. of the preamble of this proposed rule, we are proposing to suppress six measures in the Hospital VBP Program for FY 2023 and use a special rule for FY 2023 scoring, which we would codify in our regulations at 42 CFR 412.168. Specifically, we are proposing that we would calculate measure rates for all measures in the FY 2023 program year. For measures that we have proposed to suppress or measures for which we have finalized suppression, we would not use the measure rates to generate achievement and improvement points within the Hospital VBP Program's current scoring methodology. We further propose under this special rule that we would only calculate achievement and improvement points, as well as a domain score, for remaining measures in the Clinical Outcomes domain and the Efficiency and Cost Reduction domain that have not been proposed for suppression and that, because no other domains receive scores for the FY 2023 program year, we would not award TPSs to any hospital for FY 2023.

Because no hospital would receive a TPS for FY 2023, we further propose that we would reduce each hospital's base-operating DRG payment amount by two percent, as required under section 1886(o)(7)(B) of the Act, and then assign to each hospital a value-based incentive payment amount that matches the two percent reduction to the base operating DRG payment amount. The net result of these payment adjustments would be neutral for hospitals. We have stated that value-based payment systems should rely on a mix of standards, processes, outcomes, and patient experience measures (76 FR 26491). As

[645] Health Affairs, *COVID–19's Impact on Nursing Shortages, The Rise of Travel Nurses, and Price Gouging* (Jan. 28, 2022), *https://www.healthaffairs.org/do/10.1377/forefront.20220125.695159/*.

[646] *https://healthdata.gov/Hospital/COVID-19-Reported-Patient-Impact-and-Hospital-Capa/g62h-syeh*.

[647] Kriti Prasad, Colleen McLoughlin, Martin Stillman, Sara Poplau, Elizabeth Goelz, Sam Taylor, Nancy Nankivil, Roger Brown, Mark Linzer, Kyra Cappelucci, Michael Barbouche, Christine A. Sinsky. Prevalence and correlates of stress and burnout among U.S. healthcare workers during the COVID–19 pandemic: A national cross-sectional survey study. EClinicalMedicine, Volume 35. 2021. 100879. ISSN 2589–5370. *https://doi.org/10.1016/j.eclinm.2021.100879*.

[648] Vizheh, M., Qorbani, M., Arzaghi, S.M. *et al.* The mental health of healthcare workers in the COVID–19 pandemic: A systematic review. *J Diabetes Metab Disord* 19, 1967–1978 (2020). *https://doi.org/10.1007/s40200-020-00643-9*.

[649] Jeannie P. Cimiotti, et al., Nurse staffing, burnout, and health care-associated infection, American Journal of Infection Control, Volume 40, Issue 6, 2012, Pages 486–490, *https://doi.org/10.1016/j.ajic.2012.02.029*.

[650] Jinjin Shang, et al., Nurse staffing and Healthcare Associated Infection, Unit-level Analysis, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6478399/*.

[651] Aiken L, Clarke S, Sloane D. Hospital staffing, organization, and quality of care: Cross-national findings. International Journal for Quality in Health Care. Int J Qual Health Care. 2002.10.1093/intqhc/14.1.5.

[652] Healthcare-Associated Infections Increase Dramatically During Panemic, *https://www.relias media.com/articles/148560-healthcare-associated-infections-increase-dramatically-during-pandemic*.

[653] Fakih MG, et al. (2021). Coronavirus disease 2019 (COVID–19) pandemic, central-line-associated bloodstream infection (CLABSI), and catheter-associated urinary tract infection (CAUTI): The urgent need to refocus on hardwiring prevention efforts. Infection Control & Hospital Epidemiology, *https://doi.org/10.1017/ice.2021.70*.

[654] Palmore TN and Henderson DK. (2021). Healthcare-associated infections during the coronavirus disease 2019 (COVID–19) pandemic. Infection Control & Hospital Epidemiology, *https://doi.org/10.1017/ice.2021.377*.

[655] Weiner-Lastinger LM, et al. (2021). The impact of coronavirus disease 2019 (COVID–19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. Infection Control & Hospital Epidemiology, *https://doi.org/10.1017/ice.2021.362*.

[656] Baker, Meghan A et al. ''The Impact of COVID–19 on Healthcare-Associated Infections.'' Clinical infectious diseases: An official publication of the Infectious Diseases Society of America, ciab688. 9 Aug. 2021, doi:10.1093/cid/ciab688.

[657] Advani, Sonali D et al. ''The impact of coronavirus disease 2019 (COVID–19) response on hospital infection prevention programs and practices in the southeastern United States.'' Infection control and hospital epidemiology, 1–4. 2 Nov. 2021, doi:10.1017/ice.2021.460.

such, the Hospital VBP Program scoring methodology was developed to be used with several measures across multiple domains and aims to score hospitals on their overall achievement relative to national benchmarks. Unlike other hospital value-based purchasing programs that are intentionally designed to focus on specific aspects of quality, such as the HAC Reduction Program and the Hospital Readmissions Reduction Program, the Hospital VBP Program is uniquely designed to address a comprehensive set of quality and efficient metrics that evaluate multiple facets of quality. However, as discussed in the measure suppression proposals in section V.I.1.b. of the preamble of this proposed rule, the data from several measures has been significantly impacted by the COVID–19 PHE. Awarding negative or positive incentive payment adjustment percentages using TPSs calculated using the current scoring methodology would not provide a representative score of a hospitals' overall performance in providing quality of care during a pandemic. We believe that the current scoring methodology remains a balanced and comprehensive approach for tying payment to hospitals for their performance on a set of diverse measures that depict quality of care provided. However, we understand that the COVID–19 PHE has led to sudden and unexpected changes to healthcare systems. Our measure suppression policy was designed as a non-permanent approach to provide flexibility for changing conditions outside of participating hospitals' control and to avoid penalizing hospitals on measure scores that we believe are distorted by the COVID–19 PHE and are thus not truly reflective of quality of care. As we enter the third year of the pandemic, we believe that the updated knowledge of the virus and access to various treatment and mitigation efforts in place have provided hospitals with various tools to adapt to this virus. Therefore, as we discuss further in section V.I.2. of the preamble of this proposed rule, our goal is to continue resuming the use of measure data for scoring and payment adjustment purposes beginning with the FY 2024 program year.

In order to ensure that hospitals are aware of changes in their performance rates that we have observed, we are proposing to provide FY 2023 confidential feedback reports that contain the measure rates we have calculated for the FY 2023 program year, along with achievement and improvement scores for all the measures in the Cost and Efficiency Reduction domain and the Clinical Outcomes domain that have not been finalized for suppression and a Cost and Efficiency Reduction domain and a Clinical Outcomes domain score. However, as previously discussed, we would not calculate TPSs for the purpose of adjusting hospital payments under the FY 2023 Hospital VBP Program. We note that the proposed special scoring methodology for FY 2023 generally aligns with the special scoring methodology finalized in for FY 2022 in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45295 through 45296).

We invite public comment on these proposals.

We also understand that, if finalized, the FY 2023 special scoring and payment policy proposal for the Hospital VBP Program has implications for the MIPS program. Under the facility-based measurement option within MIPS described at 42 CFR 414.1380(e), clinicians eligible for facility-based measurement may have their MIPS quality and cost performance category scores based on the Total Performance Score of the applicable hospital from the Hospital VBP Program as determined under 42 CFR 414.1380(e)(5). As described at 42 CFR 414.1380(e)(1)(ii) and in the CY 2019 PFS final rule, the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program, for the fiscal year for which payment begins during the applicable MIPS performance period. Thus, for the CY 2022 MIPS performance period/CY 2024 MIPS payment year, the Total Performance Score under the Hospital VBP Program for the FY 2023 program year would be applied. If a hospital does not have a Total Performance Score under the Hospital VBP Program for FY 2023, facility-based measurement would not be available for the MIPS eligible clinicians to whom that hospital's Total Performance Score would be applicable. If our proposed special scoring policy for the Hospital VBP Program for FY 2023 is finalized, hospitals would not have a FY 2023 Total Performance Score, and the clinicians who would normally be assessed through facility-based measurement would need to identify another method of participating in MIPS for the CY 2022 MIPS performance period/CY 2024 MIPS payment year or submit an application for reweighting a performance category or categories, if applicable.

2. FY 2023 Program Year Payment Details If Proposed Special Scoring and Payment Adjustment Policies Are Not Finalized

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. We finalized details on how we would implement these provisions in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), and we refer readers to that rule for further details. We note that in section V.I.1.b. of the preamble of this proposed rule, we are proposing to suppress several measures in the Hospital VBP Program for the FY 2023 program year, and in section V.I.1.c. of the preamble of this proposed rule, we are proposing to apply special scoring and payment adjustment policies for the FY 2023 program year. If these policies are finalized, each hospital would receive the payment reduction for the Hospital VBP Program as required by statute, but every hospital would receive a value-based incentive payment amount that matches the payment reduction amount. However, if the policies in section V.I.1. of the preamble of this proposed rule are not finalized, the FY 2023 program year payment details would be as described in this section. Under section 1886(o)(7)(C)(v) of the Act, the applicable percent for the FY 2023 program year is two percent. Using the methodology, we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2023 is approximately $1.7 billion, based on the December 2021 update of the FY 2021 MedPAR file. We would update this estimate for the FY 2023 IPPS/LTCH PPS final rule using the March 2022 update of the FY 2021 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53573 through 53576), we would utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS). We would then calculate a value-based incentive payment adjustment factor to apply to the base operating DRG payment amount for each discharge occurring in FY 2023, on a per-claim

basis. Applying the current scoring methodology without any modifications reflecting the proposals in this proposed rule, we are publishing proxy value-based incentive payment adjustment factors in Table 16 associated with this proposed rule (which is available via the internet on the CMS website). The TPSs from the FY 2021 program year are the basis for the proxy factors. These FY 2021 performance scores are the most recently available performance scores because FY 2022 TPSs were not calculated due to the measure suppressions and special scoring policy finalized for the FY 2022 program year. We note that the FY 2021 TPSs were calculated using measure data from before the COVID–19 PHE was declared. Actual TPSs for the FY 2023 program year may be more variable than the FY 2021 TPSs due to the impacts of the COVID–19 PHE on FY 2023 data. We refer readers to section V.I.1.b. of the preamble of this proposed rule for additional information on the impacts of the COVID–19 PHE on the Hospital VBP Program. The slope of the linear exchange function used to calculate the proxy value-based incentive payment adjustment factors in Table 16 is 2.6279472273. This slope, along with the estimated amount available for value-based incentive payments, is also published in Table 16.

If our proposals to suppress measures and award each hospital a value-based payment amount that matches the reduction to the base operating DRG payment amount are finalized, we would not update Table 16 as Table 16A in the final rule. However, if those proposals are not finalized, we would update this table as Table 16A in the final rule (which will be available on the CMS website) to reflect changes based on the March 2022 update to the FY 2021 MedPAR file. We would also update the slope of the linear exchange function used to calculate those updated proxy value-based incentive payment adjustment factors. The updated proxy value-based incentive payment adjustment factors for FY 2023 in the FY 2023 IPPS/LTCH PPS final rule would continue to be based on historic FY 2021 program year TPSs because hospitals will not have been given the opportunity to review and correct their actual TPSs for the FY 2023 program year before the FY 2023 IPPS/LTCH PPS final rule is published. After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2023, we would post Table 16B (which would be available via the internet on the CMS website) to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2023 program year.

If our proposals to suppress measures and award each hospital a value-based payment amount that matches the reduction to the base operating DRG payment amount are finalized, we would also not post Table 16B (which we typically do to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the applicable program year, after hospitals have been given an opportunity to review and correct their actual TPSs).

We continue to be concerned about the impact of the COVID–19 PHE, but are encouraged by the rollout of COVID–19 vaccinations and treatment for those diagnosed with COVID–19 and we believe that hospitals are better prepared to treat patients with COVID–19. Our measure suppression policy focuses on a short-term, equitable approach during this unprecedented PHE, and was not intended for indefinite application. Additionally, we want to emphasize the long-term importance of value-based care and incentivizing quality care tied to payment. The Hospital VBP Program is an example of our long-standing effort to link payments to healthcare quality in the inpatient hospital setting.[658]

We understand that the COVID–19 PHE is ongoing and unpredictable in nature, however, we believe that 2022 has a more promising outlook in the fight against COVID–19. As we enter the third year of the pandemic, healthcare providers have gained experience managing the disease, surges of COVID–19 infection, and adjusting to supply chain fluctuations.[659] In 2022 and the upcoming years, we anticipate continued availability and increased uptake in the use of vaccinations,[660] including the availability and use of vaccination for young children ages 5–11, who were not eligible for vaccination for the majority of 2021 and for whom only 32 percent had received at least one dose as of February 23, 2022 [661] [662] Additionally, the Food and Drug Administration (FDA) has expanded availability of at-home COVID–19 treatment, having issued the first emergency use authorizations (EUAs) for two oral antiviral drugs for the treatment of COVID–19 in December 2021. [663] [664] Finally, the Biden-Harris Administration has mobilized efforts to distribute home test kits,[665] N–95 masks,[666] and increase COVID–19 testing in schools,[667] providing more treatment and testing to the American people. Therefore, we note that our goal is to continue resuming the use of measure data for scoring and payment adjustment purposes beginning with the FY 2024 program year. That is, for FY 2024, for each hospital, we would plan to calculate measure scores for the measures in the Hospital VBP Program for which the hospital reports the minimum measure requirements, as well as domain scores for the Hospital VBP Program domains for which the

[658] CMS has also partnered with the CDC in a joint Call to Action on safety, which is focused on our core goal to keep patients safe. Fleisher et al. (2022). *New England Journal of Medicine.* Article available here: *https://www.nejm.org/doi/full/10.1056/NEJMp2118285?utm_source=STAT+Newsletters&utm_campaign=8933b7233e-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-8933b7233e-151759045.*

[659] McKinsey and Company. (2021). How COVID–19 is Reshaping Supply Chains. Available at: *https://www.mckinsey.com/business-functions/operations/our-insights/how-covid-19-is-reshaping-supply-chains.*

[660] Schneider, E. et al. (2022). *The Commonwealth Fund.* Responding to Omicron: Aggressively Increasing Booster Vaccinations Now Could Prevent Many Hospitalizations and Deaths. Available at: *https://www.commonwealthfund.org/blog/2022/responding-omicron.*

[661] KFF, Update on COVID–19 Vaccination of 5–11 Year Olds in the U.S., *https://www.kff.org/coronavirus-covid-19/issue-brief/update-on-covid-19-vaccination-of-5-11-year-olds-in-the-u-s/.*

[662] *https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-vaccination-trends/.*

[663] U.S. Food and Drug Administration. (2021). Coronavirus (COVID–19) Update: FDA Authorizes First Oral Antiviral for Treatment of COVID–19. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-oral-antiviral-treatment-covid-19.*

[664] U.S. Food and Drug Administration. (2021). Coronavirus (COVID–19) Update: FDA Authorizes Additional Oral Antiviral for Treatment of COVID–19 in Certain Adults. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-oral-antiviral-treatment-covid-19-certain#:~:text=Today%2C%20the%20U.S.%20Food%20and,progression%20to%20severe%20COVID%2D19%2C.*

[665] The White House. (2022). Fact Sheet: The Biden Administration to Begin Distributing At-Home, Rapid COVID–19 Tests to Americans for Free. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/14/fact-sheet-the-biden-administration-to-begin-distributing-at-home-rapid-covid-19-tests-to-americans-for-free/.*

[666] Miller, Z. 2021. *The Washington Post.* Biden to give away 400 million N95 masks starting next week Available at: *https://www.washingtonpost.com/politics/biden-to-give-away-400-million-n95-masks-starting-next-week/2022/01/19/5095c050-7915-11ec-9dce-7313579de434_story.html.*

[667] The White House. (2022). FACT SHEET: Biden–Harris Administration Increases COVID–19 Testing in Schools to Keep Students Safe and Schools Open. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/12/fact-sheet-biden-harris-administration-increases-covid-19-testing-in-schools-to-keep-students-safe-and-schools-open/.*

hospital reports the minimum number of measures. We would then calculate a TPS for each eligible hospital and use the established methodology for converting the TPSs to value-based incentive payments for the given fiscal year.

3. Retention and Removal of Quality Measures

a. Retention of Previously Adopted Hospital VBP Program Measures and Relationship Between the Hospital IQR and Hospital VBP Program Measure Sets

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), we finalized a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41440 through 41441), we finalized a revision to our regulations at 42 CFR 412.164(a) to clarify that once we have complied with the statutory prerequisites for adopting a measure for the Hospital VBP Program, the statute does not require that the measure continue to remain in the Hospital IQR Program. We are not proposing any changes to these policies in this proposed rule.

b. Measure Removal Factors for the Hospital VBP Program

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41441 through 41446), we finalized measure removal factors for the Hospital VBP Program, and we refer readers to that final rule for details. We are not proposing any changes to these policies in this proposed rule.

c. Technical Measure Specification Updates To Include Covariate Adjustment for COVID–19 Beginning With the FY 2023 Program Year

In the FY 2022 IPPS/LTCH PPS final rule, we stated that we were updating the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (MORT–30–AMI), Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (MORT–30–CABG), Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (MORT–30 COPD), Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization (MORT–30–HF), and Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (COMP–HIP–KNEE) measures to exclude admissions with either a principal or secondary diagnosis of COVID–19 present on admission from the measure denominators beginning in FY 2023 (86 FR 45256 through 45258). We stated that we were making these updates pursuant to the technical updates policy we finalized in the FY 2015 IPPS/LTCH PPS final rule. Under this policy, we use a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the Hospital VBP Program (79 FR 50077 through 50079). As we stated in the FY 2022 IPPS/LTCH PPS final rule, we continue to believe that this subregulatory process is the most expeditious manner possible to ensure that quality measures remain fully up to date while preserving the public's ability to comment on updates that so fundamentally change a measure that it is no longer the same measure that we originally adopted (84 FR 42385).

As we continue to evaluate the effects of COVID–19 on the Hospital VBP Program measure set, we have observed that for some patients COVID–19 continues to have lasting effects, including fatigue, cough, palpitations, and others potentially related to organ damage, post viral syndrome, post-critical care syndrome or other reasons.[668] These clinical conditions could affect a patient's risk of mortality or complications following an index admission and, as a result, impact a hospital's performance on one or more of the four condition-specific mortality measures or the procedure-specific complication measure included in the Hospital VBP Program. In order to account for case mix among hospitals, the current risk adjustment approach for these measures include covariates for clinical comorbidities present on admission (POA) and in the 12 months prior to the index admission that are relevant and have relationships with the outcome, for example patient history of coronary artery bypass (CABG) surgery or history of mechanical ventilation. In accordance with the principles used during measure development and to adequately account for patient case mix, we are further modifying the technical measure specifications for the MORT–30–AMI, MORT–30–CABG, MORT–30–COPD, MORT–30–HF, and COMP–HIP–KNEE measures to include a covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission.

This inclusion of the covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission will be effective beginning with the FY 2023 program year for the MORT–30–AMI, MORT–30–CABG, MORT–30–COPD, MORT–30–HF, and COMP–HIP–KNEE measures. We will also include the covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission for the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT–30–PN) measure. We note that, even though we previously finalized that we would suppress the MORT–30–PN measure for the FY 2023 program year, we would still publicly report the measure, and therefore, the inclusion of the covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission will still be effective beginning with the FY 2023 program year. We will delay sending MORT–30–PN confidential hospital feedback reports until October 2022 and delay public reporting until January 2023 to allow time for hospitals to become informed about this measure update and their hospital-level results. We will resume including hospital performance on the MORT–30–PN measure in the payment adjustment calculations, using the updated MORT–30–PN measure, beginning in FY 2024. We believe that making these updates to the MORT–30–PN measure for FY 2023 in hospitals' confidential feedback reports will allow hospitals the opportunity to preview these updates to the measure specifications in FY 2023 before they are used as part of payment adjustments for the FY 2024 program year.

For more information on the application of covariate adjustments, including the technical updates we are announcing in this proposed rule, please see the Measure Updates and Specifications Reports (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*).

d. Technical Updates to the Specifications for the MORT–30–PN Measure Beginning With the FY 2024 Program Year

In the FY 2022 IPPS/LTCH PPS final rule, pursuant to the measure suppression policy finalized in that rule and described in section V.I.1. of the preamble this proposed rule, we finalized suppression of the MORT–30–PN measure (NQF #0468) for the FY 2023 program year (86 FR 45274 through 45276), and we refer readers to

[668] Raveendran, A.V., Jayadevan, R. and Sashidharan, S., *Long COVID: An overview.* Available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8056514/*. Accessed on December 15, 2021.

that final rule for additional information.

Since the publication of the FY 2022 IPPS/LTCH PPS final rule, we have continued to monitor the MORT–30–PN measure and have found that several factors, such as improved coding practices and decreased proportion of COVID–19 admissions for the MORT–30–PN cohort, have mitigated some of the impact of COVID–19 on this measure within certain data periods. Beginning in FY 2024 the MORT–30–PN measure will no longer be suppressed under the Hospital VBP Program. We are resuming the use of the MORT–30–PN measure for FY 2024 because of the following differences between the FY 2023 and FY 2024 performance periods: (1) The improved coding practices; (2) decreased proportion of COVID–19 admissions in the MORT–30–PN measure for this performance period; and (3) sufficient available data to make technical updates to the measure specifications in order to further account for how patients with a COVID–19 diagnosis might impact the quality of care assessed by this measure. Specifically, effective January 2021 the ICD10 code J12.82, Pneumonia due to coronavirus disease 2019, was added for use as a secondary diagnosis, along with a principal diagnosis of COVID–19 (U07.1), to identify patients with COVID–19 pneumonia. J12.82 is not included within the cohort of the MORT–30–PN measure, therefore mortality rates with pneumonia due to COVID–19 are not captured by this measure as of January 1, 2021. Whenever new codes are introduced, changes in coding practices are difficult to predict. At the time of the FY 2022 IPPS/LTCH PPS final rule, we did not have sufficient data to determine the effects of these coding changes on the proportion of COVID–19 patients and mortality rates with pneumonia due to COVID–19 in the MORT–30–PN measure. As additional months of data have become available since early 2021, we have now seen increased use of these codes. Secondly, as these coding changes have occurred and as the COVID–19 PHE has evolved, more recent data show the proportion of COVID–19 admissions in the MORT–30–PN measure have decreased compared to 2020 data. Finally, with the availability of additional data and the decrease in the proportion COVID–19 admissions in the MORT–30–PN measure, we are now able to make technical updates to the measure specifications in alignment with the technical updates we are making to four other mortality measures and one complication measure. Specifically, we are updating the technical specifications for the MORT–30–PN measure to exclude patients with either principal or secondary diagnoses of COVID–19 from the measure denominator beginning with the FY 2024 program year.

We are also updating the technical specifications for the MORT–30–PN measure to add a covariate that adjusts the measure outcome for a history of COVID–19 diagnosis in the 12 months prior to the admission (as discussed in section V.I.3.c. of the preamble of this proposed rule) and ensures alignment with the other four mortality and one complication measures. In our analysis, hospital-level MORT–30–PN measure scores calculated with the cohort and denominator exclusions and the addition of the covariate for a history of COVID–19 diagnosis in the 12 months prior (using data from July 1, 2018 through June 30, 2021, excluding admissions from December 2, 2019 through June 30, 2020 to apply the nationwide ECE granted due to the COVID–19 PHE (85 FR 54833 through 54835)), resulted in mean measure scores that were closer to the prior pre-COVID–19 period (July 1, 2017 through December 2, 2019) compared with the unchanged measure. We believe that excluding COVID–19 patients from the measure denominator, in addition to adjusting for a prior infection with COVID–19, will mitigate the impact of COVID–19 on this measure as much as is currently feasibly possible given the unpredictable nature of the pandemic, and ensure that this measure continues to reflect mortality rates as intended and meet the goals of the Hospital VBP Program beginning in FY 2024. We note that the MORT–30–PN measure uses three years of data. The performance period for the FY 2023 program year includes admissions from July 1, 2018 through June 30, 2021, exclusive of January 1, 2020 through June 30, 2020 data excluded due to the ECE waiver. Therefore, we continue to believe it is appropriate to suppress the currently implemented measure for use in payment calculations as finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45274 through 45276). The MORT–30–PN measure is also included in confidential feedback reports and public reporting on CMS' Care Compare website separate from the Hospital VBP Program use of the measure. Technical specifications of the Hospital VBP Program measures are provided on our website under the Measure Methodology Reports section (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html).* Additional resources about the measure technical specifications and methodology for the Hospital VBP Program are on the QualityNet website (available at *https://qualitynet.cms.gov/inpatient/hvbp*).

e. Summary of Previously Adopted Measures for FY 2023 Through FY 2026 Program Years

We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45281 through 45284) for summaries of previously adopted measures for the FY 2024 and FY 2025 program years, and to Table V.I.–03 in this section showing summaries of previously adopted measures for the FY 2024, FY 2025, and FY 2026 program years. We are proposing to suppress the HCAHPS and HAI measures for the FY 2023 program year. We are not proposing to add new measures at this time. If these measure suppression proposals are finalized as proposed, the Hospital VBP Program measure set for the FY 2023, FY 2024, FY 2025 and FY 2026 program years would contain the following measures:

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TABLE V.I.-03: SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2023, FY 2024, FY 2025, FY 2026 PROGRAM YEARS

Measure Short Name	Domain/Measure Name	NQF #
Person and Community Engagement Domain		
HCAHPS*	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition measure)	0166 (0228)
Safety Domain		
CAUTI*	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI*	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI*	American College of Surgeons - Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia*	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure	1716
CDI*	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure	1717
Clinical Outcomes Domain		
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN (updated cohort)**	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
MORT-30-COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30-CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP-KNEE	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
Efficiency and Cost Reduction Domain		
MSPB	Medicare Spending Per Beneficiary (MSPB) - Hospital	2158

* Per section V.I.1.b. of the preamble of this proposed rule, we are proposing to suppress the HCAHPS and five HAI measures for the FY 2023 program year.

** In the FY 2022 IPPS/LTCH PPS final rule, we finalized our proposal to suppress the MORT-30-PN measure for the FY 2023 program year (86 FR 45274 through 45276).

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4. Previously Adopted Baseline and Performance Periods

a. Background

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program that begins and ends prior to the beginning of such fiscal year. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998 through 57003) for a previously finalized schedule for all future baseline and performance periods for previously adopted measures. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38256 through 38261), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41466 through 41469), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42393 through 42395), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58850 through 58854), and FY 2022 IPPS/LTCH PPS final rule (86 FR 45284 through 45290) for additional previously adopted baseline and performance periods for the FY 2024 and subsequent program years.

b. Proposal To Update Baseline Periods for Certain Measures Due to the COVID–19 PHE

(1) Background

We previously finalized baseline periods for the FY 2024, 2025, 2026, 2027, and 2028 program years for all the measures included in the Hospital VBP Program, and we refer readers to Tables V.I.–04 through V.I.–08 for those

previously adopted baseline periods. However, subsequent to finalizing those baseline periods and, as described further in section V.I.1.b. of the preamble of this proposed rule, we are proposing to suppress the HCAHPS and five HAI measures for the purposes of scoring and payment for FY 2023. Because these baseline periods are used to determine achievement thresholds and are used in awarding improvement scores to hospitals, we are concerned with using COVID–19 impacted data for the FY 2025 baseline periods for scoring and payment purposes.

Accordingly, to ensure that we have reliable data that are not unfairly affected by the COVID–19 PHE for baselining purposes, we are proposing several updates to the baseline periods in this proposed rule for the FY 2025 program year.

We note that we are proposing to update the baseline periods for certain measures under the Hospital VBP Program that have a 1-year baseline period. However, for measures that have baseline periods that span across multiple years, we believe the previously established baseline periods provide enough data from before and after CY 2021 to still calculate baseline scores that would be reliable for scoring and payment purposes. Specifically, for the measures in the Clinical Outcomes domain (MORT–30–AMI, MORT–30–CABG, MORT–30–COPD, MORT–30–HF, MORT–30–PN, and COMP–HIP–KNEE), which have 36-month baseline periods, we are not proposing any changes to the previously established baseline periods for FY 2025.

(2) Proposal To Update the FY 2025 Baseline Period for the Person and Community Engagement Domain Measure (HCAHPS Survey)

In the FY 2017 IPPS/LTCH PPS final rule, we finalized that the baseline period for Person and Community Engagement Domain Measure (HCAHPS Survey) for the FY 2025 program year would be January 1, 2021 through December 31, 2021 (81 FR 56998). However, as more fully described in section V.I.1.b. of the preamble of this proposed rule, we have determined that the top-box scores for hospitals are significantly lower in Q1 and Q2 of CY 2021 than they were in Q1 and Q2 of CY 2019 (pre-pandemic), demonstrating the impact of COVID–19 on hospital performance for this measure. Therefore, in order to best mitigate the impact of using measure data affected by the COVID–19 PHE when determining achievement thresholds or awarding improvement points, we are proposing to use a baseline period of January 1, 2019 through December 31, 2019 for the FY 2025 program year. This baseline period would be paired with a performance period of January 1, 2023 through December 31, 2023. We believe using data from this period will provide sufficiently reliable data for evaluating hospital performance that can be used for FY 2025 scoring. We are selecting this revised data period because it would provide the most consistency for hospitals in terms of the comparable length to previous program years and the performance period, and it would capture a full year of data, including any seasonal effects.

(3) Proposal To Update the FY 2025 Baseline Period for the Safety Domain Measures

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57000), we finalized the performance period for all measures in the Safety domain to run on the calendar year two years prior to the applicable program year and a baseline period that runs on the calendar year four years prior to the applicable program year for the FY 2019 program year and subsequent program years. For FY 2025, the baseline period for the Safety domain measures would be January 1, 2021 through December 31, 2021. However, as more fully described in section V.I.1.b. of the preamble of this proposed rule, we have determined that the national measure rates for the HAI measures have significantly deviated in national performance in CY 2021, indicating that the COVID–19 PHE has impacted performance on this measure. Therefore, in order to mitigate the impact of using measure data affected by the COVID–19 PHE when determining achievement thresholds or awarding improvement points, we are proposing to use a baseline period of January 1, 2019 through December 31, 2019 for the FY 2025 program year. This baseline period would be paired with a performance period of January 1, 2023 through December 31, 2023. We believe using data from this period will provide sufficiently reliable data for evaluating hospital performance that can be used for FY 2025 scoring. We are selecting this revised data period because it would provide the most consistency for hospitals in terms of the comparable length to previous program years and the performance period, and it would capture a full year of data, including any seasonal effects.

c. Summary of Previously Adopted and Newly Proposed Baseline and Performance Periods for the FY 2024 Through FY 2028 Program Years

Tables V.I.–04 through 08 summarize the baseline and performance periods that we have previously adopted and those that we are proposing to adopt.

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TABLE V.I.-04: PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2024 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2019 – December 31 2019*	January 1, 2022 – December 31 2022
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2014 – June 30, 2017	July 1, 2019 – June 30, 2022**
COMP-HIP-KNEE	April 1, 2014 – March 31, 2017	April 1, 2019 – March 31, 2022**
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2019 – December 31 2019*	January 1, 2022 – December 31 2022
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2019 – December 31 2019*	January 1, 2022 – December 31 2022

*In the FY 2022 IPPS/LTCH PPS final rule, we finalized that these baseline periods would be January 1, 2019 through December 31, 2019 (86 FR 45284 through 45285).

**In accordance with the ECE granted in response to the COVID-19 PHE and the policies finalized in the September 2, 2020 interim final rule with comment titled "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency," (85 FR 54820), we will not use Q1 and Q2 2020 data that was voluntarily submitted for scoring purposes under the Hospital VBP Program.

TABLE V.I.-05: PREVIOUSLY ADOPTED AND PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2025 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2019 – December 31 2019*	January 1, 2023 – December 31 2023
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2015 – June 30, 2018	July 1, 2020 – June 30, 2023
COMP-HIP-KNEE	April 1, 2015 – March 31, 2018	April 1, 2020 – March 31, 2023**
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2019 – December 31 2019*	January 1, 2023 – December 31 2023
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2021 – December 31 2021	January 1, 2023 – December 31 2023

*As described more fully in section V.I.4.b. of the preamble of this proposed rule, we are proposing to update the baseline periods for the measures included in the Person and Community Engagement and Safety domains for FY 2025.

**In accordance with the ECE granted in response to the COVID-19 PHE and the policies finalized in the September 2, 2020 interim final rule with comment titled "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency," (85 FR 54820), we will not use Q1 and Q2 2020 data that was voluntarily submitted for scoring purposes under the Hospital VBP Program.

TABLE V.I.-06: PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2026 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2022 – December 31 2022	January 1, 2024 – December 31 2024
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2016 – June 30, 2019	July 1, 2021 – June 30, 2024
COMP-HIP-KNEE	April 1, 2016 – March 31, 2019	April 1, 2021 – March 31, 2024
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2022 – December 31 2022	January 1, 2024 – December 31 2024
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2022 – December 31 2022	January 1, 2024 – December 31 2024

TABLE V.I.-07: PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2027 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2023 – December 31 2023	January 1, 2025 – December 31 2025
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2017 – June 30, 2020**	July 1, 2022 – June 30, 2025
COMP-HIP-KNEE	April 1, 2017 – March 31, 2020**	April 1, 2022 – March 31, 2025
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2023 – December 31 2023	January 1, 2025 – December 31 2025
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2023 – December 31 2023	January 1, 2025 – December 31 2025

**These baseline periods are impacted by the ECE granted by CMS on March 22, 2020. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

TABLE V.I.-08: PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2028 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2024 – December 31 2024	January 1, 2026 – December 31 2026
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2018 – June 30, 2021**	July 1, 2023 – June 30, 2026
COMP-HIP-KNEE	April 1, 2018 – March 31, 2021**	April 1, 2023 – March 31, 2026
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2024 – December 31 2024	January 1, 2026 – December 31 2026
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2024 – December 31 2024	January 1, 2026 – December 31 2026

**These baseline periods are impacted by the ECE granted by CMS on March 22, 2020. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

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5. Performance Standards for the Hospital VBP Program

a. Background

We refer readers to sections 1886(o)(3)(A) through 1886(o)(3)(D) of the Act for the statutory provisions governing performance standards under the Hospital VBP Program. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for further discussion of achievement and improvement standards under the Hospital VBP Program. We refer readers to the FY 2013 IPPS/LTCH PPS final rule, FY 2014 IPPS/LTCH PPS final rule, and FY 2015 IPPS/LTCH PPS final rule (77 FR 53599 through 53605; 78 FR 50694 through 50699; and 79 FR 50077 through 50081, respectively) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45290 through 45292) for previously established performance standards for the FY 2024 program year. We note that the measure suppression proposals for the FY 2023 program year, discussed more fully in section V.I.1.b. of this proposed rule, will not affect the performance standards for the FY 2023 program year. However, as discussed in section V.I.1.c. of this proposed rule, we are proposing to not generate achievement or improvement points for any suppressed measures for FY 2023.

We refer readers to the FY 2021 IPPS/LTCH PPS final rule for further discussion on performance standards for which the measures are calculated with lower values representing better performance (85 FR 58855).

b. Previously Established and Estimated Performance Standards for the FY 2025 Program Year

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42398 through 42399), we established performance standards for the FY 2025 program year for the Clinical Outcomes domain measures

(MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30- CABG, and COMP–HIP–KNEE) and for the Efficiency and Cost Reduction domain measure (MSPB). We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. As discussed in section V.I.4.b. of this proposed rule, we are proposing to update the FY 2025 program year baseline periods for the measures included in the Safety domain and Person and Community Engagement domain. If these proposals are finalized, we would use data from January 1, 2019 through December 31, 2019 to calculate performance standards for the FY 2025 program year for these measures.

In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) and codified at 42 CFR 412.160, we are estimating additional performance standards for the FY 2024 program year. We note that the numerical values for the performance standards for the Safety domain and Person and Community Engagement domain for the FY 2025 program year in Tables V.I.–09 and V.I.–10 were calculated using data from January 1, 2019 through December 31, 2019. Therefore, if our proposed updates to the baseline periods for these measures are finalized, we will not update the numerical values in the FY 2023 IPPS/LTCH PPS final rule.

The previously established and estimated performance standards for the measures in the FY 2025 program year are set out in Tables V.I.–09 and V.I.–10.

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TABLE V.I.-09: PREVIOUSLY ESTABLISHED AND NEWLY ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2025 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Safety Domain♦		
CAUTI*	0.650	0
CLABSI*	0.589	0
CDI*	0.520	0.01
MRSA Bacteremia*	0.726	0
Colon and Abdominal Hysterectomy SSI*	0.717	0
	0.738	0
Clinical Outcomes Domain		
MORT-30-AMI#	0.872624	0.889994
MORT-30-HF#	0.883990	0.910344
MORT-30-PN (updated cohort) #	0.841475	0.874425
MORT-30-COPD#	0.915127	0.932236
MORT-30-CABG#	0.970100	0.979775
COMP-HIP-KNEE*#	0.025332	0.017946
Efficiency and Cost Reduction Domain		
MSPB*#	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

♦ As discussed in section V.I.4.b. of this proposed rule, we are proposing to update the FY 2025 baseline periods for measures included in the Person and Community Engagement and Safety domains to use CY 2019 data. Therefore, the performance standards displayed in this table for the Safety domain measures were calculated using CY 2019 data.

* Lower values represent better performance.

Previously established performance standards.

The HCAHPS Base Score is calculated using the eight dimensions of the HCAHPS measure. For each of the eight dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) are calculated, the larger of which is then summed across the eight dimensions to create the HCAHPS Base Score (0–80 points). Each of the eight dimensions is of equal weight; therefore, the HCAHPS Base Score ranges from 0 to 80 points. HCAHPS Consistency Points are then calculated, which range from 0 to 20 points. The Consistency Points take into consideration the scores of all eight Person and Community Engagement dimensions. The final element of the scoring formula is the summation of the HCAHPS Base Score and the HCAHPS Consistency Points, which results in the Person and Community Engagement domain score that ranges from 0 to 100 points. As discussed in section V.I.4.b.(2). of this proposed rule, we are proposing to update the FY 2025 program year baseline period for the measure included in the Person and Community Engagement domain. If finalized, according to our established methodology for calculating performance standards, we will use data from January 1, 2019 through December 31, 2019 to calculate performance standards for the FY 2025 program year for this measure.

TABLE V.I.-10: ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2025 PROGRAMYEAR: PERSON AND COMMUNITY ENGAGEMENT DOMAIN±

HCAHPS Survey Dimension	Floor (minimum)	Achievement Threshold (50th percentile)	Benchmark (mean of top decile)
Communication with Nurses	53.50	79.42	87.71
Communication with Doctors	62.41	79.83	87.97
Responsiveness of Hospital Staff	40.40	65.52	81.22
Communication about Medicines	39.82	63.11	74.05
Hospital Cleanliness & Quietness	45.94	65.63	79.64
Discharge Information	66.92	87.23	92.21
Care Transition	25.64	51.84	63.57
Overall Rating of Hospital	36.31	71.66	85.39

± As discussed in section V.I.4.b.(2). of this proposed rule, we are proposing to update the FY 2025 baseline periods for measures included in the Person and Community Engagement and Safety domains to use CY 2019 data. Therefore, the performance standards displayed in this table for the Person and Community Engagement domain measures were calculated using CY 2019 data.

c. Previously Established Performance Standards for Certain Measures for the FY 2026 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58858 through 58859), we established performance standards for the FY 2026 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB). We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The previously established performance standards for these measures are set out in the Table V.I.–11.

TABLE V.I.-11: PREVIOUSLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2026 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Clinical Outcomes Domain		
MORT-30-AMI	0.874426	0.890687
MORT-30-HF	0.885949	0.912874
MORT-30-PN (updated cohort)	0.843369	0.877097
MORT-30-COPD	0.914691	0.932157
MORT-30-CABG	0.970568	0.980473
COMP-HIP-KNEE*	0.024019	0.016873
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

d. Previously Established Performance Standards for Certain Measures for the FY 2027 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45294 through 45295), we established performance standards for the FY 2027 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB). We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The previously established performance standards for these measures are set out in Table V.I.–12.

TABLE V.I.-12: PREVIOUSLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2027 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Clinical Outcomes Domain**		
MORT-30-AMI	0.877824	0.893133
MORT-30-HF	0.887571	0.913388
MORT-30-PN (updated cohort)	0.844826	0.877204
MORT-30-COPD	0.917395	0.932640
MORT-30-CABG	0.971149	0.980752
COMP-HIP-KNEE*	0.023322	0.017018
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

** As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 5297 through 45299), we did not include data from Q1 and Q2 of CY 2020 in the calculation of these performance standards.

e. Newly Established Performance Standards for Certain Measures for the FY 2028 Program Year

As discussed previously, we have adopted certain measures for the Clinical Outcomes domain (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain (MSPB) for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513), which is codified at 42 CFR 412.160, we are establishing the following performance standards for the FY 2028 program year for the Clinical Outcomes domain and the Efficiency and Cost Reduction domain. We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The newly established performance standards for these measures are set out in Table V.I.–13.

TABLE V.I.-13 NEWLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2027 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Clinical Outcomes Domain**		
MORT-30-AMI	0.877260	0.893229
MORT-30-HF	0.885427	0.910649
MORT-30-PN (updated cohort)	0.831776	0.866166
MORT-30-COPD	0.913752	0.929652
MORT-30-CABG	0.971052	0.980570
COMP-HIP-KNEE*	0.029758	0.022002
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

** We note that these performance standards are calculated using some data from CY 2020 and CY 2021, which are included the COVID-19 PHE. However, these performance standards have been calculated using the updated technical specifications described in sections V.I.3.c. and V.I.3.d. of this proposed rule, which excludes patients diagnosed with COVID-19 and risk-adjusts for history of COVID-19 for these measures.

6. Data Requirements

a. Domain Weighting for Hospitals That Receive a Score on All Domains

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266), we finalized our proposal to retain the equal weight of 25 percent for each of the four domains in the Hospital VBP Program for the FY 2020 program year and subsequent years for hospitals that receive a score in all domains. We are not proposing any changes to these domain weights in this proposed rule.

b. Domain Weighting for Hospitals Receiving Scores on Fewer Than Four Domains

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50084 through 50085), we adopted a policy that hospitals must receive domain scores on at least three of four quality domains in order to receive a TPS, for the FY 2017 program year and subsequent years. Hospitals with sufficient data on only three domains will have their TPSs proportionately reweighted (79 FR 50084 through 50085). We are not proposing any changes to these domain weights in this proposed rule.

c. Minimum Numbers of Measures for Hospital VBP Program Domains

We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266) for our previously finalized requirements for the minimum numbers of measures for hospitals to receive domain scores. We are not proposing any changes to these policies in this proposed rule.

d. Minimum Numbers of Cases for Hospital VBP Program Measures

(1) Background

Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year. For additional discussion of the previously finalized minimum numbers of cases for measures under the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531); the CY 2012 OPPS/ASC final rule (76 FR 74532 through 74534); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53610); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085 through 50086); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570); and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266 through 38267) . We are not proposing any changes to these policies in this proposed rule.

(2) Summary of Previously Adopted Minimum Numbers of Cases

The previously adopted minimum numbers of cases for these measures are set forth in Table V.I.–14.

TABLE V.I.-14: PREVIOUSLY ADOPTED MINIMUM CASE NUMBER REQUIREMENTS FOR HOSPITAL VBP PROGRAM

Measure Short Name	Minimum Number of Cases
Person and Community Engagement Domain	
HCAHPS	Hospitals must report a minimum number of 100 completed HCAHPS surveys.
Clinical Outcomes Domain	
MORT-30-AMI	Hospitals must report a minimum number of 25 cases.
MORT-30-HF	Hospitals must report a minimum number of 25 cases.
MORT-30-PN (updated cohort)	Hospitals must report a minimum number of 25 cases.
MORT-30-COPD	Hospitals must report a minimum number of 25 cases.
MORT-30-CABG	Hospitals must report a minimum number of 25 cases.
COMP-HIP-KNEE	Hospitals must report a minimum number of 25 cases.
Safety Domain	
CAUTI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CLABSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Colon and Abdominal Hysterectomy SSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
MRSA Bacteremia	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CDI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Efficiency and Cost Reduction Domain	
MSPB	Hospitals must report a minimum number of 25 cases.

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e. Summary of Previously Adopted Administrative Policies for NHSN Healthcare-Associated Infection (HAI) Measure Data

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42400 through 42402), we finalized our proposal to use the same data to calculate the CDC NHSN HAI measures for the Hospital VBP Program that the HAC Reduction Program uses for purposes of calculating the measures under that program, beginning on January 1, 2020 for CY 2020 data collection, which would apply to the Hospital VBP Program starting with data for the FY 2022 program year performance period. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42402), we also finalized our proposal for the Hospital VBP Program to use the same processes adopted by the HAC Reduction Program for hospitals to review and correct data for the CDC NHSN HAI measures and to rely on HAC Reduction Program validation to ensure the accuracy of CDC NHSN HAI measure data used in the Hospital VBP Program. We are not proposing any changes to these policies in this proposed rule.

7. Extraordinary Circumstance Exception (ECE) Policy for the Hospital VBP Program

We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45298 through 45299) for additional details related to the Hospital VBP Program ECE policy. We are not proposing any changes to the Hospital VBP Program ECE policy in this proposed rule.

8. References to Requests for Information

a. NHSN Digital Quality Measures

We also refer readers to section IX.E.9.a. of this proposed rule, where we are requesting information on the potential future adoption of the National Healthcare Safety Network (NHSN) Healthcare-Associated *Clostridioides difficile* Infection Outcome Measure and the National Healthcare Safety Network (NHSN) Hospital-Onset Bacteremia & Fungemia Outcome Measure into the Hospital IQR Program. In addition, we are requesting information on the potential future inclusion of these digital CDC NHSN measures in the Hospital VBP Program. This request for information supports our goal of moving fully to digital quality measurement in CMS quality reporting and value-based purchasing programs, including the Hospital VBP Program.

b. Reference to the Request for Information: Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

We refer readers to section IX.B. of this proposed rule where we are seeking input on overarching principles in measuring healthcare quality disparities in hospital quality and value-based purchasing programs.

J. Hospital-Acquired Condition (HAC) Reduction Program: Proposed Updates and Changes (42 CFR 412.170)

1. Regulatory Background

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program and to the same final rule (78 FR 50708 through 50709) for a detailed discussion of the statutory basis for the Program. For additional descriptions of our previously finalized policies for the HAC Reduction Program, we also refer readers to the following final rules:

- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729);
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104);
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49570 through 49581);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57011 through 57026);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38269 through 38278);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41492);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42402 through 42411);
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58860 through 58865); and
- The FY 2022 IPPS/LTCH PPS final rule (86 FR 45300 through 45310).

We have also codified certain requirements of the HAC Reduction Program at 42 CFR 412.170 through 412.172.

2. Flexibility for Changes That Affect Quality Measures During a Performance or Measurement Period in the HAC Reduction Program

a. Measure Suppression Policy for the Duration of the COVID–19 PHE

In the FY 2022 IPPS/LTCH PPS final rule, we adopted a policy for the duration of the COVID–19 PHE enabling us to suppress a number of measures from the Total HAC Score calculations for the HAC Reduction Program if we determine that circumstances caused by the COVID–19 PHE have affected these measures and the resulting Total HAC Scores significantly (86 FR 45301 through 45304). We refer readers to the FY 2022 IPPS/LTCH PPS final rule for further details on our measure suppression policy (86 FR 45301 through 45304).

In the FY 2022 IPPS/LTCH PPS final rule, we also adopted Measure Suppression Factors to guide our determination of whether to propose to suppress HAC Reduction Program measures for one or more program years that overlap with the PHE for COVID–19 (86 FR 45302). We adopted these Measure Suppression Factors for use in the HAC Reduction Program, and, for consistency, in the following other value-based purchasing programs: Hospital Value-Based Purchasing, Hospital Readmissions Reduction Program, Skilled Nursing Facility Value-Based Purchasing Program, and End-Stage Renal Disease Quality Incentive Program. We continue to believe that these Measure Suppression Factors will help us evaluate the HAC Reduction Program's measures, and that their adoption in the other value-based purchasing programs will help ensure consistency in our measure evaluations across programs. The previously adopted Measure Suppression Factors are as follows:

- Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
- Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the COVID–19 PHE.
- Rapid or unprecedented changes in—

++ Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or

++ The generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

- Significant national shortages or rapid or unprecedented changes in—

++ Healthcare personnel;

++ Medical supplies, equipment, or diagnostic tools or materials; or

++ Patient case volumes or facility-level case mix.

We stated that we view this measure suppression policy as necessary to ensure that the HAC Reduction Program does not reward or penalize facilities based on factors that the Program's measures were not designed to accommodate (86 FR 45302).

We are proposing changes to this measure suppression policy in section V.J.2.b.(2). below.

b. Proposals To Apply the Measure Suppression Policy to FY 2023 and FY 2024 HAC Reduction Program Years

(1) Background

Through memoranda released in March 2020[669] and an interim final rule with comment (IFC) published in September 2020 (85 FR 54827 through 54828), in response to the COVID–19 PHE, we excluded, by application of our Extraordinary Circumstances Exception (ECE) policy, all data submitted regarding care provided during the first and second quarters of CY 2020 from our performance calculations for FY 2022 and FY 2023. We excluded such data because of our concerns about the national comparability of these data due to the geographic differences of COVID–19 incidence rates and hospitalizations, along with different impacts resulting from different State and local laws and policy changes implemented in response to COVID–19.

Additionally, in the FY 2022 IPPS/LTCH PPS final rule, we finalized our policy suppressing the third and fourth quarters of CY 2020[670] CDC NHSN HAI

[669] Centers for Medicare and Medicaid Services. (2020). Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19 Available at: *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf*.

[670] In the FY 2022 IPPS/LTCH PPS final rule, we finalized the suppression of the third and fourth quarters of CY 2020, which is July 1, 2020 through September 30, 2020 (Q3 2020) and October 1, 2020 through December 31, 2020 (Q4 2020).

and CMS PSI 90 data from our performance calculations for FY 2022, FY 2023, and FY 2024 under the proposed Measure Suppression Factor 1, ''significant deviation in national performance on the measure, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years''; and the Measure Suppression Factor 4 subfactor, ''significant national or regional shortages or rapid or unprecedented changes in patient case volumes or case mix'' (86 FR 45304 through 45307). We explained that although Q3 and Q4 2020 data would be suppressed from the Total HAC Score calculation, hospitals would still be required to submit such data and such data would be used for public reporting purposes.

These policies resulted in the following applicable periods for calculating Total HAC Scores for FY 2022, FY 2023, and FY 2024 HAC Reduction Programs:

Applicable Periods for FY 2022, FY 2023, and FY 2024 for the HAC Reduction Program		
Fiscal Year	**Measure Set**	**Current Applicable Periods that Resulted from ECE and Measure Suppression Policies**
FY 2022	CDC NHSN HAI	January 1, 2019 through December 31, 2019
	CMS PSI 90	July 1, 2018 through December 31, 2019
FY 2023	CDC NHSN HAI	January 1, 2021 through December 31, 2021
	CMS PSI 90	July 1, 2019 through December 31, 2019 and January 1, 2021 through June 30, 2021
FY 2024	CDC NHSN HAI	January 1, 2021 through December 31, 2022
	CMS PSI 90	January 1, 2021 through June 30, 2022

In sections V.J.2.b.(2). and (3), of this proposed rule, we are proposing to further modify some of these applicable periods.

(2) Proposed Updates to the FY 2023 HAC Reduction Program

In this proposed rule, we are proposing two updates for the FY 2023 HAC Reduction Program's measure suppression policy: (1) We are proposing to suppress the CMS PSI 90 measure and the five CDC NHSN HAI measures from the calculation of measure scores and the Total HAC Score, thereby not penalizing any hospital under the HAC Reduction Program FY 2023 program year; and (2) For the CMS PSI 90 measure, we are proposing to not calculate or report measure results for the HAC Reduction Program FY 2023 program year.

COVID–19 has had significant negative health effects—on individuals, communities, and the nation as a whole. Consequences for individuals who have COVID–19 include morbidity, hospitalization, mortality, and post-COVID conditions (also known as long COVID). As of mid-December 2021, over 50 million COVID–19 cases, 3 million new COVID–19 related hospitalizations, and over 800,000 COVID–19 deaths have been reported in the U.S.[671] One analysis projected that COVID–19 would reduce life expectancy in 2020 by 1.13 years overall, with the estimated impact disproportionately affecting members of historically underserved and under-resourced communities. According to this analysis, the estimated life expectancy reduction for Black and Latino populations is 3 to 4 times the estimate when comparing to the white population.[672] Indeed, COVID–19 has overtaken the 1918 influenza pandemic as the deadliest disease event in American history.[673] Impacts of the pandemic have continued to accelerate in 2021. The Delta variant of COVID–19 (B.1.617.2), which was first identified in India, surfaced in the United States in early-to-mid 2021. It was found that the Delta variant is 60 percent more transmissible compared to the previously dominant Alpha variant.[674] Further, in November 2021, the number of COVID–19 deaths for 2021 surpassed the total deaths for 2020. According to CDC data, the total number of deaths involving COVID–19 reached 385,453 in 2020 and 451,475 in 2021.[675] We continue to monitor and evaluate the measures in the HAC Reduction Program for impacts due to COVID–19 and the emergence of COVID–19 variants, such as Delta and Omicron variants, and will elaborate further below.

As described in section V.J.2.b.(1). of this proposed rule, we previously excluded or suppressed all quarters of CY 2020 data from the calculation of the Total HAC Score, in part, because of concerns about the national comparability of these data and significant deviation in national performance on the measure compared to historical performance. We acknowledge that the time needed to adapt to the strains of the PHE and national performance deviated from previous performance during CY 2021 and therefore are proposing to suppress all HAC Reduction Program measures (CMS PSI 90, CAUTI, CLABSI, Colon and Hysterectomy SSI, MRSA, and CDI) from the calculation of the Total HAC Score for the FY 2023 HAC Reduction Program under Measure Suppression Factor 1 significant deviation in national performance on the measure, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years; Measure Suppression Factor 3, rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; and the Measure Suppression Factor 4, significant national or regional

[671] Centers for Disease Control and Prevention. (2021). COVID Data Tracker, *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[672] Andrasfay, T., & Goldman, N. (2021). Reductions in 2020 US life expectancy due to COVID–19 and the disproportionate impact on the Black and Latino populations. Proceedings of the National Academy of Sciences of the United States of America, 118(5), e2014746118. *https://www.pnas.org/content/118/5/e2014746118.*

[673] STAT News. (2021). Covid–19 overtakes 1918 Spanish flu as deadliest disease in American history, *https://www.statnews.com/2021/09/20/covid-19-set-to-overtake-1918-spanish-flu-as-deadliest-disease-in-american-history/.*

[674] Allen H., Vusirikala A., Flannagan J., et al. Increased Household Transmission of COVID–19 cases associated with SARS–CoV–2 Variant of Concern B.1.617.2: A national case-control study. Public Health England. 2021.

[675] Centers for Disease Control. (2022). COVID–19 Death Data and Resources. Available at: *https://www.cdc.gov/nchs/nvss/covid-19.htm.*

shortages or rapid or unprecedented changes in patient case volumes or case mix.

We are concerned that the COVID19 PHE resulted in changes in HAC Reduction Program measure performance such that we will not be able to score hospitals fairly. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45304 through 45305) for previous analysis on the HAC Reduction Program measures that showed that measure rates for the CLABSI, CAUTI, and MRSA measures increased during the CY 2020 pandemic year as compared to the pre-COVID CY 2019 year immediately preceding the COVID–19 PHE.

We are proposing to suppress three of the five CDC NSHN HAI measures (CLABSI, CAUTI, and MRSA) under Measure Suppression Factor 1, significant deviation in national performance on the measures, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. To determine whether the CLABSI, CAUTI, and MRSA measure rates would continue to show increases for CY 2021, the CDC analyzed changes in standardized infection ratios (SIRs) for Q1 and Q2 of CY 2021 as compared to the SIRs in Q1 and Q2 of CY 2019. This analysis found that the CLASBI, CAUTI, and MSRA measures had statistically significant measure rate increases during Q1 and Q2 of CY 2021 as compared to pre-pandemic levels in Q1 and Q2 of CY 2019. For Q1 2021, the national SIR increased by approximately 45 percent for the CLABSI measure, approximately 12 percent for the CAUTI measure, and approximately 39 percent for the MRSA measure as compared to Q1 2019. For Q2 2021, the national SIR increased by approximately 15 percent for the CLABSI measure and approximately 8 percent for the MRSA measure. The SIRs for the CAUTI measure showed no statistically significant difference for Q2 2021 as compared to Q2 2019.

For the CDI measure, the national SIR decreased by approximately 16 percent for Q1 2021 as compared to Q1 2019 and by approximately 14 percent for Q2 2021 as compared to Q2 2019. The SSI measure showed no significant increase or decrease in SIRs during Q1 2021 and Q2 2021 as compared to Q1 2019 and Q2 2019, however there has been an appreciable decrease in procedure volume for the measure. We are proposing to suppress the SSI and CDI measures under Measure Suppression Factor 4, significant national shortages or rapid or unprecedented changes in patient case volumes and Measure Suppression Factor 3, rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials, respectively. Specifically, for the SSI measure, we are proposing to suppress the measure for FY 2023 under Measure Suppression Factor 4, rapid or unprecedented changes in patient case volumes. We note that the SSI measure has had a low procedure volume for many hospitals during the PHE, which impacts our ability to produce SIRs for that measure. For CY 2019, 2,087 hospitals (61 percent) did not have sufficient procedure-level data needed to calculate an SSI SIR for abdominal hysterectomy, and 1,262 hospitals (37 percent) did not have sufficient data to calculate an SIR for colon surgery. However, nationally, procedure volumes declined even further during the COVID–19 PHE in 2020, compared to 2019, with decreases of up to 23 percent for colon procedures and 39 percent for abdominal hysterectomy procedures.[676] As of July 2021, abdominal hysterectomy procedures were still 6 percent below predicted levels.[677] These changes in patient volumes for the SSI measure limit our ability to calculate SSI SIRs for hospitals that don't have sufficient data in FY 2023, which may impact the accuracy and reliability of overall national comparison on performance for this measure.

For the CDI measure, we are proposing to suppress the measure under Measure Suppression Factor 3, rapid or unprecedented changes in clinical guidelines, care delivery or practice, related protocols, or equipment or diagnostic tools or materials. Pandemic-related improvements to typical CDI prevention practices such as hand hygiene, PPE practices, and environmental cleaning could have contributed to the declines seen in the CDI SIR in 2021 compared to 2019.[678] In addition, a decline in outpatient antibiotic prescribing was observed starting in 2020 as healthcare utilization decreased during the COVID–19 pandemic. [679] This, combined with the continued use of inpatient antibiotic stewardship programs in hospitals, may also have contributed to the decline in the national CDI SIRs, as reducing patient antibiotic exposure is a recommended strategy for CDI prevention. More information about CDI prevention strategies can be found at *https://www.cdc.gov/cdiff/clinicians/cdi-prevention-strategies.html.*

PERCENT CHANGES IN SIRS COMPARED TO RESPECTIVE 2019 QUARTERS

	2020 Q1	2020 Q2	2020 Q3	2020 Q4	2021 Q1	2021 Q2	Preliminary 2021 Q3*
CLABSI	-11.8	27.9	46.4	47.0	45.3	14.6	48.6
CAUTI	-21.3	No change	12.7	18.8	11.5	No change	13.3
SSI: Colon surgery	-9.1	No change	-6.9	-8.3	No change	No change	-6.6
SSI: Abdominal hysterectomy	-16.0	No change	No change	-13.1	No change	No change	No change
MRSA bacteremia	-7.2	12.2	22.5	33.8	39.2	8.3	44.5%
CDI	-17.5	-10.3	-8.8	-5.5	-15.6	-14.1	-14.5%

*This data is preliminary as of the time of the FY 2023 IPPS/LTCH PPS proposed rule publication. The Q3 2021 HAI measure data submission deadline was 2/15/2022 and the SIR for Q3 2021 has not yet been finalized.

[676] Weiner-Lastinger, L, et al. The impact of coronavirus disease 2019 (COVID–19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. Infection Control & Hospital Epidemiology (2022), 43, 12–25. doi:10.1017/ice.2021.362.

[677] Butler, S, et al. (2021). Epic Research. Elective Surgeries Approach Pre-Pandemic Volumes. Available at: *https://epicresearch.org/articles/elective-surgeries-approach-pre-pandemic-volumes.*

[678] Weiner-Lastinger LM, et al. (2021). The impact of coronavirus disease 2019 (COVID–19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. Infection Control & Hospital Epidemiology, *https://doi.org/10.1017/ice.2021.362.*

[679] The intersection of antibiotic resistance (AR), antibiotic use (AU), and COVID–19. (2021). Department of Health and Human Services website. *https://www.hhs.gov/sites/default/files/antibiotic-resistance-antibiotic-use-covid-19-paccarb.pdf.* Published February 10, 2021. Accessed June 28, 2021.

Additionally, because we cannot identify all potential elements that could be impacting the overall HAI experience at hospitals during an unprecedented PHE as well as potential geographic disparities in the impact of the PHE that could cause uneven impact on facilities based on their location, like shortages of healthcare personnel, we believe all five CDC NHSN HAI measures should be suppressed. Therefore, we believe it is appropriate to suppress all five HAI measures from the HAC Reduction Program for the FY 2023 program year, to ensure an accurate and reliable national comparison of performance on hospital safety.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45304 through 45305), we observed that the skewed measure performance may be due to circumstances unique to the effects of the pandemic such as staffing shortages and turnover, patients who are more susceptible to infections due to increased hospitalization stays, and longer indwelling catheters and central lines. We believe that the continued skewed measure performance is impacted by similar circumstances unique to the effects of the COVID–19 PHE. We further believe that our proposal to suppress the HAI measure data from CY 2021 is appropriate because the impact of the COVID–19 PHE on the measures cannot be addressed through risk-adjustment. Under current data collection requirements for the CDC NHSN HAI measures the data are collected at each hospital's ward level, meaning that the hospital submits infection data for a given ward rather than at the individual patient level. Accordingly, we are not able to identify the number of patients with HAIs who also had COVID–19 and therefore cannot risk-adjust for or otherwise account for COVID–19 diagnoses. Modifying CDC's risk adjustment methodology is a multi-year process that requires substantial time to review, analyze, and implement updated methodology for the calculation of the SIR. In order to address the impact of the ongoing COVID–19 PHE on HAI incidence, as reported to CDC NHSN, we believe suppression of the CY 2021 measure data is the best path forward for participating hospitals. Therefore, we are proposing to suppress all five HAI measures in the HAC Reduction Program for the FY 2023 program year.

In accordance with the previously adopted measure suppression policy (86 FR 45301 through 45304), we are proposing to suppress the CMS PSI 90 measure and the five CDC NHSN HAI measures for the HAC Reduction Program FY 2023 program year. We will continue to provide the measure results for the CDC NHSN HAI measures to hospitals via their hospital-specific reports (HSRs). We will also continue providing information regarding hospital performance to hospitals and other interested persons via the Care Compare tool hosted by Health and Human Services, currently available at *https://www.medicare.gov/care-compare*, and the Provider Data Catalog. As previously noted, under this policy, we would continue to use claims data for the CMS PSI 90 measure and participating hospitals would continue to report CDC NHSN HAI measure data to the CDC, so that we can monitor the effect of the circumstances on quality measurement and determine appropriate policies in the future.

Similarly, our analysis of the CMS PSI 90 measure suggested that comparability of performance on the measure has also been impacted by the PHE. Additionally, after the nationwide ECE (85 FR 54827 through 54828) and the FY 2022 IPPS/LTCH PPS final rule measure suppression policies (86 FR 45304 through 45307) the CMS PSI 90 reference period for the FY 2023 program year does not include data affected by the COVID–19 PHE. Conversely, the applicable period for the CMS PSI 90 measure does include data affected by COVID–19 PHE. Due to the fact that the reference period for this measure does not include data affected by the COVID–19 PHE and the applicable period does include such data, this would result in risk adjustment parameters that do not account for the impact of COVID–19 on affected patients. We believe that this misalignment would produce distorted measure results and potentially yield biased CMS PSI 90 measure results among hospitals highly impacted by the COVID–19 PHE. Therefore, for the FY 2023 program year we propose to not calculate measure results for CMS PSI 90, to not provide the measure results for the CMS PSI 90 measure to hospitals via their hospital-specific reports (HSRs), and to not publicly report those measure results on the Care Compare tool hosted by Health and Human Services and the Provider Data Catalog. We refer readers to section V.J.3.c.(1). and (2) of this proposed rule where we discuss the impact of the COVID–19 PHE on the CMS PSI 90 measure and a technical update to the measure specifications to risk-adjust for COVID–19 diagnoses.

For the remaining measures, specifically the CDC NHSN HAI measures, we would use the previously finalized applicable periods [680] to calculate measure results (that is, SIRs for each of the CDC NHSN HAI measures) the FY 2023 program year. We would use those measure results in feedback reports to hospitals and as part of program activities, fulfilling our obligation under section 1886(p)(5) of the Act to provide confidential reports to applicable hospitals with information on their performance on measures with respect to hospital-acquired conditions. Consumers may continue to access information on hospital performance with regards to hospital-acquired conditions through several channels, including the Care Compare tool hosted by Health and Human Services, currently available at *https://www.medicare.gov/care-compare*, the Provider Data Catalog, available at *https://data.cms.gov/provider-data/*.

Ultimately, if we finalize our proposals, all hospitals would receive a Total HAC Score of zero, and no hospitals would receive a penalty for FY 2023. We would confidentially and publicly report the measure scores of ''N/A'', Total HAC Score of zero and payment reduction indicators of ''no penalty'' for all hospitals for the FY 2023 program year. For the five CDC NHSN HAI measures, we would also report the measure results, both via HSRs and public reporting methods. For the CMS PSI 90 measure results, we would not calculate or report on the measure results and would indicate 'N/A' in confidential and public reporting. We would resume calculating measure scores in the FY 2024 program year, as discussed in section V.J.2.b.(3). of this proposed rule.

In determining how to address the impact of the COVID–19 PHE on hospital performance and calculating Total HAC Scores for FY 2023, we also considered suppressing some CY 2021 quality measure data as an alternative to suppressing all measures. Under this alternative, we considered suppressing the CY 2021 data for the CLABSI, CAUTI, and MRSA measures on the basis that performance on those measures continued to be affected by the COVID–19 PHE. We considered scoring hospitals based solely on their performance on SSI, CDI, and CMS PSI 90; however, we had concerns about running the HAC Reduction Program on only half of the program's measures as this may result in measure scores that are significantly better or worse than in immediately preceding years. In

[680] In the FY 2022 IPPS/LTCH PPS final rule, we finalized that the applicable periods for the FY 2023 HAC Reduction Program are for the CDC NHSN HAI measures the 12-month period from January 1, 2021 through December 31, 2021.

addition, a Total HAC score based on only three program measures would be less reliable, with more random noise in identification of bottom quartile hospitals, than a score based on six program measures. Therefore, we believe it is appropriate to suppress all five CDC NSHN HAI measures and the CMS PSI 90 measure from the calculation of measure scores and Total HAC Scores for the FY 2023 program year.

We also considered making no modifications to the program and suppressing no additional measure data from the FY 2023 Total HAC Scores rather than extending the measure suppression policy. As discussed, when considering this approach in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45305), this alternative would be operationally easier to implement, but would mean assessing participating hospitals using quality measure data that have been distorted by the COVID–19 PHE without additional adjustments to the measure. Additionally, given the geographic disparities in the COVID–19 PHE's effects, this policy could place hospitals in regions that were hit harder by the pandemic in CY 2021 at a disadvantage compared to hospitals in regions that were more heavily affected in CY 2020. Ultimately, we believe that our proposal to suppress all measures from the FY 2023 HAC Reduction Program more fairly addresses the impact of the COVID–19 PHE for participating hospitals.

Finally, we considered reusing a previous fiscal year's applicable period to serve as the applicable period for FY 2023. Although this option would enable us to continue operating the program, it has the disadvantage of double penalizing hospitals that were in a prior fiscal year's worst performing quartile even if the hospital had implemented policy and operational changes to improve their performance in future program years. Under this option, no new quality data would be used to inform hospitals or drive quality improvement.

We continue to be concerned about the pandemic, but are encouraged by the development and rollout of prevention techniques like COVID–19 vaccinations and treatment for those diagnosed with COVID–19. Our measure suppression policy focuses on a short-term, equitable approach during this unprecedented PHE, and was not intended for indefinite application. We also recognize that measure performance for some measures may not immediately return to levels seen prior to the PHE, particularly for the CDC NHSN HAI measures for which we do not receive patient-level data. Additionally, we wanted to emphasize the long-term importance of value-based care and incentivizing quality care tied to payment. The HAC Reduction Program is an example of our long-standing effort to link payments to healthcare quality in the inpatient hospital setting payment.[681] Therefore, we note that our goal is to continue resuming the use of measure data for the purposes of scoring and payment adjustment beginning with the FY 2024 program year.

We understand that the COVID–19 PHE is ongoing and unpredictable in nature, however, we believe that 2022 has a more promising outlook in the fight against COVID–19. As we enter the third year of the pandemic, healthcare providers and systems have gained experience managing the disease, surges of COVID–19 infection, and adjusting to supply chain fluctuations.[682] In 2022 and the upcoming years, we anticipate continued availability and increased uptake in the use of vaccinations and the associated boosters,[683] including vaccination for children which was not available for most of 2021.[684] Additionally, the FDA issued emergency use authorizations (EUAs) for the first oral antiviral COVID–19 pill on December 22, 2021, and later approved a second the following day, expanding access to at-home COVID–19 treatment options.[685] [686] Finally, the Biden-Harris Administration has mobilized efforts to distribute home test kits,[687] N–95 masks,[688] and increase COVID–19 testing in schools,[689] providing more treatment and testing to the American people. Given these developments, we will continue to assess the impact of the PHE on measure data used for the HAC Reduction Program.

We invite public comments on our proposals.

(3) Proposal To Suppress CY 2021 CDC NHSN HAI Measure Data From the FY 2024 HAC Reduction Program Year

As described in section V.J.2.b.(1). of this proposed rule, we previously excluded or suppressed all quarters of CY 2020 data for all the program measures from the calculation of the Total HAC Score, in part, because of concerns about the national comparability of these data and significant deviation in national performance on the measure compared to historical performance. The exclusion and suppression of those data resulted in a shortened applicable period for the CMS PSI 90 measure for the FY 2024 HAC Reduction Program, specifically the 18-month period of January 1, 2021 through June 30, 2022. The applicable period for the CDC NHSN HAI measures for the FY 2024 program year was unaffected and remained as the 24-month period of January 1, 2021, through December 31, 2022.

As described previously, we continue to be concerned about measure performance and the national comparability of such performance during CY 2021. We therefore are proposing to suppress CY 2021 CDC

[681] CMS has also partnered with the CDC in a joint Call to Action on safety, which is focused on our core goal to keep patients safe. Fleisher et al. (2022). *New England Journal of Medicine.* Article available here: *https://www.nejm.org/doi/full/10.1056/NEJMp2118285?utm_source=STAT+Newsletters&utm_campaign=8933b7233e-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-8933b7233e-151759045*.

[682] Schneider, E. et al. (2022). *The Commonwealth Fund.* Responding to Omicron: Aggressively Increasing Booster Vaccinations Now Could Prevent Many Hospitalizations and Deaths. Available at: *https://www.commonwealthfund.org/blog/2022/responding-omicron*.

[683] Schneider, E. et al. (2022). *The Commonwealth Fund.* Responding to Omicron: Aggressively Increasing Booster Vaccinations Now Could Prevent Many Hospitalizations and Deaths. Available at: *https://www.commonwealthfund.org/blog/2022/responding-omicron*.

[684] Centers for Disease Control and Prevention. (2022). CDC Expands booster Shot Eligibility and Strengthens Recommendations for 12–17 Year Olds. Available at: *https://cdc.gov/media/releases/2022/s0105-Booster-Shot.html#:~:text=Today%2C%20CDC%20is%20endorsing%20the,initial%20Pfizer-BioNTech%20vaccination%20series*.

[685] U.S. Food and Drug Administration. (2021). Coronavirus (COVID–19) Update: FDA Authorizes First Oral Antiviral for Treatment of COVID–19. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-oral-antiviral-treatment-covid-19*.

[686] U.S. Food and Drug Administration. (2021). Coronavirus (COVID–19) Update: FDA Authorizes Additional Oral Antiviral for Treatment of COVID–19 in Certain Adults. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-oral-antiviral-treatment-covid-19-certain#:~:text=Today%2C%20the%20U.S.%20Food%20and,progression%20to%20severe%20COVID%2D19%2C*.

[687] The White House. (2022). Fact Sheet: The Biden Administration to Begin Distributing At-Home, Rapid COVID-19 Tests to Americans for Free. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/14/fact-sheet-the-biden-administration-to-begin-distributing-at-home-rapid-covid-19-tests-to-americans-for-free/*.

[688] Miller, Z. (2021). *The Washington Post.* Biden to give away 400 million N95 masks starting next week Available at: *https://www.washingtonpost.com/politics/biden-to-give-away-400-million-n95-masks-starting-next-week/2022/01/19/5095c050-7915–11ec-9dce-7313579de434_story.html*.

[689] The White House. (2022). FACT SHEET: Biden-Harris Administration Increases COVID-19 Testing in Schools to Keep Students Safe and Schools Open. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/12/fact-sheet-biden-harris-administration-increases-covid-19-testing-in-schools-to-keep-students-safe-and-schools-open/*.

NHSN HAI data from the FY 2024 HAC Reduction Program under Measure Suppression Factor 1, ''significant deviation in national performance on the measure, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years''; and the Measure Suppression Factor 4 subfactor, ''significant national or regional shortages or rapid or unprecedented changes in patient case volumes or case mix.'' Under current data collection processes for the CDC NHSN HAI measures, we are not able to risk-adjust for or otherwise account for COVID–19 diagnoses and therefore must suppress the CY 2021 data in order to account for COVID–19 diagnoses in the CDC NHSN HAI data. For the FY 2024 program year, the resulting applicable period for CDC NHSN HAI measures would be the 12-month period of January 1, 2022, to December 31, 2022.

To account for the impact of the COVID–19 PHE on CY 2021 data in the CMS PSI 90 measure, we are updating the measure specifications to risk-adjust for COVID–19 diagnoses, as described in section V.J.3.c.(2). of this proposed rule, beginning with the FY 2024 program year. Our analysis of the COVID–19 PHE impacts on CY 2021 data found that the decrease in volume continued in CY 2021 across nearly all component Patient Safety Indicator (PSI) measures, especially those related to surgical procedures (for which the denominator volume was 8 percent to 45 percent lower in the first two quarters of CY 2021 than in the corresponding quarters of CY 2019). Our analysis also found that unadjusted rates continued to be high in CY 2021 for patients with a COVID–19 diagnosis compared to patients without a COVID–19 diagnosis. We refer readers to section V.J.3.c.(2). for more information about COVID–19 impacts on the CMS PSI 90 measure.

For the CMS PSI 90 measure, the applicable period remains unchanged from January 1, 2021, through June 30, 2022.[690] If finalized, these policies would result in the following applicable periods for FY 2023, FY 2024, and FY 2025 HAC Reduction Programs:

Applicable Periods for FY 2023, FY 2024, and FY 2025 for the HAC Reduction Program

Fiscal Year	Measure Set	Current Applicable Periods that Resulted from ECE and Measure Suppression Policies
FY 2023	CDC NHSN HAI	January 1, 2021, through December 31, 2021
	CMS PSI 90	July 1, 2019, through December 31, 2019; and January 1, 2021, through June 30, 2021
FY 2024	CDC NHSN HAI	January 1, 2022, through December 31, 2022
	CMS PSI 90	January 1, 2021, through June 30, 2022
FY 2025	CDC NHSN HAI	January 1, 2022, through December 31, 2023
	CMS PSI 90	July 1, 2021, through June 30, 2023

We invite public comments on this proposal to suppress CY 2021 CDC NHSN HAI Measure data from the FY 2024 HAC Reduction Program year.

3. Measures for FY 2023 and Subsequent Years

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41474) for more information about how the HAC Reduction Program supports our goal of bringing quality measurement, transparency, and improvement together with value-based purchasing to the hospital inpatient care setting through the Meaningful Measures Framework.

a. Current Measures

The HAC Reduction Program has adopted six measures to date. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized the use of five CDC NHSN HAI measures: (1) CAUTI; (2) CDI; (3) CLABSI; (4) Colon and Abdominal Hysterectomy SSI; and (5) MRSA bacteremia. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57014), we finalized the use of the CMS PSI 90 measure. These previously finalized measures, with their full measure names, are shown in this table.

[690] For the FY 2025 HAC Reduction Program year, there is no CY 2021 data included in the applicable period for the HAI measures so the applicable period remains unchanged and would be January 1, 2022, to December 31, 2023. For the CMS PSI 90 measure, the applicable period is July 1, 2021, through June 30, 2023. As discussed, to account for the impact of the COVID–19 PHE on CY 2021 CMS PSI 90 measure data, we are updating the measure specifications to risk-adjust for COVID–19 diagnoses.

HAC Reduction Program Measures for FY 2023 and Subsequent Years		
Short Name	**Measure Name**	**NQF #**
CMS PSI 90	CMS Patient Safety and Adverse Events Composite (CMS PSI 90)	0531
CAUTI	CDC NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CDI	CDC NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717
CLABSI	CDC NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	CDC NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716

Technical specifications for the CMS PSI 90 measure can be found on the *QualityNet* website at *https://qualitynet.cms.gov/inpatient/measures/psi/resources*. Technical specifications for the CDC NHSN HAI measures can be found at CDC's NHSN website at *https://www.cdc.gov/nhsn/acute-care-hospital/index.html*. Both websites provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

In this proposed rule, we are not proposing to add or remove any measures. However, we discuss our proposal to suppress all of the measures for the FY 2023 program year, as discussed in section V.J.2.b.(2). of the preamble of this proposed rule, and our proposal to suppress CY 2021 CDC NHSN HAI data from the FY 2024 program year, as discussed in section V.J.2.b.(3). of the preamble of this proposed rule.

b. Measure Removal Factors Policy

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42404 through 42406) for information about our measure removal and retention factors for the HAC Reduction Program. In this proposed rule, we are not proposing any measure removal and retention factor policy changes.

c. Technical Measure Specification Updates to the CMS PSI 90 Measure

(1) Technical Measure Specification Update to the Minimum Volume Threshold for the CMS PSI 90 Measure beginning With the FY 2023 Program Year

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50100 through 50101), we finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the HAC Reduction Program. We stated our belief that this policy adequately balances our need to incorporate updates to HAC Reduction Program measures in the most expeditious manner possible while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted.

Currently, the minimum volume threshold for the CMS PSI 90 measure requires hospitals to have three or more eligible discharges for at least one component indicator in order to receive a CMS PSI 90 measure score for the HAC Reduction Program (81 FR 57012). Although the CMS PSI 90 measure surpasses the accepted reliability standard, based on an Intracluster Correlation Coefficient (ICC) for hospital-level reporting of at least 0.60 (in a standard 24-month performance period, the CMS PSI 90 measure demonstrated median reliability of 0.74), a small subset of hospitals have a reliability close to zero for their CMS PSI 90 composite score due to the current minimum volume threshold for the measure.

To address this subset of hospitals with a CMS PSI 90 composite score with reliability close to zero, we are instituting a stricter minimum volume threshold for the measure, which would prevent those small hospitals from receiving a CMS PSI 90 composite score. Consistent with the current minimum volume threshold policy, hospitals that do not meet the threshold criteria would not receive a measure result or, subsequently, a measure score (that is, a Winsorized z-score) for the CMS PSI 90 measure and it would not factor into the calculation of their Total HAC Score. Accordingly, in this proposed rule, we are announcing an increased minimum volume threshold for the CMS PSI 90 measure, under which hospitals would be required to meet both of the following criteria in order to receive a CMS PSI 90 composite score:

- One or more component PSI measure with at least 25 eligible discharges; and
- Seven or more component PSI measures with at least three eligible discharges.

We note that this change to the CMS PSI 90 minimum volume threshold criteria will be applied to both the version of the measure used in HAC Reduction Program scoring calculations as well as the version of the measure displayed on the main pages of the Care Compare tool hosted by the U.S. Department of Health and Human Services, currently available at *https://www.medicare.gov/care-compare*, via updates to the next version of the CMS PSI 90 software. Additional information regarding the technical specifications for the CMS PSI 90 measure can be found on the *QualityNet* website at *https://qualitynet.cms.gov/inpatient/measures/psi/resources*.

An analysis of the impact of this threshold change on HAC Reduction Program results indicates that it would impact the scoring of a small number of low-volume hospitals. As a result of this threshold change, approximately five percent of hospitals would no longer receive a CMS PSI 90 composite score (and, subsequently, a CMS PSI 90 measure score) and approximately half of those hospitals, or 2.5 percent of all hospitals, would no longer receive a Total HAC Score. Accordingly, there will be a decrease in the number of hospitals in the worst-performing quartile. We anticipate that the majority of the hospitals no longer receiving a Total HAC Score will be small hospitals with fewer than 100 beds. Rural hospitals, which tend to have lower capacity, are also more impacted by the

change than urban hospitals. The threshold change only impacts a small number of hospitals in the HAC Reduction Program while improving overall measure reliability.

(2) Technical Measure Specification Update to Risk-Adjust for COVID–19 Diagnoses in the CMS PSI 90 Measure Beginning With the FY 2024 HAC Reduction Program Year

We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45305) for previous analysis on the impact of the COVID–19 PHE on the CMS PSI 90 measure. Our analysis found that the decrease in volume continued in CY 2021 across all component Patient Safety Indicator (PSI) measures, especially those related to surgical procedures for which the denominator volume was 8 percent to 45 percent lower in the first two quarters of CY 2021 than in the corresponding quarters of CY 2019. Our analysis also found that unadjusted rates continued to be high in CY 2021 for patients with a COVID–19 diagnosis compared to patients without a COVID–19 diagnosis, across most of the 10 component measures in CMS PSI 90. However, PSI 90 component rates among patients without COVID–19 were virtually unchanged through the COVID–19 PHE. CMS has found that adjusting for COVID–19 at the patient level entirely removes the incremental risk associated with this diagnosis. After risk-adjustment for COVID–19, PSI component rates appear consistently flat across the first two quarters of 2021.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50100 through 50101), we finalized a subregulatory process to make nonsubstantive updates to measures used for the HAC Reduction Program. To address the impact of the COVID–19 PHE on the CMS PSI 90 measure, we are announcing a technical update to the CMS PSI 90 software to include COVID–19 diagnosis as a risk-adjustment parameter for the FY 2024 program year and subsequent years.

d. HAC Reduction Program Requests for Information

(1) Digital CDC NHSN Measures

We refer readers to section IX.E.9.a. of this proposed rule, where we request information on the potential future adoption of two digital NHSN measures, the NHSN Healthcare-associated *Clostridioides difficile* Infection Outcome Measure and the NHSN Hospital-Onset Bacteremia & Fungemia Outcome Measure, into the Hospital IQR Program, PCHQR Program, and the LTCH QRP. In addition, we request information on the potential inclusion of these digital CDC NHSN measures in the HAC Reduction Program. This request for information supports our goal of moving fully to digital quality measurement in CMS quality reporting and value-based purchasing programs, including the HAC Reduction Program.

(2) Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

We refer readers to section IX.B. of this proposed rule where we are seeking input on overarching principles in measuring healthcare quality disparities in hospital quality and value-based purchasing programs.

4. Proposal To Update the CDC NHSN HAI Data Submission Requirements for Newly Opened Hospitals Beginning in the FY 2023 HAC Reduction Program Year

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57013), we finalized CDC NHSN HAI data submission requirements for newly-opened hospitals under the HAC Reduction Program that referred to the date that a hospital filed a notice of participation (NOP) with the Hospital IQR Program. At the time, the HAC Reduction Program obtained measure results that hospitals submitted to the CDC NHSN from the Hospital IQR Program. However, in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41545 through 41553), we transferred our collection of the CDC NHSN HAI measures from the Hospital IQR Program to the HAC Reduction Program beginning with CY 2020 data. Given the transition from the Hospital IQR Program, the NOP requirements noted in the FY 2017 IPPS/LTCH PPS final rule do not apply.

In this proposed rule, we are proposing to update the definition of ''newly-opened hospitals'' for the CDC NHSN HAI measures to include hospitals with a Medicare Accept Date within the last 12 months of the performance period.[691] Under the HAC Reduction Program scoring methodology, hospitals that are defined as newly-opened hospitals for the CDC NHSN HAI measures do not receive a measure score for any of the CDC NHSN HAI measures.

The number of hospitals impacted by this change in criteria is small, less than one-quarter percent of hospitals. Hospitals with a Medicare Accept Date between the 12th and the 6th month before the end of the HAI performance period (January 1, 2021 to June 30, 2021 for the FY 2023 program year) do not meet the current criteria for newly-opened hospitals for the CDC NHSN HAI measures, but would meet the updated criteria.[692] In addition, all of these hospitals do not have 12 months of CMS PSI 90 data and because of this already do not receive a measure score for that measure. Therefore, all impacted hospitals would not receive a Total HAC Score for the program year and could not be subject to the one percent payment reduction. As per the measure suppression policy discussed in section V.J.2.b.(2). above we are proposing to suppress all six measures in the program for the FY 2023 program year, so no hospitals will be impacted by this change for the FY 2023 program year.

An analysis of the number of hospitals not meeting the current definition of ''new hospitals'' that would meet the criteria under this new proposed definition indicate that 0.22 percent of hospitals would have been affected by this definition change in the FY 2021 program year and 0.09 percent in the FY 2020 program year.

We invite public comments on this proposal to update the newly-opened hospital definition for CDC NHSN HAI measures beginning in the FY 2023 program year.

5. HAC Reduction Program Scoring Methodology and Scoring Review and Corrections Period

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41484 through 41489), we adopted the Equal Measure Weights approach to scoring and clarified the Scoring Calculations Review and Correction Period (83 FR 41484) for the HAC Reduction Program. Hospitals must register for a *QualityNet* website's secure portal account in order to access their annual hospital-specific reports. In this proposed rule we are not proposing to make any changes to the Scoring Calculations Review and Correction Period process.

We note that in section V.J.2.b.(2). of this proposed rule, we are proposing to temporarily suppress all measures from the FY 2023 HAC Reduction Program.

[691] Because the CMS PSI 90 measure requires at least 12 months of measure data (81 FR 50712), hospitals that open during the final 12 months of the performance period would also not receive a CMS PSI 90 measure score.

[692] There is a small subset of hospitals with a Medicare Accept Date between the 6th and 9th month before the end of the HAI performance period (April 1, 2021, to June 30, 2021 for the FY 2023 program year) and a Hospital IQR Program Notice of Participation Date during the last quarter of the HAI performance period (before October 1, 2021 or after December 31, 2021 for the FY 2023 program year), that are also currently defined as newly-opened hospitals. These hospitals' newly-opened status would not be impacted by this criteria change.

We are proposing to calculate the measure results for the five CDC NHSN HAI measures for the FY 2023 HAC Reduction Program, but to not use those measure results to calculate measure scores (that is, Winsorized z-scores) for any of the measures because of our concerns regarding the comparability of measure results. Additionally, we are proposing to not calculate measure results for CMS PSI 90 measure nor publicly report the measure on the Care Compare tool hosted by Health and Human Services and the Provider Data Catalog. We are also proposing that all hospitals would receive a Total HAC Score of zero, and no hospitals would receive a penalty for FY 2023. We intend to resume the previously adopted HAC Reduction Program scoring methodology in FY 2024 (with the proposed suppression of CY 2021 CDC NHSN HAI data as discussed in section V.J.2.b.(3).) and for subsequent years. In section V.J.2.b.(2)., we invite public comment on the proposal to temporarily suppress all measures from the FY 2023 HAC Reduction Program.

6. Validation of HAC Reduction Program Data

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41478 through 41484), we adopted processes to validate the CDC NHSN HAI measure data used in the HAC Reduction Program, because the Hospital IQR Program finalized its proposals to remove CDC NHSN HAI measures from its program. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42406 through 42410), we provided additional clarification to the validation selection and scoring methodology. We also refer readers to the *QualityNet* website for more information regarding chart-abstracted data validation of measures. In the FY 2020 IPPS/LTCH PPS final rule (85 FR 58862 through 58865), we finalized our policy to align the HAC Reduction Program validation process with that of the Hospital IQR Program. Specifically, we aligned the hospital selection and submission quarters beginning with CY 2021 data for the FY 2024 Hospital IQR and HAC Reduction Programs validation so that we only require one pool of hospitals to submit data for validation. Additionally, we finalized a policy requiring hospitals to submit digital files when submitting medical records for validation of HAC Reduction Program measures, for the FY 2024 program year and subsequent years.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58862 through 58865), we finalized our policy that for the FY 2024 program year and subsequent years, we will use measure data from all of CY 2021 for both the HAC Reduction Program and the Hospital IQR Program, which must be reported using the validation schedule posted on the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System.

In section V.J.2.b.(2). and V.J.2.b.(3). of this proposed rule, we are proposing to suppress all measures from the FY 2023 program and CY 2021 CDC NHSN HAI data from the FY 2024 HAC Reduction Program, respectively. As discussed in those sections, hospitals are still required to submit such data and such data will be used for validation purposes. If hospitals do not submit measure data for validation during the FY 2024 program year, then those hospitals will automatically receive the maximum Winsorized z-score for the measure in the FY 2024 program year payment calculation. We are not proposing any changes to the policies regarding measure validation in this proposed rule.

7. Clarification of the Removal of the No Mapped Locations Policy Beginning With the FY 2023 Program Year

Under the HAC Reduction Program, hospitals have historically been able to receive a ''no mapped locations (NML)'' exemption [693] for the CLABSI and CAUTI measures.[694] This exemption has been applied when hospitals do not map an applicable ward (that is, Intensive Care Units (ICUs), surgical, medical, and medical-surgical wards) in the NHSN system, do not submit data for the measures, and do not submit an IPPS Measure Exception Form.[695]

In this proposed rule we would like to clarify the removal of the No Mapped Locations (NML) policy. The CDC has confirmed that the NML exemption does not indicate that a hospital does not need to report data, and that hospitals requesting to be exempt from reporting for CMS quality programs including the HAC Reduction Program, should submit an IPPS Measure Exception Form on the QualityNet website at *https://qualitynet.cms.gov/files/5e3459aa152a7d001f93d36c?filename=IPPS_MeasureExceptionForm_CY2020.pdf*.

Therefore, we want to clarify that beginning in FY 2023 and subsequent years, the NML designation will no longer apply, and hospitals will be required to appropriately submit data to the NHSN or, if hospitals do not have the applicable locations for the CLABSI and CAUTI measures, the hospital must submit an IPPS Measure Exception Form to be exempt from CLABSI and CAUTI reporting for CMS programs. If the hospitals do not submit an IPPS Measure Exception Form and continue to not submit data to the NHSN, these hospitals would receive the maximum measure score (that is, Winsorized z-score) under the HAC Reduction Program for not reporting data. In the FY 2020 IPPS/LTCH PPS final rule, we instructed hospitals that do not have adequate locations for CLABSI or CAUTI reporting to submit the IPPS Measure Exception Form to the HAC Reduction Program beginning on January 1, 2020 (84 FR 42406), and the removal of the NML policy has previously been communicated in the FY 2022 HAC Reduction Program Frequently Asked Questions [696] and the FY 2022 HAC Reduction Program HSR User Guide.[697] Additionally, because NML only applies to a small subset of hospitals, we plan to execute targeted outreach via email to those hospitals that had received the exception in the past two program years notifying them of the removal of the NML policy.

For more details on the NML designation and policy, we refer readers to the FY 2022 Hospital Specific Report (HSR) User Guide located on QualityNet website at *https://qualitynet.cms.gov/files/61152cf0a248cb001efce449?filename=FY_2022_HACRP_HSR_User_Guide.pdf* and the FY 2022 HAC Reduction Program Frequently Asked Questions website at *https://qualitynet.cms.gov/files/61152d1252b92f00229e9717?filename=FY_2022_HACRP_FAQ.pdf*.

8. Extraordinary Circumstances Exception (ECE) Policy for the HAC Reduction Program

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49579 through 49581) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38276 through 38277) for discussion of our Extraordinary Circumstances Exception

[693] Prior to FY 2018, the program used the term No Facilities Waiver for this same situation. Centers for Medicare & Medicaid Services. (2017). HACRP HAI Webinar Slides Final. Available at: *https://www.qualityreportingcenter.com/globalassets/migrated-pdf/vbp-iqr-hacrp_hai_webinar_slides_vfinal508.pdf*.

[694] Centers for Medicare and Medicaid Services. (2021). FY 2022 HACRP HSR User Guide. Available at: *https://qualitynet.cms.gov/files/61152cf0a248cb001efce449?filename=FY_2022_HACRP_HSR_User_Guide.pdf*.

[695] The valid OMB control number for the IPPS Measure Exception Form is 0938–1022.

[696] Centers for Medicare and Medicaid Services. (2021). FY 2022 HACRP FAQs. Available at: *https://qualitynet.cms.gov/files/61152d1252b92f00229e9717?filename=FY_2022_HACRP_FAQ.pdf*.

[697] Centers for Medicare and Medicaid Services. (2021). FY 2022 HACRP HSR User Guide. Available at: *https://qualitynet.cms.gov/files/61152cf0a248cb001efce449?filename=FY_2022_HACRP_HSR_User_Guide.pdf*.

(ECE) policy. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49579 through 49581), we adopted an ECE policy for the HAC Reduction Program, which recognized that there may be periods of time during which a hospital is not able to submit data in an accurate or timely fashion due to an extraordinary circumstance beyond its control. When adopting this policy, we noted that we considered the feasibility and implications of excluding data for certain measures for a limited period of time from the calculations for a hospital's measure results or Total HAC Score for the applicable performance period. By minimizing the data excluded from the program, the policy enabled affected hospitals to continue to participate in the HAC Reduction Program for a given fiscal year if they otherwise continued to meet applicable measure minimum threshold requirements. We expressed the belief that this approach would help alleviate the burden for a hospital that might be adversely impacted by a natural disaster or other extraordinary circumstance beyond its control, while enabling the hospital to continue to participate in the HAC Reduction Program. In developing this policy, we considered a policy and process similar to that for the Hospital IQR Program, as finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651), modified by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) (designation of a non-CEO hospital contact), and further modified in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277) (amended § 412.40(c)(2)) to refer to ''extension or exemption'' instead of the former ''extension or waiver''). We also considered how best to align an extraordinary circumstance exception policy for the HAC Reduction Program with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs, such as the Hospital Value-Based Purchasing (VBP) Program, to the extent feasible. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38276 through 38277), we modified the requirements for the HAC Reduction Program ECE policy to further align with the processes used by other quality reporting and value-based purchasing programs for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control.

In response to the COVID–19 PHE, we announced relief for clinicians, providers, hospitals, and facilities participating in Medicare quality reporting and value-based purchasing programs. On September 2, 2020, we published the interim final rule with comment period (IFC), ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 54820). The IFC updated the ECE we granted in response to the COVID–19 PHE, for the HAC Reduction Program and several other quality reporting programs (85 FR 54827 through 54838). In the IFC, we updated the previously announced application of our ECE policy for the HAC Reduction Program (85 FR 54830 through 54832) to the COVID–19 PHE to exclude any CDC NHSN HAI data submitted regarding care provided during the first and second quarters of CY 2020 from our calculation of performance for FY 2022 and FY 2023.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45308 through 45310), we clarified our ECE policy to highlight that an ECE granted under the HAC Reduction Program may allow an exception from quality data reporting requirements and may grant a request to exclude any data submitted (whether submitted for claims purposes or to the CDC NHSN) from the calculation of a hospital's measure results or Total HAC Score for the applicable period, depending on the exact circumstances under which the request was made.

Finally, in the FY 2022 IPPS/LTCH PPS final rule we clarified that, although an approved ECE for the HAC Reduction Program would exclude excepted data and grant an exception with respect to data reporting requirements for the period during which performance or ability to submit data was impacted or both, a hospital would still be evaluated for the remainder of the applicable period during which performance and ability to submit data was not impacted (to the extent that enough data are available to ensure that the calculation is statistically sound) or both. We clarified that an approved ECE for the HAC Reduction Program does not exempt hospitals from payment reductions under the HAC Reduction Program (86 FR 45309 through 45310).

We are not proposing any changes to our previously finalized ECE Policy in this proposed rule.

K. Rural Community Hospital Demonstration Program

1. Introduction

The Rural Community Hospital Demonstration was originally authorized by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). The demonstration has been extended three times since the original 5-year period mandated by the MMA, each time for an additional 5 years. These extensions were authorized by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148), section 15003 of the 21st Century Cures Act (Pub. L. 114–255) (Cures Act) enacted in 2016, and most recently, by section 128 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260). In this proposed rule, we summarize the status of the demonstration program, and the ongoing methodologies for implementation and budget neutrality.

We are also proposing the amount to be applied to the national IPPS payment rates to account for the costs of the demonstration in FY 2023, and, in addition, the reconciled amount of demonstration costs for FY 2017, the most recent year for which finalized cost reports have become available.

2. Background

Section 410A(a) of Public Law 108–173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1) Public Law 108–173, is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

3. Policies for Implementing the 5-Year Extension Period Authorized by Public Law 116–260

Our policy for implementing the 5-year extension period authorized by Public Law 116–260 (the Consolidated Appropriations Act, 2021) follows upon that for the previous extensions, under the Affordable Care Act (Pub. L. 111–

148) and the Cures Act (Pub. L. 114–255).

Section 410A of Public Law 108–173 (MMA) initially required a 5-year period of performance. Subsequently, sections 3123 and 10313 of Public Law 111–148 required the Secretary to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period.

Public Law 111–148 required the Secretary to provide for the continued participation of rural community hospitals in the demonstration program during this 5-year extension period, in the case of a rural community hospital participating in the demonstration program as of the last day of the initial 5-year period, unless the hospital made an election to discontinue participation. In addition, Public Law 111–148 limited the number of hospitals participating to no more than 30.

Section 15003 of the Cures Act required the Secretary to conduct the demonstration for a 10-year extension period (in place of the 5-year extension period required by the Affordable Care Act. Specifically, section 15003 of the Cures Act amended section 410A(g)(4) of Public Law 108–173 (MMA) to require that, for hospitals participating in the demonstration as of the last day of the initial 5-year period, the Secretary would provide for continued participation of such rural community hospitals in the demonstration during the 10-year extension period, unless the hospital made an election, in such form and manner as the Secretary may specify, to discontinue participation. In addition, section 15003 of the Cures Act added subsection (g)(5) to section 410A of Public Law 108–173 to require that, during the second 5 years of the 10-year extension period, the Secretary would apply the provisions of section 410A(g)(4) of Public Law 108–173 to rural community hospitals not described in subsection (g)(4) but that were participating in the demonstration as of December 30, 2014, in a similar manner as such provisions apply to hospitals described in subsection (g)(4).

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38280), we finalized our policy with regard to the effective date for the application of the reasonable cost-based payment methodology under the demonstration for those previously participating hospitals choosing to participate in the second 5-year extension period. According to our finalized policy, each previously participating hospital began the second 5 years of the 10-year extension period and payment for services provided under the cost-based payment methodology under section 410A of the MMA (as amended by section 15003 of the Cures Act) on the date immediately after the period of performance ended under the first 5-year extension period.

Seventeen of the 21 hospitals that completed their periods of participation under the extension period authorized by the Affordable Care Act elected to continue in the 5-year extension period authorized by the Cures Act. Therefore, for these hospitals, the period of participation under this second 5-year extension started on dates ranging from May 1, 2015, through January 1, 2017, depending on when they had initially started.

On November 20, 2017, we announced that 13 additional hospitals were selected to participate in the demonstration in addition to these 17 hospitals continuing participation from the first 5-year extension period. (These two groups are referred to as ''newly participating'' and ''previously participating'' hospitals, respectively.) We announced that each of these newly participating hospitals would begin its 5-year period of participation effective with the start of the first cost-reporting period on or after October 1, 2017. One of the newly participating hospitals withdrew from the demonstration program prior to beginning participation in the demonstration on July 1, 2018. In addition, one of the previously participating hospitals closed effective January 2019, and another withdrew effective October 1, 2019. Therefore, 27 hospitals were participating in the demonstration as of October 1, 2019—15 previously participating and 12 newly participating.

Each hospital has had its own end date applicable to this third five-year period for the demonstration. For four of the previously participating hospitals, this end date fell within FY2020, while for 11 of the previously participating hospitals, the end date would fall within CY 2021. (One of the hospitals within this group chose in February of 2020 to withdraw effective September of the previous year). The newly participating hospitals were all scheduled to end their participation either at the end of FY 2022 or during FY 2023.

Section 128 of Public Law 116–260 requires a 15-year extension period, to begin on the date immediately following the last day of the initial 5-year period, instead of the 10-year extension period mandated by the Cures Act. In addition, the statute provides for continued participation for all hospitals participating in the demonstration program as of December 30, 2019. Therefore, in FY 2022 IPPS final rule (86 FR 45314), we stated that we interpreted the statute as providing for an additional 5-year period under the reasonable cost-based reimbursement methodology for the demonstration for the hospitals that were participating as of this date.

Given that four hospitals ended the 5-year period authorized by the Cures Act during FY 2020, we finalized the policy from previous extensions, that is, to apply the cost-based reimbursement methodology to the date following the last day of this previous period for each hospital that elects to continue participation. Likewise, each of the 22 hospitals with a scheduled end date during 2021, 2022, or 2023 is eligible for an additional 5-year period starting from the day after the specified end date. Accordingly, the period of participation for the last hospital in the demonstration under this most recent legislative authorization would extend until June 30, 2028.

4. Budget Neutrality

a. Statutory Budget Neutrality Requirement

Section 410A(c)(2) of Public Law 108–173 requires that, in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount that the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral on its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. We note that the payment methodology for this demonstration, that is, cost-based payments to participating small rural hospitals, makes it unlikely that increased Medicare outlays would produce an offsetting reduction to Medicare expenditures elsewhere. Therefore, in the 12 IPPS final rules spanning the period from FY 2005 through FY 2016, we adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. (A different methodology was applied for FY 2017.) As we discussed

in the FYs 2005 through 2017 IPPS/LTCH PPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 77 FR 50145; 80 FR 49585; and 81 FR 57034, respectively), we believe that the statutory language of the budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

b. General Budget Neutrality Methodology

We have generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we have estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, ''as submitted'' cost reports for the hospitals participating in that year. Update factors representing nationwide trends in cost and volume increases have been incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. Conversely, if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. We have calculated this difference for FYs 2005 through 2016 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

c. Budget Neutrality Methodology for the Extension Period Authorized by Public Law 116–260

For the newly enacted extension period, under the Consolidated Appropriations Act, 2021, we continue upon the general budget neutrality methodology used in previous years, and to specifically follow upon the determinations for the previous extension period, under the Cures Act.

(1) Budget Neutrality Methodology for Previous Extension Period Under the Cures Act

We finalized our budget neutrality methodology for periods of participation under this previous 5-year extension period in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38285 through 38287). Similar to previous years, we stated in this rule, as well as in the FY 2019 and FY 2020 IPPS/LTCH PPS proposed and final rules (83 FR 20444 and 41503, and 84 FR19452 and 42421, respectively) that we would incorporate an estimate of the costs of the demonstration, generally determined from historical, ''as submitted'' cost reports for the participating hospitals, and appropriate update factors, into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. In addition, we stated that we would continue to apply our general policy from previous years of including, as a second component to the budget neutrality offset amount, the amount by which the actual costs of the demonstration for an earlier, given year (as determined from finalized cost reports, when available) differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year.

In these proposed and final rules, we described several distinct components to the budget neutrality offset amount for the specific fiscal years of the extension period authorized by the Cures Act.

We included a component to our overall methodology similar to previous years, according to which an estimate of the costs of the demonstration for both previously and newly participating hospitals for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. In the FY 2019 IPPS final rule (83 FR 41506), we included such an estimate of the costs of the demonstration for each of FYs 2018 and 2019 into the budget neutrality offset amount for FY 2019. In the FY 2020 IPPS final rule (84 FR 42421), we included an estimate of the costs of the demonstration for FY 2020 for 28 hospitals. In the FY 2021 IPPS final rule (85 FR 58873), we included an estimate of the costs of the demonstration for FY 2021 for the 22 hospitals for which the cost-based reimbursement methodology was to apply for all or part of FY 2021. In the FY 2022 IPPS final rule (86 FR 45316), we included an estimate of the costs of the demonstration for FY 2022 for the 26 hospitals expected to participate in that fiscal year.

Similar to previous years, we continued to implement the policy of determining the difference between the actual costs of the demonstration as determined from finalized cost reports for a given fiscal year and the estimated costs indicated in the corresponding year's final rule, and including that difference as a positive or negative adjustment in the upcoming year's final rule. (For each previously participating hospital that decided to participate in the 5-year extension period under the Cures Act, the cost-based payment methodology under the demonstration began on the date immediately following the end date of its period of performance for the still previous extension period (under the Affordable Care Act). In addition, for previously participating hospitals that converted to CAH status during the time period of the second 5-year extension period, the demonstration payment methodology was applied to the date following the end date of its period of performance for the first extension period to the date of conversion). In the FY 2020 final rule, we included the difference between the amount determined for the cost of the demonstration in each of FYs 2014 and 2015 and the estimated amount included in the budget neutrality offset in the final rule for each of these respective fiscal years. In the FY 2022 final rule, we included the difference between the amount determined for the cost of the demonstration in FY 2016 and the estimated amount included in the budget neutrality offset in the final rule for that fiscal year.

(2) Methodology for Estimating Demonstration Costs for FY 2023

We are using a methodology similar to previous years, according to which an estimate of the costs of the demonstration for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year, that is, FY 2023. We are conducting this estimate for FY 2023 based on the 26 hospitals that are continuing participation in the demonstration for fiscal year 2023. The methodology for calculating this amount

for FY 2023 proceeds according to the following steps:

Step 1: For each of these 26 hospitals, we identify the reasonable cost amount calculated under the reasonable cost-based methodology for covered inpatient hospital services, including swing beds, as indicated on the ''as submitted'' cost report for the most recent cost reporting period available. For each of these hospitals, the ''as submitted'' cost report is defined as the submitted report with a cost report period end date in CY 2020. We sum these hospital-specific amounts (derived from the cost for each hospital for inpatient hospital services, including swing beds, based on the CY 2020 ''as submitted'' cost reports) to arrive at a total general amount representing the sum of the costs for covered inpatient hospital services applicable for 2020 across the 26 hospitals eligible to participate during FY 2023. Then, we multiply the 2020 amount (for inpatient hospital services including swing beds) by the IPPS final market basket percentage increases for FY 2021 and FY 2022, and then again by the proposed FY 2023 IPPS market basket increase. The proposed market basket percentage increase for FY 2023 is 3.1 percent, explained in more detail in section II.A of the Addendum to this proposed rule). The result for the 26 hospitals is the general estimated reasonable cost amount for covered inpatient hospital services for FY 2023.

Consistent with our methods in previous years for formulating this estimate, we are applying the IPPS market basket percentage increases for FYs 2021 through 2023 to the applicable estimated reasonable cost amount (previously described) in order to model the estimated FY 2023 reasonable cost amount under the demonstration. We believe that the IPPS market basket percentage increases appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved.

Step 2: For each of the participating hospitals, we identify the estimated amount that would otherwise be paid in FY 2023 under applicable Medicare payment methodologies for covered inpatient hospital services, including swing beds (as indicated on the same set of ''as submitted'' cost reports as in Step 1), if the demonstration were not implemented. We sum these 2020 hospital-specific amounts, and, in turn, multiply this sum by the FYs 2021, 2022 and 2023 IPPS applicable percentage increases. (For FY 2023, we are using the proposed applicable percentage increase, per section II.A of the Addendum of this proposed rule.) This methodology differs from Step 1, in which we apply the market basket percentage increases to the hospitals' applicable estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS payments constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates.

Step 3: We subtract the amount derived in Step 2 from the amount derived in Step 1. According to our methodology, the resulting amount indicates the total difference for the 26 hospitals (for covered inpatient hospital services, including swing beds), which would be the general estimated amount of the costs of the demonstration for FY 2023.

For this proposed rule, the resulting amount is $71,955,710, which we are incorporating into the budget neutrality offset adjustment for FY 2023. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical and projected update factors for cost and payment. We propose that if more recent data subsequently become available (for example, a more recent estimate of the market basket update), we would use such data, if appropriate to estimate the costs for the demonstration program for FY 2023 in accordance with our methodology for determining the budget neutrality estimate. We would also incorporate any statutory change that might affect the methodology for determining hospital costs either with or without the demonstration.

(3) Reconciling Actual and Estimated Costs of the Demonstration for Previous Years

As described earlier, we have calculated the difference for FYs 2005 through 2016 between the actual costs of the demonstration, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

At this time, for the FY 2023 proposed rule, all of the finalized cost reports are available for the 17 hospitals that completed cost report periods beginning in FY 2017 under the demonstration payment methodology; these cost reports show the actual costs of the demonstration for this fiscal year to be $35,989,928. We note that the FY 2017 IPPS final rule included no budget neutrality offset amount for that fiscal year. The final rule for FY 2017 preceded the re-authorization of the demonstration under the Cures Act. Anticipating that the demonstration would end in 2016, we projected no demonstration cost estimate for the upcoming fiscal year, FY 2017, while we stated that we would continue to reconcile actual costs when all finalized cost reports for previous fiscal years under the demonstration became available (81 FR 57037). Thus, keeping with past practice, for this proposed rule we are including the actual costs of the demonstration as determined from finalized cost reports for FY 2017 within the budget neutrality offset amount for this upcoming fiscal year.

We observe that the cost amounts shown by finalized cost reports may change in the case of revised settlements by the MACs. We propose that if such a re-settlement of any of the FY 2017 finalized cost reports occurs ahead of the FY 2023 IPPS final rule, we would accordingly adjust the amount for the actual costs of the demonstration for FY 2017 when compiling the total budget neutrality offset amount for the FY 2023 final rule.

(4) Total Proposed Budget Neutrality Offset Amount for FY 2023

Therefore, for this FY 2023 IPPS/LTCH PPS proposed rule, the proposed budget neutrality offset amount for FY 2023 is based on the sum of two amounts:

- The amount determined under section X.4.c.(2) of the preamble of this proposed rule, representing the difference applicable to FY 2023 between the sum of the estimated reasonable cost amounts that would be paid under the demonstration for covered inpatient services to the 26 hospitals participating in the fiscal year and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. This estimated amount is $71,955,710.
- The amount determined under section X.4.c.(3) of the preamble of this proposed rule, indicating the amount by which the actual costs of the demonstration in FY 2017 (as shown by finalized cost reports from that fiscal year) differ from the amount determined for FY 2017. Since no budget neutrality offset was conducted in FY 2017, the amount of this difference is the actual cost amount for FY 2017 $35,989,928.

We propose to subtract the sum of these amounts ($107,945,638) from the national IPPS rates for FY 2023.

However, we note that the total amount of the adjustment may change if there are any revisions prior to the final rule to the data used to formulate this estimate. We would also revise the budget neutrality offset amount in case of any re-settlement to finalized cost reports or changes to statutory provisions that affect the methodology for determining the budget neutrality estimate for the upcoming year.

VI. Proposed Changes to the IPPS for Capital Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the FY 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at 42 CFR 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under § 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, the regulations at 42 CFR 412.300(b) define a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS, a new hospital is paid 85 percent of its allowable Medicare inpatient hospital capital related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Payments for Hospitals Located in Puerto Rico

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57061), we revised the regulations at 42 CFR 412.374 relating to the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017 to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, for discharges occurring on or after January 1, 2016, made by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 601 of Public Law 114–113 increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. As such, under revised § 412.374, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the capital Federal rate.

C. Proposed Annual Update for FY 2023

The proposed annual update to the national capital Federal rate, as provided for in 42 CFR 412.308(c), for FY 2023 is discussed in section III. of the Addendum to this FY 2023 IPPS/LTCH PPS proposed rule.

In section II.C. of the preamble of this FY 2023 IPPS/LTCH PPS proposed rule, we present a discussion of the MS–DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as the adjustment to the standardized amount under section 1886(d) of the Act that we are proposing for FY 2023, in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA. Because these provisions require us to make an adjustment only to the operating IPPS standardized amount, we are not proposing to make a similar adjustment to the national capital Federal rate (or to the hospital-specific rates).

VII. Proposed Changes for Hospitals Excluded From the IPPS

A. Proposed Rate-of-Increase in Payments to Excluded Hospitals for FY 2023

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount,

as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously. Furthermore, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, and RNHCIs. Consistent with the regulations at §§ 412.23(g) and 413.40(a)(2)(ii)(A) and (c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update target amounts for short–term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. In the FY 2018 IPPS/LTCH PPS final rule, we rebased and revised the IPPS operating basket to a 2014 base year, effective for FY 2018 and subsequent fiscal years (82 FR 38158 through 38175), and finalized the use of the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent fiscal years. As discussed in section IV. of the preamble of the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45207), we rebased and revised the IPPS operating basket to a 2018 base year. Therefore, we used the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2022 and subsequent fiscal years.

For this FY 2023 IPPS/LTCH PPS proposed rule, based on IGI's 2021 fourth quarter forecast, we estimate that the 2018-based IPPS operating market basket update for FY 2023 is 3.1 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, the FY 2023 rate-of-increase percentage that would be applied to the FY 2022 target amounts in order to calculate the FY 2023 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa would be 3.1 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we are proposing that if more recent data become available for the FY 2023 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2023.

In addition, payment for inpatient operating costs for hospitals classified under section 1886(d)(1)(B)(vi) of the Act (which we refer to as ''extended neoplastic disease care hospitals'') for cost reporting periods beginning on or after January 1, 2015, is to be made as described in 42 CFR 412.526(c)(3), and payment for capital costs for these hospitals is to be made as described in 42 CFR 412.526(c)(4). (For additional information on these payment regulations, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38321 through 38322).) Section 412.526(c)(3) provides that the hospital's Medicare allowable net inpatient operating costs for that period are paid on a reasonable cost basis, subject to that hospital's ceiling, as determined under § 412.526(c)(1), for that period. Under § 412.526(c)(1), for each cost reporting period, the ceiling was determined by multiplying the updated target amount, as defined in § 412.526(c)(2), for that period by the number of Medicare discharges paid during that period. Section 412.526(c)(2)(i) describes the method for determining the target amount for cost reporting periods beginning during FY 2015. Section 412.526(c)(2)(ii) specifies that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount will equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197).

For FY 2023, in accordance with §§ 412.22(i) and 412.526(c)(2)(ii) of the regulations, for cost reporting periods beginning during FY 2022, the proposed update to the target amount for extended neoplastic disease care hospitals (that is, hospitals described under § 412.22(i)) is the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for FY 2022, which would be equal to the percentage increase in the hospital market basket, which is estimated to be the percentage increase in the 2018-based IPPS operating market basket (that is, the estimate of the market basket rate-of-increase). Accordingly, the proposed update to an extended neoplastic disease care hospital's target amount for FY 2023 is 3.1 percent, which is based on IGI's 2021 fourth quarter forecast. Furthermore, we are proposing that if more recent data become available for the FY 2023 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the IPPS operating market basket update for FY 2023.

B. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

2. Frontier Community Health Integration Project Demonstration

a. Introduction

The Frontier Community Health Integration Project Demonstration was originally authorized by section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275). The demonstration has been extended by section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) for an additional 5 years. In this proposed rule, we are summarizing the status of the demonstration program, and the ongoing methodologies for implementation and budget neutrality for the demonstration extension period.

b. Background and Overview

As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), section 123 of the Medicare Improvements for Patients and Providers Act of 2008, as amended by

section 3126 of the Affordable Care Act, authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. The demonstration was titled ''Demonstration Project on Community Health Integration Models in Certain Rural Counties,'' and commonly known as the Frontier Community Health Integration Project (FCHIP) Demonstration.

The authorizing statute stated the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is a Medicare Rural Hospital Flexibility Program (MRHFP) grantee under section 1820(g) of the Act (that is, a CAH); and is located in a state in which at least 65 percent of the counties in the state are counties that have 6 or less residents per square mile.

The authorizing statute stipulated several other requirements for the demonstration. In addition, section 123(g)(1)(B) of Public Law 110–275 required that the demonstration be budget neutral. Specifically, this provision stated that, in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public Law 110–275 stated that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration. CMS selected CAHs to participate in four interventions, under which specific waivers of Medicare payment rules would allow for enhanced payment for telehealth, skilled nursing facility/nursing facility beds, ambulance services, and home health services. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Section 123 of Public Law 110–275 initially required a 3-year period of performance. The FCHIP Demonstration began on August 1, 2016, and concluded on July 31, 2019 (referred to in this section as the ''initial period''). Subsequently, section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) extended the demonstration by 5 years (referred to in this section as the ''extension period''). The Secretary is required to conduct the demonstration for an additional 5-year period. CAHs participating in the demonstration project during the extension period shall begin such participation in the cost reporting year that begins on or after January 1, 2022.

As described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), 10 CAHs were selected for participation in the demonstration initial period. The selected CAHs were located in three states—Montana, Nevada, and North Dakota—and participated in three of the four interventions identified in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42427 through 42428) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58894 through 58896) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328). Each CAH was allowed to participate in more than one of the interventions. None of the selected CAHs were participants in the home health intervention, which was the fourth intervention.

In the FY 2022 IPPS/LTCH PPS final rule, CMS concluded that the initial period of the FCHIP Demonstration (covering the performance period of August 1, 2016, to July 31, 2019) had satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, CMS did not apply a budget neutrality payment offset policy for the initial period of the demonstration.

Section 129 of Public Law 116–260, stipulates that only the 10 CAHs that participated in the initial period of the FCHIP Demonstration are eligible to participate during the extension period. Among the eligible CAHs, six have elected to participate in the extension period. The selected CAHs are located in two states—Montana and North Dakota—and are implementing three of the four interventions. The eligible CAH participants elected to change the number of interventions and payment waivers they would participate in during the extension period. CMS accepted and approved the CAHs intervention and payment waiver updates. For the extension period, five CAHs are participants in the telehealth intervention, four CAHs are participants in the skilled nursing facility/nursing facility bed intervention, and three CAHs are participants in the ambulance services intervention. As with the initial period, each CAH was allowed to participate in more than one of the interventions during the extension period. None of the selected CAHs are participants in the home health intervention, which was the fourth intervention.

c. Intervention Payment and Payment Waivers

As described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS waived certain Medicare rules for CAHs participating in the demonstration initial period to allow for alternative reasonable cost-based payment methods in the three distinct intervention service areas: Telehealth services, ambulance services, and skilled nursing facility/nursing facility (SNF/NF) beds expansion. The payments and payment waiver provisions only apply if the CAH is a participant in the associated intervention. Given updates to Medicare payment rules and regulations, CMS has modified and/or updated the Intervention Payment and Payment Waivers for the extension period. The FCHIP payment waivers for the demonstration extension period consist of the following:

(1) Telehealth Services Intervention Payments

CMS waives section 1834(m)(2)(B) of the Act, which specifies the facility fee to the originating site. CMS modifies the facility fee payment specified under section 1834(m)(2)(B) of the Act to make reasonable cost-based reimbursement to the participating CAH where the participating CAH serves as the originating site for a telehealth service furnished to an eligible telehealth individual, as defined in section 1834(m)(4)(B). CMS would reimburse the participating CAH serving as the originating site at 101 percent of its reasonable costs for overhead, salaries and fringe benefits associated with telehealth services at the participating CAH. CMS would not fund or provide reimbursement to the participating CAH for the purchase of new telehealth equipment.

CMS waives section 1834(m)(2)(A) of the Act, which specifies the payment made for a telehealth service furnished by the distant site practitioner. CMS modifies the distant site payment specified under section 1834(m)(2)(A) of the Act to make reasonable cost-based reimbursement to the participating CAH for telehealth services furnished by a physician or practitioner located at distant site that is a participating CAH that is billing for the physician or

practitioner professional services. Whether the participating CAH has or has not elected Optional Payment Method II for outpatient services, CMS would pay the participating CAH 101 percent of reasonable costs for telehealth services when a physician or practitioner has reassigned their billing rights to the participating CAH and furnishes telehealth services from the participating CAH as a distant site practitioner. This means that participating CAHs that are billing under the Standard Method on behalf of employees who are physicians or practitioners (as defined in section 1834(m)(4)(D) and (E), respectively) would be eligible to bill for distant site telehealth services furnished by these physicians and practitioners. Additionally, CAHs billing under the Optional Method would be reimbursed based on 101 percent of reasonable costs, rather than paid based on the Medicare physician fee schedule, for the distant site telehealth services furnished by physicians and practitioners who have reassigned their billing rights to the CAH. For distant site telehealth services furnished by physicians or practitioners who have not reassigned billing rights to a participating CAH, payment to the distant site physician or practitioner would continue to be made as usual under the Medicare physician fee schedule. Currently these services are eligible to be furnished and paid in this way due to a waiver issued during the PHE. Except as described herein, CMS does not waive any other provisions of section 1834(m) of the Act for purposes of the telehealth services intervention payments, including the scope of Medicare telehealth services as established under section 1834(m)(4)(F).

(2) Ambulance Services Intervention Payments

CMS waives 42 CFR 413.70(b)(5)(D) and section 1834(l)(8) of the Act, which provides that payment for ambulance services furnished by a CAH, or an entity owned and operated by a CAH, is 101 percent of the reasonable costs of the CAH or the entity in furnishing the ambulance services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH, excluding ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals to or from the CAH. The participating CAH would be paid 101 percent of reasonable costs for its ambulance services regardless of whether there is any provider or supplier of ambulance services located within a 35-mile drive of the participating CAH or participating CAH-owned and operated entity. CMS would not make cost-based payment to the participating CAH for any new capital (for example, vehicles) associated with ambulance services. This waiver does not modify any other Medicare rules regarding or affecting the provision of ambulance services.

(3) SNF/NF Beds Expansion Intervention Payments

CMS waives 42 CFR 485.620(a), 42 CFR 485.645(a)(2), and section 1820(c)(2)(B)(iii) of the Act which limit CAHs to maintaining no more than 25 inpatient beds, including beds available for acute inpatient or swing bed services. CMS waives 1820(f) of the Act permitting designating or certifying a facility as a critical access hospital for which the facility at any time is furnishing inpatient beds which exceed more than 25 beds. Under this waiver, if the participating CAH has received swing bed approval from CMS, the participating CAH may maintain up to ten additional beds (for a total of 35 beds) available for acute inpatient or swing bed services; however, the participating CAH may only use these 10 additional beds for nursing facility or skilled nursing facility level of care. CMS would pay the participating CAH 101 percent of reasonable costs for its SNF/NF services furnished in the 10 additional beds.

d. Budget Neutrality

(1) Budget Neutrality Requirement

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), we finalized a policy to address the budget neutrality requirement for the demonstration initial period. We also discussed this policy in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42427 through 42428) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58894 through 58996). As explained in the FY 2022 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms meaning that the demonstration would produce savings from reduced transfers and admissions to other health care providers, offsetting any increase in Medicare payments as a result of the demonstration. However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we finalized for the demonstration initial period of performance in the FY 2022 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met.

For the FY 2023 proposed rule, CMS is proposing to adopt the budget same neutrality policy contingency plan used during the demonstration initial period to ensure that the budget neutrality requirement in section 123 of Public Law 110 275 is met during the demonstration extension period. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for the participating CAHs, shows that increases in Medicare payments under the demonstration during the 5-year extension period are not sufficiently offset by reductions elsewhere, we would recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide.

As explained in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality for the demonstration initial period by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration extension period is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration extension period were not implemented, CMS policy is to comply with the budget neutrality requirement finalized in the FY 2022 IPPS/LTCH PPS final rule, by reducing payments to all CAHs, not just those participating in the demonstration extension period.

In the FY 2022 IPPS/LTCH PPS final rule, we stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP Demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. We explained our belief that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not

implemented, and does not identify the range across which aggregate payments must be held equal.

Under the policy finalized in the FY 2022 IPPS/LTCH PPS final rule, we adopted the policy finalized in the FY 2017 IPPS/LTCH PPS final rule, in the event the demonstration initial period was found not to have been budget neutral, any excess costs would be recouped over a period of 3 cost reporting years. For the FY 2023 proposed rule, we seek public comment on this proposal, as we are revising an aspect of the policy finalized in the FY 2022 IPPS/LTCH PPS final rule. Our new proposed policy is in the event the demonstration extension period is found not to have been budget neutral, any excess costs would be recouped within one fiscal year. We believe our new proposed policy is a more efficient timeframe for the government to conclude the demonstration operational requirements (such as analyzing claims data, cost report data and/or other data sources) to adjudicate the budget neutrality payment recoupment process due to any excess cost that occurred as result of the demonstration extension period.

(2) FCHIP Budget Neutrality Methodology and Analytical Approach

As explained in the FY 2022 IPPS/LTCH PPS final rule, we finalized a policy to address the demonstration budget neutrality methodology and analytical approach for the initial period of the demonstration. For this FY 2023 proposed rule, CMS is proposing to adopt the budget neutrality methodology and analytical approach used during the demonstration initial period to ensure budget neutrality for the extension period. The analysis of budget neutrality during the initial period of the demonstration identified both the costs related to providing the intervention services under the FCHIP Demonstration and any potential downstream effects of the intervention-related services, including any savings that may have accrued.

The budget neutrality analytical approach for the demonstration initial period incorporated two major data components: (1) Medicare cost reports; and (2) Medicare administrative claims. As described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS computed the cost of the demonstration for each fiscal year of the demonstration initial period using Medicare cost reports for the participating CAHs, and Medicare administrative claims and enrollment data for beneficiaries who received demonstration intervention services.

In addition, in order to capture the full impact of the interventions, CMS developed a statistical modeling, Difference-in-Difference (DiD) regression analysis to estimate demonstration expenditures and compute the impact of expenditures on the intervention services by comparing cost data for the demonstration and non-demonstration groups using Medicare administrative claims across the demonstration period of performance under the initial period of the demonstration. The DiD regression analysis would compare the direct cost and potential downstream effects of intervention services, including any savings that may have accrued, during the baseline and performance period for both the demonstration and comparison groups.

Second, the Medicare administrative claims analysis would be reconciled using data obtained from auditing the participating CAHs' Medicare cost reports. We would estimate the costs of the demonstration using ''as submitted'' cost reports for each hospital's financial fiscal year participation within each of the demonstration extension period performance years. Each CAH has its own Medicare cost report end date applicable to the five-year period of performance for the demonstration extension period. The cost report is structured to gather costs, revenues and statistical data on the provider's financial fiscal period. As a result, we would determine the final budget neutrality results for the demonstration extension once complete data is available for each CAH for the demonstration extension period.

d. Proposed Policies for Implementing the 5-Year Extension and Provisions Authorized by Section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260)

As stated in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), our policy for implementing the 5-year extension period for section 129 of Public Law 116–260 follows same budget neutrality methodology and analytical approach as the demonstration initial period methodology. While we expect to use the same methodology that was used to assess the budget neutrality of the FCHIP Demonstration during initial period of the demonstration to assess the financial impact of the demonstration during this extension period, upon receiving data for the extension period, we may update and/or modify the FCHIP budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured. For the FY 2023 proposed rule, CMS is proposing to adopt the same budget neutrality methodology and analytical approach used during the demonstration initial period to be used for the demonstration extension period.

e. Total Proposed Budget Neutrality Offset Amount for FY 2023

At this time, for the FY 2023 proposed rule, while this discussion represents our anticipated approach to assessing the financial impact of the demonstration extension period based on upon receiving data for the full demonstration extension period, we may update and/or modify the FCHIP Demonstration budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured.

Therefore, we do not propose to apply a budget neutrality payment offset to payments to CAHs in FY 2023. This policy would have no impact for any national payment system for FY 2023.

VIII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2023

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act originally defined an LTCH as a hospital that has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days. Section 1886(d)(1)(B)(iv)(II) of the Act also provided an alternative definition of LTCHs (''subclause II'' LTCHs). However, section 15008 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1886 of the Act to exclude former ''subclause II'' LTCHs from being paid under the LTCH PPS

and created a new category of IPPS-excluded hospitals, which we refer to as ''extended neoplastic disease care hospitals,'' to be paid as hospitals that were formally classified as ''subclause (II)'' LTCHs (82 FR 38298).

Section 123 of the BBRA requires the PPS for LTCHs to be a ''per discharge'' system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resource use and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002, **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through 2007), the system used information from LTCH patient records to classify patients into distinct long-term care-diagnosis-related groups (LTCDRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity-long-term care-diagnosis related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable-cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this section of the preamble of this proposed rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002, final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002, final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002, final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the ''site neutral'' payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria for exclusion are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57068 through 57075).

In the FY 2018 IPPS/LTCH PPS final rule, we implemented several provisions of the 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255) that affected the LTCH PPS. (For more information on these provisions, we refer readers to 82 FR 38299.)

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41529), we made conforming changes to our regulations to implement the provisions of section 51005 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which extends the transitional blended payment rate for site neutral payment rate cases for an additional 2 years. We refer readers to section VII.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a discussion of our final policy. In addition, in the FY 2019 IPPS/LTCH PPS final rule, we removed the 25-percent threshold policy under 42 CFR 412.538, which was a payment adjustment that was applied to payments for Medicare patient LTCH discharges when the number of such patients originating from any single referring hospital was in excess of the applicable threshold for given cost reporting period.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439), we further revised our regulations to implement the provisions of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) that relate to the payment adjustment for discharges from LTCHs that do not maintain the requisite discharge payment percentage and the process by which such LTCHs may have the payment adjustment discontinued.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. In accordance with section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), as amended by section 15007 of Public Law 114–255, we amended our regulations to specify that Medicare Advantage plans' and site neutral payment rate discharges are excluded from the calculation of the

average length of stay for all LTCHs, for discharges occurring in cost reporting period beginning on or after October 1, 2015.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1), section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b1 (note)) (Statewide-all payer systems, subject to the rate-of increase test at section 1814(b) of the Act), or section 3201 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) (42 U.S.C. 1315a).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87, and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for services furnished during the days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (in accordance with § 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient coverage as a result of the remaining Medicare days, the LTCH also is currently permitted to charge the beneficiary for services delivered on those uncovered days (in accordance with § 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to expressly limit the charges that may be imposed upon beneficiaries whose LTCHs' discharges are paid at the site neutral payment rate under the LTCH PPS. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57102), we amended the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, an LTCH's payment for discharges occurring in cost reporting periods beginning in FYs 2016 through 2019) are considered to be site neutral payment rate payments.

4. Best Available Data

We refer readers to section I.F. of the preamble of this proposed rule for our discussion on our proposal to use the most recent data available for the FY 2023 LTCH PPS ratesetting, including the FY 2021 MedPAR claims and FY 2020 cost report data. In section I.F. of the preamble of this proposed rule we also discuss our proposal to modify our ratesetting methodology for FY 2023 to account for the ongoing COVID–19 PHE.

B. Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2023

1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

Under both the IPPS and the LTCH PPS, the DRG-based classification system uses information on the claims for inpatient discharges to classify patients into distinct groups (for example, DRGs) based on clinical characteristics and expected resource needs. When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. We referred to this patient classification system as the ''long-term care diagnosis-related groups (LTC–DRGs).'' As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), we adopted the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O, applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. As noted previously, we adopted the same DRG patient classification system utilized at that time under the IPPS. The MS–DRG classifications are updated annually, which has resulted in the number of MS–DRGs changing over time. For FY 2023, there would be 767 MS–DRG, and by extension, MS–LTC–DRG, groupings based on the proposed changes, as discussed in section II.E. of the preamble of this proposed rule.

Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect the differences in patient resource use of LTCH patients, consistent with section 123(a)(1) of the BBRA. That is, we assign an appropriate weight to the MS–LTC–DRGs to account for the differences in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCH patients.

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG

structure. As noted previously in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–10–PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs) or are minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 0JBH3ZX)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge that varies based on the MS–LTC–DRG to which a beneficiary's discharge is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis.
- Additional or secondary diagnoses.
- Surgical procedures.
- Age.
- Sex.
- Discharge status of the patient.

Currently, for claims submitted using the version ASC X12 5010 format, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under the HIPAA transactions and code sets regulations at 45 CFR parts 160 and 162, covered entities must comply with the adopted transaction standards and operating rules specified in subparts I through S of part 162. Among other requirements, on or after January 1, 2012, covered entities were required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102(c)).

HIPAA requires covered entities to use the applicable medical data code set requirements when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, both of which were required to be implemented October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the preamble of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56790) and section II.E.1. of the preamble of this proposed rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD–10–CM/PCS.*

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the preamble of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

MACs enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain types of cases are selected for further explanation (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the MAC determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the MAC and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Proposed Changes to the MS–LTC–DRGs for FY 2023

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, in this proposed rule, we are proposing to update the MS–LTC–DRG classifications effective October 1, 2022 through September 30, 2023 (FY 2023) consistent with the proposed changes to specific MS–DRG classifications presented in section II.F. of the preamble of this proposed rule. Accordingly, the proposed MS–LTC–DRGs for FY 2023 presented in section II.F. of the preamble of this proposed rule are the same as the MS–DRGs being proposed for use under the IPPS for FY 2023. In addition, because the proposed MS–LTC–DRGs for FY 2023 are the same as the proposed MS–DRGs for FY 2023, the other proposed changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under proposed GROUPER Version 40, as discussed in section II.E. of the preamble of this

proposed rule, including the proposed changes to the MCE software and the ICD–10–CM/PCS coding system, are also applicable under the LTCH PPS for FY 2023.

3. General Summary of the FY 2023 MS–LTC–DRG Relative Weights Methodology

In this section of this proposed rule, we provide a general summary of our proposed modifications to the methodology for determining the FY 2023 MS–LTC–DRG relative weights under the LTCH PPS.

a. Proposed Averaging of Relative Weights for FY 2023

In section I.F. of the preamble to this proposed rule, we discuss our proposal to use FY 2021 claims data for the FY 2023 LTCH PPS ratesetting. We recognize the impact COVID–19 cases in the FY 2021 claims data have on the relative weight calculations for a few COVID–19-related MS–LTC–DRGs. Specifically, we have determined that the COVID–19 cases grouped to a few MS–LTC–DRGs have, on average, meaningfully different costs than the non-COVID–19 cases grouped to these MS–LTC–DRGs. As a result, for these MS–LTC–DRGs, the relative weights calculated using all cases will be meaningfully different than the relative weights calculated excluding COVID–19 cases. For example, using the FY 2021 MedPAR data, the relative weight for MS–LTC–DRG 870 (Septicemia or severe sepsis with MV >96 hours) is approximately 3.1 percent higher when the relative weights are calculated including COVID–19 cases compared to when the relative weights are calculated excluding COVID–19 cases. In section I.F. of the preamble to this proposed rule, we also discuss that we believe it is reasonable to assume there will be fewer COVID–19 hospitalizations among Medicare beneficiaries in LTCHs in FY 2023 than there were in FY 2021, although we cannot know the actual number of COVID–19 hospitalizations among Medicare beneficiaries in LTCHs in FY 2023. We are proposing to modify our relative weight methodology for FY 2023 to align with an assumption that there will be fewer, but not zero, COVID–19 cases in FY 2023 compared to FY 2021. To account for this assumption, we are proposing an averaging approach to determine the MS–LTC–DRG relative weights for FY 2023. Specifically, we are proposing to calculate the relative weights both including and excluding COVID–19 cases, and then average the two sets of relative weights together. We believe this proposal is appropriate as it will reduce, but not remove entirely, the effect of COVID–19 cases on the relative weight calculations. Given the uncertainty in the number of COVID–19 cases in FY 2023, we believe this proposal is appropriate. By averaging the relative weights in this manner, we believe the result would reflect a reasonable estimation of the mix of cases for FY 2023 based on the information available at this time on the trajectory of the COVID–19 PHE (as discussed in section I.F. of the preamble to this proposed rule), and a more accurate estimate of the relative resource use for cases treated in FY 2023. We believe the relative weights calculated using our proposed modified methodology would be more accurate than if we applied our standard methodology, that is, with relative weights calculated based on 100 percent of the relative weights calculated using all applicable LTCH cases. The technical details of this proposal are discussed in section VIII.B.4. of the preamble to this proposed rule. As discussed in section I.O of Appendix A of this proposed rule, as an alternative to our proposed approach, we considered following our historical approach for calculating the relative weights and not proposing this modification. That is, we considered proposing to determine the FY 2023 MS–LTC–DRG weights using all applicable LTCH cases without any modifications to account for COVID–19 cases. We note, this proposed averaging approach and alternative considered for the calculation of the FY 2023 MS–LTC–DRG relative weights are consistent with the proposed approach and alternative considered under the IPPS for FY 2023 as discussed in section II.E.c. of the preamble and section I.O of Appendix A, respectively, to this proposed rule.

b. Proposed Cap on Relative Weight Decreases

In recent years, we have received comments about significant fluctuations in the relative weights for some MS–LTC–DRGs. Some commenters requested that CMS establish a transition policy to mitigate the negative effects of significant year-to-year reductions to relative weights. In addition, we acknowledge long-standing concerns of commenters about fluctuations in low-volume MS–LTC–DRGs, which consistently fluctuate more significantly than higher volume MS–LTC–DRGs. In general, typical year-to-year fluctuations in case mix and the presence of some very high-cost or very low-cost cases (that are not statistical outliers) do not have a significant impact on the relative weights for most MS–LTC–DRGs with at least 25 cases (that is, MS–LTC–DRGs that are not low-volume or no-volume as discussed later in section VIII.B.4. of this preamble). However, for some MS–LTC–DRGs, particularly those with low volume, these fluctuations in the volume or mix of cases and the presence of a few high-cost or low-cost cases can have a disproportionate impact on both, thus resulting in greater instability in the relative weights for these MS–LTC–DRGs, which can reduce the predictability and stability of an individual LTCH's Medicare payments from year to year.

Predictability and stability of rates is one of the fundamental principles of a prospective payment system. We have reconsidered requests made by commenters that we mitigate the financial impacts of significant year-to-year fluctuations in relative weights. We note that in section V.B.5. of the addendum to this proposed rule, we are proposing a permanent 5 percent cap on yearly decreases to an LTCH's wage index to mitigate the financial impacts of wage index decreases to increase predictability and stability in LTCH PPS payments. Given the concerns commenters have raised about the financial impacts of significant year-to-year fluctuations in MS–LTC–DRGs relative weights, we are revisiting the appropriateness of establishing a policy to address these concerns.

Consistent with the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, including adjustments to DRG weights, we are proposing a permanent 10-percent cap on the reduction to a MS–LTC–DRG's relative weight in a given year, beginning in FY 2023. (The details on the application of this proposed adjustment are discussed in section VIII.B.4. of the preamble to this proposed rule.) For example, if the relative weight for MS–LTC–DRG XYZ in FY 2022 is 1.100 and the relative weight for FY 2023 would otherwise be 0.9350, which would represent a decrease of 15 percent from FY 2022, the reduction would be limited to 10 percent such that the proposed relative weight for FY 2023 would be 0.9900 (that is, 0.90 × FY 2022 weight of 1.100). We are proposing that this 10-percent cap would be applied to the relative weights for MS–LTC–DRGs with applicable LTCH cases. Under this proposal, the 10-percent cap would not apply to no-volume MS–LTC–DRGs (that is an MS–LTC–DRG with no applicable LTCH cases) whose relative

weight was determined by a cross-walk to another MS–LTC–DRG's relative weight. We believe it is not necessary to apply the 10-percent cap to no-volume MS–LTC–DRGs because the financial impact of fluctuations in the relative weights for these no-volume MS–LTC–DRGs is extremely small as evident by there being zero applicable LTCH cases grouped to these MS–LTC–DRGs in the MedPAR claims data.

We are also proposing that the 10-percent cap on the reduction in a MS–LTC–DRG's relative weight in a given year be budget neutral. This means we would apply a budget neutrality adjustment to the MS–LTC–DRG relative weights, after application of the 10-percent cap, to ensure that our proposed 10-percent cap on relative weight reductions policy results in no change in aggregate LTCH PPS standard Federal rate payments. Our proposal to apply the proposed 10-percent cap on the reduction in a MS–LTC–DRG's relative weight in a given year in a budget neutral manner is consistent with the existing budget neutrality requirement for annual MS–LTC–DRG reclassification and recalibration, which we adopted to mitigate estimated fluctuations in estimated aggregate LTCH PPS payments (72 FR 26881–26882).

We believe the impact of the application of a cap on relative weight reductions on an LTCH's total LTCH PPS payments in a given year would be relatively small because a change in the relative weight would be applied to a single MS–LTC–DRG, unlike the impact of the wage index adjustment, which adjusts the payment for each discharge and impacts approximately two-thirds of an LTCH's total LTCH PPS payments in a given year. In considering the amount of the cap we should propose, we balanced the number of MS–LTC–DRGs that would receive the cap with the magnitude of the budget neutrality factor that would be applied to all MS–LTC–DRGs, while also maintaining an accurate reflection of the relative resource use across the MS–LTC–DRG weights overall. We considered that a higher cap, such as twenty percent cap, would limit declines in the relative weights for fewer MS–LTC–DRGs while a lower cap, such as a five percent cap, would limit declines in the relative weights for more MS–LTC–DRGs, but would also result in a larger budget neutrality adjustment. On balance, we believe that a 10-percent cap would mitigate financial impacts resulting from fluctuations in the relative weights, particularly for low-volume MS–LTC–DRGs, without the larger budget neutrality adjustment associated with a smaller cap, and without distorting the integrity of the MS–LTC–DRG relative weights overall as a reflection of relative resource use. We note that this proposed 10-percent cap on reductions to a MS–LTC–DRG's relative weight would apply only to a given MS–LTC–DRG with its current MS–LTC–DRG number. In cases where CMS creates new MS–LTC–DRGs or modifies the MS–LTC–DRGs as part of its annual reclassifications resulting in renumbering of one or more MS–LTC–DRGs, we are proposing that this limit on the reduction in the relative weight would not apply to any MS–LTC–DRGs affected by the renumbering (that is, the proposed 10-percent cap would not apply to the relative weight for any new or renumbered MS–LTC–DRGs for the fiscal year). The technical details of this proposal are discussed in section VIII.B.4. of the preamble to this proposed rule. This proposal is consistent with the proposed permanent 10-percent cap on decreases to a MS–DRG relative weight under the IPPS as discussed in section II.E.d. of the preamble of this proposed rule.

We are proposing to amend our regulations at 42 CFR 412.515 to reflect this proposed permanent cap on MS–LTC–DRG relative weight reductions. We are seeking comments on our proposal to establish a permanent 10-percent cap on decreases to a MS–LTC–DRG relative weight each year.

c. Proposed Conforming Changes to Other Components of the Proposed FY 2023 MS–LTC–DRG Relative Weights Methodology

In general, for FY 2023, we are proposing to continue applying the other components of our existing methodology for determining the MS–LTC–DRG relative weights (as discussed in greater detail in section VIII.B.4. of the preamble of this proposed rule) that are not impacted by our previously described proposed modifications to our methodology. We note that in conjunction with our proposal to establish the MS–LTC–DRG relative weights using an average of the relative weights calculated both including and excluding the COVID–19 claims, as described in greater detail later in this section, to align with an assumption that there will be fewer, but not zero, COVID–19 cases in FY 2023 compared to FY 2021 (as discussed previously), under our proposed modification to our relative weight methodology for FY 2023, we would calculate the MS–LTC–DRG relative weights methodology, described later in this section, twice—once to determine the relative weights based on claims data that include COVID–19 cases and again to determine the relative weights based on claims data that exclude COVID–19 cases. Specifically, in determining the relative weights based on both sets of claims, we are proposing to apply our established policies related to the hospital-specific relative value methodology, the treatment of severity levels in the MS LTC DRGs, low-volume and no-volume MS LTC DRGs, and adjustments for nonmonotonicity, only using data from applicable LTCH cases (which includes our policy of only using cases that would meet the criteria for exclusion from the site neutral payment rate). We discuss all components of our MS–LTC–DRG relative weight methodology in greater detail in section VIII.B.4.g. of the preamble of this proposed rule.

4. Proposed Development of the FY 2023 MS–LTC–DRG Relative Weights

a. General Overview of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is costlier (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment rate by the applicable relative weight in determining payment to LTCHs for each case. Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in an MS–LTC–DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS–LTC–DRG with a relative weight of 1.

The established methodology to develop the MS–LTC–DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). However, there have been some modifications of our historical procedures for assigning

relative weights in cases of zero volume and nonmonotonicity or both resulting from the adoption of the MS–LTC–DRGs, along with the change made in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 2016 to use LTCH claims data from only LTCH PPS standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH PPS standard Federal payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge). (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and nonmonotonicity or both, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550).) For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal payment rate cases (or cases that would have qualified for such payment had the LTCH PPS dual payment rate structure been in effect at the time) to determine the MS–LTC–DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617).

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–LTC–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section in Step 3 of our proposed methodology) and assigned the relative weight of the quintile); and (3) no-volume MS–LTC–DRGs that are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described later in this section in Step 8 of our proposed methodology). For FY 2023, we are proposing to continue to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2023 MS–LTC–DRG relative weights.

As discussed in section VIII.B.3.a. of the preamble to this proposed rule, for FY 2023, we are proposing to establish the MS–LTC–DRG relative weights as an average of the relative weights calculated both including and excluding the COVID–19 claims. As discussed in section VIII.B.3.b. of the preamble to this proposed rule, we also are proposing a 10-percent cap on the reduction in a MS–LTC–DRG's relative weight in a given year, beginning in FY 2023.

b. Proposed Development of the MS–LTC–DRG Relative Weights for FY 2023

In this section, we present our proposed methodology for determining the MS–LTC–DRG relative weights for FY 2023. In general, we are proposing to continue to apply the components of our existing methodology that are not impacted by our proposed modifications to use an average of the relative weights calculated both including and excluding the COVID–19 claims and the application of a 10-percent cap on the reduction in a MS–LTC–DRG's relative weight, discussed in section VIII.B.3 of the preamble to this proposed rule. For example, we are proposing to continue with the application of established policies related to the hospital-specific relative value methodology, the treatment of severity levels in the MS–LTC–DRGs, low-volume and no-volume MS–LTC–DRGs, adjustments for nonmonotonicity, and only using data from applicable LTCH cases (which includes our policy of only using cases that would meet the criteria for exclusion from the site neutral payment rate). We note that under our proposal to establish the MS–LTC–DRG relative weights using an average of the relative weights calculated both including and excluding the COVID–19 claims, particular components of our existing relative weight methodology would be performed twice (once when determining relative weights based on claims data that include COVID–19 cases and again when determining relative weights based on claims data that exclude COVID–19 cases). Later in this section we list and provide a brief description of our proposed steps for determining the FY 2023 MS–LTC–DRG relative weights. Each proposed step is discussed in greater detail later in this section.

- *Step 1—Prepare data for MS–LTC–DRG relative weight calculation.* In this step, we select and group the applicable claims data used in the development of the proposed MS–LTC–DRG relative weights. For FY 2023, we are proposing to prepare two sets of claims: A claims dataset that includes COVID–19 cases and a claims dataset that excludes COVID–19 cases.
- *Step 2—Remove cases with a length of stay of 7 days or less.* In this step, we trim the applicable claims data to remove cases with a length of stay 7 days or less. For FY 2023, we are proposing to perform this step on each set of claims data (claims dataset that includes COVID–19 cases and claims dataset that excludes COVID–19 cases).
- *Step 3—Establish low-volume MS–LTC–DRG quintiles.* In this step, we employ our established quintile methodology for low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 cases). For FY 2023, we are proposing to perform this step on each set of claims data (claims dataset that includes COVID–19 cases and claims dataset that excludes COVID–19 cases).
- *Step 4—Remove statistical outliers.* In this step, we trim the applicable claims data to remove statistical outlier cases. For FY 2023, we are proposing to perform this step on each set of claims data (claims dataset that includes COVID–19 cases and claims dataset that excludes COVID–19 cases).
- *Step 5—Adjust charges for the effects of Short Stay Outliers (SSOs).* In this step, we adjust the number of applicable cases in each MS–LTC–DRG (or low-volume quintile) for the effect of SSO cases. For FY 2023, we are proposing to perform this step on each set of claims data (claims dataset that includes COVID–19 cases and claims dataset that excludes COVID–19 cases).
- *Step 6—Calculate the relative weights on an iterative basis using the hospital-specific relative weights methodology.* In this step, we use our established hospital-specific relative value (HSRV) methodology, which is an iterative process, to calculate the relative weights. For FY 2023, we are proposing to use the HSRV methodology to calculate relative weights using the claims that include COVID–19 cases and again using the claims that exclude the COVID–19 cases.
- *Step 7—Adjust the relative weights to account for nonmonotonically increasing relative weights.* In this step, we make adjustments that ensure that within each base MS–LTC–DRG, the relative weights increase by MS–LTC–DRG severity. For FY 2023, we are proposing to adjust each set of relative weights (that is, the relative weights calculated including COVID–19 cases and the relative weights calculated excluding COVID–19 cases).
- *Step 8—Determine a relative weight for MS–LTC–DRGs with no applicable LTCH cases.* In this step, we cross-walk each no-volume MS–LTC–DRG to another MS–LTC–DRG for which we calculated a relative weight. For FY 2023, we are proposing to cross-walk no-volume MS–LTC–DRGs in each set of relative weights (that is, the set of relative weights calculated including COVID–19 cases and the set of relative

weights calculated excluding COVID–19 cases).

• *Step 9—Normalize each set of relative weights.* In this step, we make a normalization adjustment so that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index. For FY 2023, we are proposing to normalize the set of relative weights calculated including COVID–19 cases and the set relative weights calculated excluding COVID–19 cases.

• *Step 10—Average the two sets of normalized relative weights.* In this step, we average the set of normalized relative weights calculated including COVID–19 cases and the set of normalized relative weights calculated excluding COVID–19 cases. In addition to the relative weights, we also average the geometric mean length of stays and arithmetic mean length of stays.

• *Step 11—Budget neutrality the averaged relative weights.* In this step, to ensure budget neutrality in the proposed annual update to the MS–LTC–DRG classifications and relative weights, we adjust the relative weights by a normalization factor and budget neutrality factor that ensures estimated aggregate LTCH PPS payments would be unaffected by the proposed updates to the MS–LTC–DRG classifications and relative weights. This step is performed prior to applying the proposed 10-percent cap.

• *Step 12—Apply the 10-percent cap to decreases in MS–LTC–DRG relative weights.* In this step we limit the reduction of the relative weight for a MS–LTC–DRG to 10 percent of its prior year value. This 10-percent cap does not apply to zero-volume MS–LTC–DRGs.

• *Step 13—Calculate the MS–LTC–DRG cap budget neutrality factor.* In this step, to ensure budget neutrality in the application of the proposed MS–LTC–DRG cap policy, we adjust the relative weights by a budget neutrality factor that ensures estimated aggregate LTCH PPS payments would be unaffected by our application of the cap to the MS–LTC–DRG relative weights.

Later in this section we describe each of the 13 proposed steps for calculating the proposed FY 2023 MS–LTC–DRG relative weights in greater detail. In this discussion, we note when the proposed step was performed twice under our proposal for averaging relative weights calculated including COVID–19 cases and relative weights calculated excluding COVID–19 cases.

Step 1—Prepare data for MS–LTC–DRG relative weight calculation.

For this FY 2023 IPPS/LTCH PPS proposed rule, consistent with our proposal in section I.F. of the preamble of this proposed rule to use FY 2021 data in the FY 2023 LTCH PPS ratesetting, we obtained total charges from FY 2021 Medicare LTCH claims data from the December 2021 update of the FY 2021 MedPAR file and used proposed Version 40 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we are proposing that if better data become available, we would use those data and the finalized Version 40 of the GROUPER in establishing the FY 2023 MS–LTC–DRG relative weights in the final rule.

To calculate the FY 2023 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, we are proposing to continue to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80 FR 49624). Specifically, we began by first evaluating the LTCH claims data in the December 2021 update of the FY 2021 MedPAR file to determine which LTCH cases would meet the criteria for exclusion from the site neutral payment rate under § 412.522(b) or had the dual rate LTCH PPS payment structure applied to those cases at the time of discharge. We identified the FY 2021 LTCH cases that were not assigned to MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945, and 946, which identify LTCH cases that do not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; and that either—

• The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the immediately preceding stay in that subsection (d) hospital included at least 3 days in an ICU, as we define under the ICU criterion; or

• The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the claim for the LTCH discharge includes the applicable procedure code that indicates at least 96 hours of ventilator services were provided during the LTCH stay, as we define under the ventilator criterion. Claims data from the FY 2021 MedPAR file that reported ICD–10–PCS procedure code 5A1955Z were used to identify cases involving at least 96 hours of ventilator services in accordance with the ventilator criterion. (We note that we have previously addressed the treatment of cases that would have been excluded from the site neutral payment rate under the statutory provisions that provided for temporary exception from the site neutral payment rate under the LTCH PPS for certain spinal cord specialty hospitals or for certain severe wound care discharges from certain LTCHs provided by sections 15009 and 15010 of Public Law 114–255, respectively. These statutory provisions were not in effect for any discharges occurring in FY 2021 (or beyond), so it is no longer necessary to address their treatment for purposes of developing the MS LTC DRG relative weights. We also note that section 3711(b)(2) of the CARES Act, which provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID–19 PHE period, was in effect for the entirety of FY 2021. Therefore, all LTCH PPS cases in FY 2021 were paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria. However, for purposes of setting rates for LTCH PPS standard Federal rate cases for FY 2023 (including MS–LTC–DRG relative weights), we used FY 2021 cases that meet the statutory patient criteria without consideration to how those cases were paid in FY 2021.)

Furthermore, consistent with our historical methodology, we excluded any claims in the resulting data set that were submitted by LTCHs that were all-inclusive rate providers and LTCHs that are paid in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, consistent with our historical practice and our policies, we excluded any Medicare Advantage (Part C) claims in the resulting data. Such claims were identified based on the presence of a GHO Paid indicator value of ''1'' in the MedPAR files.

In addition, as discussed in section VIII.B.3.a. of this proposed rule, for FY 2023, we are proposing to establish the MS–LTC–DRG relative weights as an average of the relative weights calculated both including and excluding the COVID–19 claims. To calculate the set of relative weights based on claims that excluded COVID–19 cases, we performed an additional trim to remove COVID–19 cases. We identified COVID–19 cases as any claim in the FY 2021 MedPAR file with a principal or secondary diagnosis of COVID–19 (ICD–10–CM diagnosis code U07.1).

In summary, in general, we identified the claims data used in the development of the FY 2023 MS–LTC–DRG relative weights in this proposed rule by trimming claims data that would have been paid the site neutral payment rate had the provisions of the CARES Act not been in effect. We trimmed the

claims data of all-inclusive rate providers reported in the December 2021 update of the FY 2021 MedPAR file and any Medicare Advantage claims data. There were no data from any LTCHs that are paid in accordance with a demonstration project reported in the December 2021 update of the FY 2021 MedPAR file, but, had there been any, we would have trimmed the claims data from those LTCHs as well, in accordance with our established policy.

We used the remaining data (that is, the applicable LTCH data) in the subsequent proposed steps to calculate the set of relative weights based on claims that include COVID–19 cases. In addition, we performed a trim to remove COVID–19 cases based on a principal or secondary diagnosis of COVID–19. We used these data in the subsequent proposed steps to calculate the set of relative weights based on claims that exclude COVID–19 cases.

Step 2—Remove cases with a length of stay of 7 days or less.

The next step in our proposed calculation of the proposed FY 2023 MS–LTC–DRG relative weights is to remove cases with a length of stay of 7 days or less. The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in an LTCH because these stays do not fully receive or benefit from treatment that is typical in an LTCH stay, and full resources are often not used in the earlier stages of admission to an LTCH. If we were to include stays of 7 days or less in the computation of the proposed FY 2023 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at an LTCH by including data from these very short stays. Therefore, consistent with our existing relative weight methodology, in determining the proposed FY 2023 MS–LTC–DRG relative weights, we are proposing to remove LTCH cases with a length of stay of 7 days or less from applicable LTCH cases for both sets of claims (that is the applicable LTCH claims that include COVID–19 cases and the applicable LTCH claims that exclude COVID–19 cases). (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 3—Establish low-volume MS–LTC–DRG quintiles.

To account for MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, we are proposing to continue to employ the quintile methodology for low-volume MS–LTC–DRGs, such that we grouped the ''low-volume MS–LTC–DRGs'' (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 81 FR 25148)). Under our proposal in section VIII.B.3.a. of the preamble to this proposed rule to establish the FY 2023 MS–LTC–DRG relative weights as an average of the relative weights calculated both including and excluding the COVID–19 claims, we are proposing to employ our quintile methodology when calculating the relative weights for each set of claims (that is the claims that include COVID–19 cases and the claims that exclude COVID–19 cases).

In this proposed rule, based on the best available data (that is, the December 2021 update of the FY 2021 MedPAR files), we identified 233 MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases in the claims data that included COVID–19 cases, and 232 MS LTC–DRGs that contained between 1 and 24 applicable LTCH cases in the claims data that excluded COVID–19 cases. These lists of MS–LTC–DRGs were then divided into 1 of the 5 low-volume quintiles. We assigned the low-volume MS–LTC–DRGs to specific low-volume quintiles by sorting the low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for this proposed rule, the number of MS–LTC–DRGs with less than 25 applicable LTCH cases in each set of claims was not evenly divisible by 5. The quintiles based on the claims data that included COVID–19 cases each contained at least 46 MS–LTC–DRGs (233/5 = 46 with a remainder of 3). Meanwhile, the quintiles based on the claims data that excluded COVID-cases also each contained at least 46 MS–LTC–DRGs (232/5 = 46 with a remainder of 2). We are proposing to employ our historical methodology of assigning each remainder low-volume MS–LTC–DRG to the low-volume quintile that contains an MS–LTC–DRG with an average charge closest to that of the remainder low-volume MS–LTC–DRG.

For the claims that include COVID–19 cases, the application of our quintile methodology resulted in 2 low-volume quintiles containing 46 MS–LTC DRGs (Quintiles 1 and 5) and 3 low-volume quintiles containing 47 MS–LTC–DRGs (Quintiles 2, 3, and 4). For the claims that excluded COVID–19 cases, the application of our quintile methodology resulted in 3 low-volume quintiles containing 46 MS–LTC DRGs (Quintiles 1, 4, and 5) and 2 low-volume quintiles containing 47 MS–LTC–DRGs (Quintiles 2 and 3). In cases where these initial assignments of low-volume MS–LTC–DRGs to quintiles results in nonmonotonicity within a base-DRG, we are proposing to make adjustments to the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in Step 7 of our proposed methodology.

To determine the FY 2023 relative weights for the low-volume MS–LTC–DRGs, consistent with our historical practice, we are proposing to use the five low-volume quintiles from each set of claims described previously. We determined a relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the methodology described in Step 6 of our proposed methodology. We assigned the same relative weight and average length of stay to each of the low-volume MS–LTC–DRGs that make up an individual low-volume quintile. These calculations were performed separately for the relative weight set based on claims that include COVID–19 cases and the relative weight set based on claims that exclude COVID–19 cases. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low-volume of applicable LTCH cases would vary in the future. Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights result in appropriate payment for LTCH cases grouped to low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases. We note our description in previous rules did not specify the point in our methodology when the low-volume MS–LTC–DRG quintiles are established. Although we are now including this step explicitly, this is not a change to our historical methodology for determining the MS–LTC–DRG relative weights.

For this proposed rule, we are providing the lists of the composition of the proposed low-volume quintiles for low-volume MS–LTC–DRGs in a

supplemental data file for public use posted via the internet on the CMS website for this proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of Table 11. This supplemental data file includes the composition of the proposed low-volume quintiles for low-volume MS–LTC–DRGs based on the claims that include COVID–19 cases and the composition of the proposed low-volume quintiles for low-volume MS–LTC–DRGs based on the claims that exclude COVID–19 cases.

Step 4—Remove statistical outliers.

The next step in our proposed calculation of the proposed FY 2023 MS–LTC–DRG relative weights is to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. Consistent with our existing relative weight methodology, we are proposing to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) This step was performed on both sets of claims (that is the applicable LTCH claims that include COVID–19 cases and the applicable LTCH claims that exclude COVID–19 cases). After removing cases with a length of stay of 7 days or less and statistical outliers, in each set of claims, we were left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this proposed rule, we refer to these cases as ''trimmed applicable LTCH cases.''

Step 5—Adjust charges for the effects of Short Stay Outliers (SSOs).

As the next step in the proposed calculation of the proposed FY 2023 MS–LTC–DRG relative weights, consistent with our historical approach, we are proposing to adjust each LTCH's charges per discharge for those remaining cases in each set of claims (that is, trimmed applicable LTCH cases that include COVID–19 cases and the trimmed applicable LTCH cases that exclude COVID–19 cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, we are proposing to make this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay of all cases grouped to the MS–LTC–DRG. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the proposed FY 2023 MS–LTC–DRG relative weights would lower the relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, we propose to continue to adjust for SSO cases under § 412.529 in this manner because it would result in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 6—Calculate the relative weights on an iterative basis using the hospital-specific relative value (HSRV) methodology.

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, in this FY 2023 IPPS/LTCH PPS proposed rule, we are proposing to continue to use a hospital-specific relative value (HSRV) methodology to calculate the MS–LTC–DRG relative weights for FY 2023. We believe that this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we reduced the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for an LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs). In other words, by multiplying an LTCH's relative charge values by the LTCH's case-mix index, we account for the fact that the same relative charges are given greater weight at an LTCH with higher average costs than they would at an LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. By standardizing charges in this manner, we count charges for a Medicare patient at an LTCH with high average charges as less resource-intensive than they would be at an LTCH with low average charges. For example, a $10,000 charge for a case at an LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at an LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

Consistent with our historical relative weight methodology, we propose to calculate the proposed FY 2023 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. Under our proposal in section VIII.B.3.a. of the preamble to this proposed rule to establish the FY

2023 MS–LTC–DRG relative weights as an average of the relative weights calculated both including and excluding the COVID–19 claims, we are proposing to apply the HSRV methodology when calculating the relative weights for each sets of claims (that is the claims that include COVID–19 cases and the claims that exclude COVID–19 cases).

Therefore, in accordance with our established methodology, for FY 2023, we are proposing to continue to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in Step 5 of our proposed methodology) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The average adjusted charge is then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. We used an initial case-mix index value of 1.0 for each LTCH.

For each proposed MS–LTC–DRG, we calculated the FY 2023 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the MS–LTC–DRG (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent cases from Step 5 for each MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent applicable LTCH cases from Step 5 for each MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its SSO-adjusted trimmed applicable LTCH cases (that is, its case-mix) was calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from previous) are then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of MS–LTC–DRG relative weights across all LTCHs. This iterative process continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 7—Adjust the relative weights to account for nonmonotonically increasing relative weights.

The MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions may consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG ''without CC/MCC'' has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the FY 2023 proposed MS–LTC–DRG relative weights based on each set of claims (that is claims that include COVID–19 cases and the claims that exclude COVID–19 cases), consistent with our historical methodology, we are proposing to continue to combine MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). For both sets of weights, the one based on claims that include COVID–19 cases and the one based on claims that exclude COVID–19 cases, any adjustments for nonmonotonicity that were made in determining the proposed FY 2023 MS–LTC–DRG relative weights by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website.

Step 8—Determine a relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, consistent with our historical methodology, we identified the MS–LTC–DRGs for which there were no claims in the December 2021 update of the FY 2021 MedPAR file and, therefore, for which no charge data was available for these MS–LTC–DRGs. Because patients with a number of the diagnoses under these MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we generally assign a relative weight to each of the no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' MS–LTC–DRGs, ''error'' MS–LTC–DRGs, and MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed later in this section of this proposed rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

Consistent with our existing methodology, we are proposing to crosswalk each no-volume proposed MS–LTC–DRG to another proposed MS–LTC–DRG for which we calculated a relative weight (determined in accordance with the methodology as previously described). Then, the ''no-volume'' proposed MS–LTC–DRG is assigned the same relative weight (and average length of stay) of the proposed MS–LTC–DRG to which it was crosswalked (as described in greater detail in this section of this proposed rule).

For this proposed rule, there was only one claim grouped to MS–LTC–DRG 273

(Percutaneous and other intracardiac procedures with MCC) in the December 2021 update of the FY 2021 MedPAR file. This claim had a COVID–19 diagnosis code. Therefore, when determining relative weights based on all applicable LTCH claims, a relative weight was computed for MS–LTC–DRG 273. However, when determining relative weights based on the set of claims that excluded COVID–19 cases, a relative was not computed for MS–LTC–DRG 273. When establishing the relative weights based on claims that exclude COVID–19 cases, instead of assigning a cross-walked relative weight for MS–LTC–DRG 273, we are proposing to assign MS–LTC–DRG 273 the relative weight calculated using all applicable LTCH cases. In the absence of a non-COVID–19 claim for this MS–LTC–DRG, we believe the relative weight based on a COVID–19 claim grouped to this same MS–LTC–DRG would more accurately reflect the relative resource use of this MS–LTC–DRG than a relative weight based on a proposed cross-walked MS–LTC–DRG.

Of the 767 proposed MS–LTC–DRGs for FY 2023, we identified 427 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases. We do not include MS–LTC–DRG 273, discussed previously, in this count. The 427 MS LTC DRGs for which there were no trimmed applicable LTCH cases includes the 11 ''transplant'' MS–LTC–DRGs, the 2 ''error'' MS–LTC–DRGs, and the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs, which are discussed in this section of this rule, such that we identified 399 MS–LTC–DRGs that for which, we are proposing to assign a relative weight using our existing ''no-volume'' MS–LTC–DRG methodology (that is, 427 − 11 − 2 − 15 = 399). We are proposing to assign relative weights to each of the 399 no-volume MS–LTC–DRGs based on clinical similarity and relative costliness to 1 of the remaining 340 (767 − 427 = 340) MS–LTC–DRGs for which we calculated relative weights based on the trimmed applicable LTCH cases in the FY 2021 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the ''cross-walked'' MS–LTC–DRGs as one of the 340 MS–LTC–DRGs to which we cross-walked each of the 399 ''no-volume'' MS–LTC–DRGs.) Then, in general, we are proposing to assign the 399 no-volume MS–LTC–DRGs the relative weight of the cross-walked MS–LTC–DRG (when necessary, we made adjustments to account for nonmonotonicity).

We cross-walked the no-volume MS–LTC–DRG to a MS–LTC–DRG for which we calculated relative weights based on the December 2021 update of the FY 2021 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume MS–LTC–DRGs in FY 2023, the relative weights assigned based on the cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

Then we assigned the proposed relative weight of the cross-walked MS–LTC–DRG as the relative weight for the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight (and average length of stay) for FY 2023. We note that, if the cross-walked MS–LTC–DRG had 25 applicable LTCH cases or more, its relative weight (calculated using the methodology as previously described in Steps 1 through 4) is assigned to the no-volume MS–LTC–DRG as well. Similarly, if the MS–LTC–DRG to which the no-volume MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, was designated to 1 of the low-volume quintiles for purposes of determining the relative weights, we assigned the relative weight of the applicable low-volume quintile to the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight for FY 2023. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume MS–LTC–DRG resulted, additional adjustments are required to maintain monotonically increasing relative weights.)

For this proposed rule, we are providing the list of the no-volume MS–LTC–DRGs and the MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked MS–LTC–DRGs) for FY 2023 in a supplemental data file for public use posted via the internet on the CMS website for this proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of Table 11.

To illustrate this methodology for determining the proposed relative weights for the FY 2023 MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example.

Example: There were no trimmed applicable LTCH cases in the FY 2021 MedPAR file that we are using for this proposed rule for proposed MS–LTC–DRG 061 (Ischemic stroke, precerebral occlusion or transient ischemia with thrombolytic agent with MCC). We determined that proposed MS–LTC–DRG 070 (Nonspecific cerebrovascular disorders with MCC) is similar clinically and based on resource use to proposed MS–LTC–DRG 061. Therefore, we are proposing to assign the same relative weight (and average length of stay) of proposed MS–LTC–DRG 70 of 0.837 for FY 2023 to MS–LTC–DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume would vary in the future. Consistent with our historical practice, we are proposing to use the best available claims data to identify the trimmed applicable LTCH cases from which we determined the relative weights in the final rule.

For FY 2023, consistent with our historical relative weight methodology, we are proposing to establish a relative weight of 0.0000 for the following transplant MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 001); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 002); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 005); Liver Transplant without MCC (MS–LTC–DRG 006); Lung Transplant (MS–LTC–DRG 007); Simultaneous Pancreas/Kidney Transplant (MS–LTC–DRG 008); Simultaneous Pancreas/Kidney Transplant with Hemodialysis (MS–LTC–DRG 019); Pancreas Transplant (MS–LTC–DRG 010); Kidney Transplant (MS–LTC–DRG 652); Kidney Transplant with Hemodialysis with MCC (MS–LTC–DRG 650), and Kidney Transplant with Hemodialysis without MCC (MS LTC DRG 651). This is because Medicare only covers these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified.

At the present time, we include these 11 transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy, we are proposing to established a relative weight of 0.0000 for the 2 ''error'' MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

Additionally, we are proposing to establish a relative weight of 0.0000 for the following ''psychiatric or rehabilitation'' MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). We are proposing to establish a relative weight 0.0000 for these 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs because the blended payment rate and temporary exceptions to the site neutral payment rate would not be applicable for any LTCH discharges occurring in FY 2023, and as such payment under the LTCH PPS would be no longer be made in part based on the LTCH PPS standard Federal payment rate for any discharges assigned to those MS–LTC–DRGs.

Step 9—Normalize the two sets of relative weights.

The next step in our proposed calculation of the proposed FY 2023 MS–LTC–DRG relative weights is to normalize the set of relative weights that were calculated using claims that include COVID–19 cases and to normalize the set of relative weights that were calculated using claims that excluded COVID–19 cases. The normalization adjustment is intended to ensure that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index. To calculate the normalization factors, we grouped applicable LTCH cases from each set of claims using the proposed FY 2023 Version 40 GROUPER, and used the proposed FY 2023 MS–LTC–DRG relative weights associated with each set to calculate the average case-mix index (CMI) for each set; we grouped the same applicable LTCH cases from each set of claims using the FY 2022 GROUPER Version 39 and MS–LTC–DRG relative weights and calculated the average CMI for each set; and computed the ratio by dividing the average CMI for each set for FY 2022 by the average CMI for each set for FY 2023. These ratios are the normalization factors that were applied to each respective set of unnormalized weights. Because the calculation of the normalization factor involves the relative weights for the MS–LTC–DRGs that contained applicable LTCH cases to calculate the average CMIs, any low-volume MS–LTC–DRGs are included in the calculation (and the MS–LTC–DRGs with no applicable LTCH cases are not included in the calculation). The table displays the normalization factors that were calculated and applied for each set of relative weights.

Claims used in Calculation	Normalization Factor
All applicable LTCH cases, including COVID-19 cases	1.33568
All applicable LTCH cases, excluding COVID-19 cases	1.33183

Step 10—Average the two sets of normalized relative weights.

After each set of relative weights was normalized, we computed a simple average of the normalized relative weights and geometric mean length of stays from each set, by using 50 percent of the relative weights calculated using applicable LTCH cases that include COVID–19 cases and 50 percent of the relative weights calculated using applicable LTCH cases that exclude COVID–19 cases.

Step 11—Budget neutralize the averaged relative weights.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).

To achieve budget neutrality under the requirement at § 412.517(b), under our established methodology, for each annual update the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, we are proposing to continue to apply budget neutrality adjustments in determining the proposed FY 2023 MS–LTC–DRG relative weights so that our proposed update the MS–LTC–DRG classifications and relative weights for FY 2023 are made in a budget neutral manner. In addition, as discussed in section VIII.B.3.b. of the preamble to this proposed rule, we are proposing that the proposed 10-percent cap on the reduction in a MS–LTC–DRG's relative weight in a given year be budget neutral. Therefore, for FY 2023, we are proposing to apply two budget neutrality factors to determine the MS–LTC–DRG relative weights. In this step, we describe the determination of the budget neutrality adjustment that accounts for the proposed update of the MS–LTC–DRG classifications and relative weights prior to the application of the ten-percent cap. In steps 12 and

13, we describe the application of the proposed 10-percent cap policy (step 12) and the determination of the proposed budget neutrality factor that accounts for the application of the proposed 10-percent cap policy (step 13).

As described previously, the relative weights constructed up to this point in our methodology were calculated based on two different set of claims (the applicable LTCH cases that included COVID–19 cases and the applicable LTCH cases that excluded COVID–19 cases) and then averaged together. However, when modeling payments for determining the budget neutrality factors, we are proposing to use the set of LTCH cases that include COVID–19 cases. In the absence of a set of MedPAR claims that reflect our expectation that there will be fewer (but not zero) COVID–19 cases in FY 2023 as compared to the COVID–19 cases in the FY 2021 claims data, we believe this is the best data available for determining the budget neutrality factors. We note this is consistent with the approach being proposed under the IPPS as discussed in section II.A.4. of the Addendum of this proposed rule. We are also soliciting feedback from commenters on alternative ways to use the FY 2021 claims data for purposes of calculating the FY 2023 budget neutrality factors.

In this proposed rule, to ensure budget neutrality for the proposed update to the MS–LTC–DRG classifications and relative weights prior to the application of the 10-percent cap (that is, uncapped relative weights), under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology. Therefore, in the first step of our MS–LTC–DRG update budget neutrality methodology, for FY 2023, we propose to calculate and apply a proposed normalization factor to the recalibrated relative weights (the result of Steps 1 through 10 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the changes to the classification system. That is, the normalization adjustment is intended to ensure that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the proposed normalization factor for FY 2023, we propose to use the following three steps: (1.a.) Use the applicable LTCH cases from the best available data (that is, LTCH discharges from the FY 2021 MedPAR file, including the COVID–19 cases as discussed previously) and group them using the proposed FY 2023 GROUPER (that is, Version 40 for FY 2023) and the proposed recalibrated FY 2023 MS–LTC–DRG uncapped relative weights (determined in Steps 1 through 10 discussed previously) to calculate the average case-mix index; (1.b.) group the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2022 GROUPER (Version 39) and FY 2022 MS–LTC–DRG relative weights and calculate the average case-mix index; and (1.c.) compute the ratio of these average case-mix indexes by dividing the average case-mix index for FY 2022 (determined in Step 1.b.) by the average case-mix index for FY 2023 (determined in Step 1.a.). As a result, in determining the proposed MS–LTC–DRG relative weights for FY 2023, each recalibrated MS–LTC–DRG uncapped relative weight is multiplied by the proposed normalization factor of 0.99885 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produces ''normalized relative weights.''

In the second step of our MS–LTC–DRG update budget neutrality methodology, we calculated a proposed budget neutrality adjustment factor consisting of the ratio of estimated aggregate FY 2023 LTCH PPS standard Federal payment rate payments for applicable LTCH cases (the sum of all calculations under Step 1.b. stated previously) before reclassification and recalibration to estimated aggregate payments for FY 2023 LTCH PPS standard Federal payment rate payments for applicable LTCH cases after reclassification and recalibration (that is, the sum of all calculations under Step 1.a. stated previously).

That is, for this proposed rule, for FY 2023, we propose to determine the budget neutrality adjustment factor using the following three steps: (2.a.) Simulate estimated total FY 2023 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the uncapped normalized relative weights for FY 2023 and proposed GROUPER Version 40 (as described previously); (2.b.) simulate estimated total FY 2023 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2022 GROUPER (Version 39) and the FY 2022 MS–LTC–DRG relative weights in Table 11 of the FY 2022 IPPS/LTCH PPS final rule; and (2.c.) calculate the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the proposed FY 2023 MS–LTC–DRG relative weights, each uncapped normalized relative weight is then multiplied by a proposed budget neutrality factor of 0.9932185 (the value determined in Step 2.c.) in the second step of the budget neutrality methodology.

Step 12—Apply the 10-percent cap to decreases in MS–LTC–DRG relative weights.

As discussed in section VIII.B.3.b. of the preamble to this proposed rule, we are proposing a 10-percent cap on the reduction in a MS–LTC–DRG's relative weight in a given year, beginning in FY 2023. Specifically, in cases where the relative weight for a MS–LTC–DRG would decrease by more than 10-percent in a given year, we propose to limit the reduction to 10-percent for that year. Under this proposal, this 10-percent cap would only be applied to the relative weights for MS–LTC–DRGs with applicable LTCH cases and would not be applied to the no-volume MS–LTC–DRGs identified in Step 8. Therefore, in this step, for each proposed FY 2023 MS–LTC–DRG with applicable LTCH cases (excludes zero-volume MS–LTC–DRGs) we compared its FY 2023 relative weight (after application of the proposed normalization and proposed budget neutrality factors determined in Step 11), to its FY 2022 MS–LTC–DRG relative weight. For any MS–LTC–DRG where the FY 2023 relative weight would otherwise have declined more than 10 percent, we established a proposed capped FY 2023 MS–LTC–DRG relative weight that would be equal to 90 percent of that MS–LTC–DRG's FY 2022 relative weight (that is, we set the proposed FY 2023 relative weight equal to the FY 2022 weight × 0.90).

Step 13—Calculate the MS–LTC–DRG cap budget neutrality factor.

As discussed in section VIII.B.3.b. of the preamble to this proposed rule, we also are proposing to apply a budget neutrality adjustment to the MS–LTC–DRG relative weights so that the proposed 10-percent cap on relative weight reductions is implemented in a budget neutral manner. Therefore, we are proposing to determine the budget neutrality adjustment factor for our proposed 10-percent cap on relative weight reductions using the following three steps: (a) Simulate estimated total FY 2023 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed capped relative weights for FY 2023 (determined in Step 12) and proposed GROUPER Version 40; (b) simulate estimated total FY 2023 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed uncapped relative weights for FY 2023 (determined in Step 11) and proposed GROUPER Version 40; and (c) calculate the ratio of these

estimated total payments by dividing the value determined in step (b) by the value determined in step (a). In determining the proposed FY 2023 MS–LTC–DRG relative weights, each capped relative weight is then multiplied by a proposed budget neutrality factor of 0.9966694 (the value determined in step (c)) to achieve the proposed budget neutrality requirement.

Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website, lists the proposed MS–LTC–DRGs and their respective proposed relative weights, proposed geometric mean length of stay, and proposed five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)) for FY 2023. We also are making available on our website the two sets of relative weights that were averaged together in determining the proposed FY 2023 MS–LTC–DRG relative weights. That is, the set of relative weights based on applicable LTCH cases that included COVID–19 cases and the set of relative weights based on applicable LTCH cases that excluded COVID–19 cases. We also are making available on the website the proposed MS–LTC–DRG relative weights prior to the application of the proposed 10 percent cap on MS–LTC–DRG relative weight reductions and corresponding proposed cap budget neutrality factor.

C. Proposed Changes to the LTCH PPS Payment Rates and Other Proposed Changes to the LTCH PPS for FY 2023

1. Overview of Development of the Proposed LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal payment rates is currently set forth at 42 CFR 412.515 through 412.533 and 412.535. In this section, we discuss the factors that we are proposing to use to update the LTCH PPS standard Federal payment rate for FY 2023, that is, effective for LTCH discharges occurring on or after October 1, 2022 through September 30, 2023. Under the dual rate LTCH PPS payment structure required by statute, beginning with discharges in cost reporting periods beginning in FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at 42 CFR 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

Prior to the implementation of the dual payment rate system in FY 2016, all LTCH discharges were paid similarly to those now exempt from the site neutral payment rate. That legacy payment rate was called the standard Federal rate. For details on the development of the initial standard Federal rate for FY 2003, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the standard Federal rate (FYs 2003 through 2015)/LTCH PPS standard Federal payment rate (FY 2016 through present) as implemented under 42 CFR 412.523(c)(3), we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42445 through 42446).

In this FY 2023 IPPS/LTCH PPS proposed rule, we present our proposed policies related to the annual update to the LTCH PPS standard Federal payment rate for FY 2023.

The proposed update to the LTCH PPS standard Federal payment rate for FY 2023 is presented in section V.A. of the Addendum to this proposed rule. The components of the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2023 are discussed in this section, including the statutory reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2023 as required by the statute (as discussed in section VIII.C.2.c. of the preamble of this proposed rule). We are proposing to make an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level for FY 2023 on estimated aggregate LTCH PPS payments, in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B. of the Addendum to this proposed rule).

2. Proposed FY 2023 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for input price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2017-based LTCH market basket for use under the LTCH PPS beginning in FY 2021 (85 FR 58907 through 58909). For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476), and for a complete discussion of the LTCH market basket and a description of the methodologies used to determine the operating and capital-related portions of the 2017-based LTCH market basket, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926).

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a ''rate year.'' We note that, because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Proposed Annual Update to the LTCH PPS Standard Federal Payment Rate for FY 2023

As previously noted, we adopted the 2017-based LTCH market basket for use under the LTCH PPS beginning in FY 2021. The 2017-based LTCH market basket is primarily based on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs. (For additional details on the development of the 2017-based LTCH market basket, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926).) We continue to believe that the 2017-based LTCH market basket appropriately reflects the cost structure of LTCHs for the reasons discussed when we adopted its use in the FY 2021 IPPS/LTCH PPS final rule. Therefore, in this proposed rule, we are proposing to use the 2017-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2023.

Section 1886(m)(3)(A) of the Act provides that, beginning in FY 2010, any annual update to the LTCH PPS standard Federal payment rate is reduced by the adjustments specified in clauses (i) and (ii) of subparagraph (A), as applicable. Clause (i) of section 1886(m)(3)(A) of the Act provides for a reduction, for FY 2012 and each subsequent rate year, by ''the productivity adjustment'' described in section 1886(b)(3)(B)(xi)(II) of the Act. Clause (ii) of section 1886(m)(3)(A) of the Act provided for a reduction, for each of FYs 2010 through 2019, by the ''other adjustment'' described in section 1886(m)(4)(F) of the Act; therefore, it is not applicable for FY 2023.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

c. Proposed Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under 42 CFR 412.523(c)(4). The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, applies a 2.0 percentage points reduction to any update under 42 CFR 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP) (42 CFR 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year. Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved, and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year. These requirements are codified in the regulations at 42 CFR 412.523(c)(4). (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section VIII.C. of the preamble of this proposed rule.)

d. Proposed Annual Market Basket Update Under the LTCH PPS for FY 2023

Consistent with our historical practice, we estimate the market basket increase and the productivity adjustment based on IGI's forecast using the most recent available data. Based on IGI's fourth quarter 2021 forecast, the FY 2023 market basket update for the LTCH PPS using the 2017-based LTCH market basket is 3.1 percent. The current estimate of the productivity adjustment for FY 2023 based on IGI's fourth quarter 2021 forecast is 0.4 percent.

For FY 2023, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment, described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, we are proposing to reduce the FY 2023 market basket increase by the FY 2023 productivity adjustment. To determine the proposed market basket increase for LTCHs for FY 2023, as reduced by the proposed productivity adjustment, consistent with our established methodology, we are subtracting the proposed FY 2023 productivity adjustment from the proposed FY 2023 market basket increase. (For additional details on our established methodology for adjusting the market basket increase by the productivity adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).)

For FY 2023, section 1886(m)(5) of the Act requires that, for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points. Therefore, for LTCHs that fail to submit quality reporting data under the LTCH QRP, the proposed 3.1 percent market basket update to the LTCH PPS standard Federal payment rate for FY 2023 would be reduced by the 0.4 percentage point productivity adjustment as required under section 1886(m)(3)(A)(i) of the Act and by the additional 2.0 percentage points reduction required by section 1886(m)(5) of the Act.

In this FY 2023 IPPS/LTCH PPS proposed rule, in accordance with the statute, we are proposing to reduce the proposed FY 2023 market basket update of 3.1 percent (based on IGI's fourth quarter 2021 forecast of the 2017-based LTCH market basket) by the proposed FY 2023 productivity adjustment of 0.4 percentage point (based on IGI's fourth quarter 2021 forecast). Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, consistent with 42 CFR 412.523(c)(3)(xvii), we are proposing to establish an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2023 of 2.7 percent (that is, the most recent estimate of the LTCH PPS market basket increase of 3.1 percent less the productivity adjustment of 0.4 percentage point). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under 42 CFR 412.523(c)(3)(xvii) in conjunction with 42 CFR 412.523(c)(4), we are proposing to further reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act. Accordingly, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 0.7 percent (that is, 2.7 percent minus 2.0 percentage points) for FY 2023 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. Consistent with our historical practice, we are proposing to use a more recent estimate of the market basket and the productivity adjustment, if appropriate, in the final rule to establish an annual update to the LTCH PPS standard Federal payment rate for FY 2023. We note that, consistent with historical practice, we are also proposing to adjust the FY 2023 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B.5. of the Addendum to this proposed rule).

IX. Quality Data Reporting Requirements for Specific Providers and Suppliers

In section IX. of the preamble of this proposed rule, we seek public comment on the following focus areas and proposed changes to the Medicare quality reporting programs:

- In section IX.A., assessment of the impact of climate change and health equity.
- In section IX.B., overarching principles in measuring healthcare quality disparities in hospital quality programs.

- In section IX.C., advancement of digital quality measurement and use of Fast Healthcare Interoperability Resources (FHIR) in hospital quality programs.
- In section IX.D., advancing the Trusted Exchange Framework and Common Agreement (TEFCA).
- In section IX.E., the Hospital IQR.
- In section IX.F., the PCHQR Program.
- In section IX.G., the LTCH QRP.
- In section IX.H., the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs) (previously known as the Medicare EHR Incentive Program).

A. Current Assessment of Climate Change Impacts on Outcomes, Care, and Health Equity—Request for Information

1. Background

A recent consensus statement signed by more than 200 medical journals noted climate change represents the greatest threat to global public health of the coming century.[698] Pollution associated with the burning of fossil fuels is known to cause serious harm and loss in productivity, and resultant climate instability introduces a combination of catastrophic weather events and chronic disease impacts that create serious burdens on organizations providing health care.[699] There is also evidence that climate change disproportionately harms underserved populations (for example, racial and ethnic minority groups, indigenous people, members of religious minorities, people with disabilities, sexual and gender minorities, individuals with limited English proficiency, older adults, and rural populations).[700] Long-term discrimination and disparities based on social determinants of health mean that these groups are often less equipped to withstand climate threats and are more susceptible to associated harm.[701] For example, Black Americans are much likelier to experience premature mortality as a result of extreme heat, and childhood asthma rates related to warming temperatures will be much higher in minority communities, as well.[702] Out of concern for the health of individuals, and to maintain uninterrupted operations in service of patients, we believe the healthcare sector should more fully explore how to effectively prepare for climate threats. Because healthcare facilities also emit greenhouse gases (GHGs) that contribute to climate change and its impacts, we believe that they should study how best to reduce those emissions, as well.

2. Solicitation of Comments on the Current State of Health System Climate Change Efforts

In this Request for Information (RFI), we are seeking comment on how hospitals, nursing homes, hospices, home health agencies, and other providers can better prepare for the harmful impacts of climate change on their patients, and how we can support them in doing so. Because research has shown that climate change causes harm to individuals (through both catastrophic events and chronic disease)[703] and because there is evidence to show that climate change will disproportionately harm underserved populations,[704] we believe that it is critical to study and prepare for these impacts.

Generally, we are seeking stakeholder input on what the U.S. Department of Health and Human Services (HHS) and CMS can do to support hospitals, nursing homes, hospices, home health agencies, and other providers in more effectively: (a) Determining likely climate impacts (that is, both immediate impacts associated with climate-related disasters and long-term chronic disease implications of climate change) on their patients, residents and consumers so that they can develop plans to mitigate those impacts; (b) understanding exceptional threats that climate-related emergencies (for example, storms, floods, extreme heat, wildfires) present to continuous facility operations (including potential disruptions in patient services associated with catastrophic events as a result of power loss, limited transportation, evacuation challenges, etc.) so they can better address those; and (c) understanding how to take action on reducing their emissions and tracking their progress in this regard. We believe this will inform the development and updating of policies that can assist providers in responding to climate-related challenges (for example, policies related to emergency preparedness) as well as the updating of HHS climate-health tools and resources.

We also invite public comments on the following topics (understanding that some provider types might have done more work in this area than others):

- The availability of information, such as analyses of climate change impacts (whether developed internally or collected from outside sources), that hospitals, nursing homes, hospices, home health agencies, and other providers can access to better understand climate threats to their patients, community, and staff.
- The degree to which different provider types currently complete comprehensive climate change risk assessments to better understand risks to their patient populations and the costs incurred due to catastrophic climate events and climate-related chronic disease.
- The degree to which facility efforts to prepare for climate impacts overlap with the work they already complete to meet CMS's Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, and the degree to which related CMS requirements sufficiently (or insufficiently) prepare them for the threats created by climate change and help or hinder these efforts.
- The degree to which hospitals, nursing homes, hospices, home health agencies, and other providers measure and share performance associated with their response to climate-related catastrophes (for example, measuring harm to vulnerable populations as a result of such events, or extent of disruption in service).
- The nature of facility plans for assisting the community and patients to prepare for and recover from climate-related events, as well as the nature of plans for evacuating patients with differing needs, including those with disabilities.
- The degree to which climate change, and climate change linked to health equity, is publicly addressed in strategic plans and objectives in your facility or system, and the degree to which hospital leadership regularly reviews progress on goals related to climate preparedness and mitigation

[698] Atwoli, L, Banqui A, Benfield T, et al. (2021). Call for emergency action to limit global temperature increases, restore biodiversity, and protect health. Lancet, 398(10304):939–41.

[699] Eckelman, M, Huang K, et al. (2020). Health Care Pollution and Public Health Damage in the United States: An Update. Health Affairs, 39:12.

[700] U.S. Environmental Protection Agency. (2021). Climate Change and Social Vulnerability in the United States: A Focus on Six Impacts. U.S. Environmental Protection Agency, EPA 430–R–21–003.

[701] U.S. Environmental Protection Agency. (2021). Climate Change and Social Vulnerability in the United States: A Focus on Six Impacts. U.S. Environmental Protection Agency, EPA 430–R–21–003.

[702] U.S. Environmental Protection Agency. (2021). Climate Change and Social Vulnerability in the United States: A Focus on Six Impacts. U.S. Environmental Protection Agency, EPA 430–R–21–003.

[703] Eckelman, M, Huang K, et al. (2020). Health Care Pollution and Public Health Damage in the United States: An Update. Health Affairs,39:12.

[704] U.S. Environmental Protection Agency. (2021). Climate Change and Social Vulnerability in the United States: A Focus on Six Impacts. U.S. Environmental Protection Agency, EPA 430–R–21–003.

and invests in health professional training on this topic.

- Whether health systems and facilities have time-bound, public aims for GHG emissions reduction, and, if yes, whether those aims relate to direct facility emissions, emissions associated with purchased energy, emissions associated with supply chain or some combination of these.
- The measures that health systems and facilities use to track their progress on GHG emissions reduction and use of renewable energy, as well as the data collection tools that they may use support this tracking.
- The tools and supports that health systems and facilities most heavily rely on to support their efforts to reduce GHG emissions.
- How HHS and CMS can support hospitals, nursing homes, hospices, home health agencies, and other providers in their efforts to more fully prepare for climate change's catastrophic and chronic impacts on their operations and the people they serve, as well as what incentives (for example, recognition, payment, reporting) might assist them in taking more action on climate readiness and emissions reduction.
- Whether accrediting organizations assess facilities' readiness for climate-related threats and their efforts to reduce GHG emissions.

B. Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs—Request for Information

1. Background

Significant and persistent inequities in healthcare outcomes exist in the United States (U.S.). Belonging to a racial or ethnic minority group; being a member of a religious minority; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; or being near or below the poverty level, are often associated with worse health outcomes.[705] [706] [707] [708] [709] [710] [711] [712] [713] We are committed to achieving equity in healthcare outcomes for our beneficiaries by supporting healthcare providers' quality improvement activities to reduce health disparities, enabling beneficiaries to make more informed decisions, and promoting healthcare provider accountability for healthcare disparities.[714]

Health equity is an important component of an equitable society. Equity, as defined in Executive Order 13985, is ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; LGBTQ+ persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [715] We define health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, religion, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes. We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our beneficiaries need to thrive.[716]

Advancing health equity will require a variety of efforts across the healthcare system. The reduction in healthcare disparities is one aspect of improving equity that we have prioritized. In a RFI that we included in the FY 2022 IPPS/LTCH PPS final rule, titled ''Closing the Health Equity Gap in CMS Hospital Quality Programs'' (86 FR 45349 through 45360), we described programs and policies we have implemented over the past decade with the aim of identifying and reducing healthcare disparities, including: The CMS Mapping Medicare Disparities Tool [717] and the CMS Disparity Methods stratified reporting.[718] CMS has also supported HHS efforts to implement of the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (78 FR 58539);[719] as well as improvement of the collection of social determinants of health in standardized patient assessment data in four post-acute care settings and the collection of health-related social need data by model participants in the Accountable Health Communities Model.[720] [721] [722]

[705] Joynt KE, Orav E, Jha AK. (2011). Thirty-day readmission rates for Medicare beneficiaries by race and site of care. JAMA, 305(7):675–681.

[706] Milkie Vu et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6) (2016) at 58; S.B. Nadimpalli, et al., The Association between Discrimination and the Health of Sikh Asian Indians.

[707] Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income inequality and thirty-day outcomes after acute myocardial infarction, heart failure, and pneumonia: Retrospective cohort study. British Medical Journal, 346.

[708] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and equity of care in U.S. hospitals. New England Journal of Medicine, 371(24):2298–2308.

[709] Polyakova, M., et al. (2021). Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. Health Affairs, 40(2): 307–316.

[710] Rural Health Research Gateway. (2018). Rural communities: Age, income, and health status. Rural Health Research Recap. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[711] HHS Office of Minority Health. (2020). Progress Report to Congress: 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Available at: *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=57.*

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[713] Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. preprint. medRxiv. 2020;2020.07.21. 20159327. doi:10.1101/2020.07.21.20159327. Available at: *https://pubmed.ncbi.nlm.nih.gov/32743608/.*

[714] Centers for Medicare and Medicaid Services. (2016). CMS Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf.*

[715] 86 FR 7009 (January 25, 2021). Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Available at: *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[716] Centers for Medicare & Medicaid Services. (2022). Health Equity. Available at: *https://www.cms.gov/pillar/health-equity.*

[717] Centers for Medicare and Medicaid Services. (2021). CMS Office of Minority Health. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities.*

[718] Centers for Medicare and Medicaid Services. Disparity Methods Confidential Reporting. Available at: *https://qualitynet.cms.gov/inpatient/measures/disparity-methods.*

[719] 78 FR 58539 (September 24, 2013). National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care. Available at: *https://www.federalregister.gov/documents/2013/09/24/2013-23164/national-standards-for-culturally-and-linguistically-appropriate-services-clas-in-health-and-health.*

[720] Centers for Medicare and Medicaid Services. (2021). Accountable Health Communities Model. Available at: *https://innovation.cms.gov/innovation-models/ahcm.*

[721] Centers for Medicare and Medicaid Services. The Accountable Health Communities Health-Related Social Needs Screening Tool. Available at: *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.*

Continued

Measuring healthcare disparities and reporting these results to healthcare providers is a cornerstone of our approach to advancing healthcare equity. It is important to consistently measure differences in care received by different groups of our beneficiaries, and this can be achieved by methods to stratify quality measures. Measure stratification is defined for this purpose as calculating measure results for specific groups or subpopulations of patients. Assessing healthcare disparities through stratification is only one method for using healthcare quality measurement to address health equity, but it is an important approach that allows healthcare providers to tailor quality improvement initiatives, decrease disparity, track improvement over time, and identify opportunities to evaluate upstream drivers of health. The use of measure stratification to assess disparities has been identified by our Office of Minority Health as a critical component of an organized response to health disparities.[723] To date, we have performed analyses of disparities in our quality programs by using a series of stratification methodologies identifying quality of care for patients with heightened social risk or with demographic characteristics with associations to poorer outcomes. In 2015, we began providing entity-level quality and member experience data to all Medicare Part C/D health plans stratified by race and ethnicity. In 2018, we introduced confidential reporting of hospital quality measure data stratified by dual eligibility in the Hospital IQR Program (81 FR 25199; 82 FR 38403 through 38409).[724]

We are continuing to evaluate opportunities to expand our measure stratification reporting initiatives using existing sources of data. Our goal is to provide comprehensive and actionable information on health disparities to healthcare providers participating in our quality programs to support quality improvement efforts. We are doing this, in part, by starting with confidential reporting of stratified measure results that highlight potential gaps in care between groups of patients. This includes examining the possibility of reporting disparities in care based on additional social risk factors and demographic variables associated with historic disadvantage in the healthcare system, and examining disparities through the use of stratified healthcare quality measures across a variety of care settings. As we consider expanding our disparity measurement initiatives through the use of measure stratification, we believe that we should model these efforts on existing best practices, such as considering stakeholder feedback and making use of lessons learned through the development of our existing disparity reporting efforts.

There are several key elements that we intend to take into account as we consider advancing the use of measurement and stratification as tools to address healthcare disparities and advance healthcare equity. We seek input on key considerations in five specific areas that could inform our approach. Each is described in more detail later in this section:

- *Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Programs*—This section identifies potential approaches for measuring healthcare disparities through measure stratification in CMS quality reporting programs.
- *Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting Across CMS Quality Reporting Programs*—This section describes considerations that could inform the selection of healthcare quality measures to prioritize for stratification.
- *Principles for Social Risk Factor and Demographic Data Selection and Use*—This section describes several types of social risk factor and demographic data that could be used in stratifying measures for healthcare disparity measurement.
- *Identification of Meaningful Performance Differences*—This section reviews several strategies for identifying meaningful differences in performance when measure results are stratified.
- *Guiding Principles for Reporting Disparity Results*—This section reviews considerations we could take into account in determining how quality programs will report measure results stratified by social risk factors and demographic variables to healthcare providers, as well as the ways different reporting strategies could hold healthcare providers accountable for identified disparities.

2. Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Programs

One of our goals in developing methods to measure disparities in care for beneficiaries is to provide actionable and useful results to healthcare providers. By quantifying healthcare disparities (for example, through quality measure stratification), we aim to provide useful tools for healthcare providers to drive improvements. We hope that these results support healthcare provider efforts to examine the underlying drivers of disparities in their patients' care and to develop their own innovative and targeted quality improvement interventions. With stratified disparity information available, it may be possible to drive system-wide advancement through incremental, provider-level improvement.

There are multiple conceptual approaches to stratifying measures. Since 2018, we have focused on illuminating healthcare disparities by reporting stratified results of existing quality measures by dual eligible status in two complementary ways.[725] First, after stratification by dual eligible status, measure results for subgroups of patients served by an individual healthcare provider can be directly compared. This type of comparison identifies such disparities, or gaps in care or outcomes between groups at a hospital. This approach is sometimes referred to as ''within-provider'' disparity and can be done for most measures that include patient-level data for most care settings. ''Within-provider'' disparities are a helpful means by which to quantitatively express disparities in care at the provider level.[726] Second, a healthcare provider's performance on a measure for only dual eligible patients is compared to other healthcare providers' performance for that same subgroup of patients (sometimes referred to as ''across-provider'' disparities measurement). This type of comparison illuminates the healthcare provider's

[722] Centers for Medicare and Medicaid Services. (2021). IMPACT Act Standardized Patient Assessment Data Elements. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/-IMPACT-Act-Standardized-Patient-Assessment-Data-Elements.*

[723] Centers for Medicare & Medicaid Services. (2021). Building an Organizational Response to Health Disparities [Fact Sheet]. U.S. Department of Health and Human Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf.*

[724] Centers for Medicare & Medicaid Services, Office of Minority Health. Racial, Ethnic, & Gender Disparities in Health Care in Medicare Advantage. (2021). Available at: *https://www.cms.gov/files/document/racial-ethnic-gender-disparities-health-care-medicare-advantage.pdf.*

[725] QualityNet. Disparity Methods Confidential Reporting Overview. Available at: *https://qualitynet.cms.gov/inpatient/measures/disparity-methods.*

[726] Centers for Medicare & Medicaid Services. (2015). Risk Adjustment Fact Sheet. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/Risk-Adjustment-Fact-Sheet.pdf.*

performance for only the dual eligible subgroup, allowing comparisons for specific performance to be better understood and compared to peers, or against state and national benchmarks.

Taken separately, each approach may provide an incomplete picture of disparities in care for a particular measure, but when reported together with overall quality performance, these results can give detailed information about where differences in care exist. Using dual eligibility as an example, a healthcare provider may underperform when compared to national averages for their dual eligible population (''across-provider'' disparity), but if they also underperform for patients who are not dual eligible, the measured difference, or ''within-provider'' disparity, could be negligible even though performance for the group that has been historically marginalized remains poor. In this case, simply providing stratified within-provider results could show little difference in care between patient groups seen by the provider but the combined results show the provider is underperforming on care for some patients compared to other providers.

Similar approaches have been recommended by the Assistant Secretary of Planning and Evaluation (ASPE) as ways to measure health equity in their 2020 Report to Congress.[727] In their report, ASPE suggested measuring and reporting quality specifically for beneficiaries with social risk factors, stratifying measures by social risk factors, and encouraging the development of health equity measures such as these for incorporation into quality reporting programs.

We are especially sensitive to the need to ensure all disparity reporting avoids measurement bias. Stratified results must be carefully examined for potential measurement or algorithmic bias[728] that is introduced through stratified reporting. Furthermore, results of stratified reporting must be evaluated for any type of selection bias that fails to capture disparity due to inadequate representation of subgroups of patients in measure cohorts. As part of the implementation of any type of measure stratification, we would carefully examine stratified results and methods to mitigate the potential for drawing incorrect conclusion from results.

3. Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting Across CMS Quality Reporting Programs

We are considering expanding our efforts to provide stratified reporting for additional clinical quality measures, provided they offer meaningful and valid feedback to healthcare providers on their care for populations that may face social disadvantage or other forms of discrimination or bias. Further development of stratified reporting of healthcare quality measures can provide healthcare providers with more granular results that support targeting resources and initiatives to improve health equity as a means to improving the overall quality of care. We are mindful that it may not be possible to calculate stratified results for all quality measures, or that there may be situations where stratified reporting may not be desired. To help inform prioritization of the next generation of candidate measures for stratified reporting, we are soliciting feedback on several systematic principles under consideration that we believe will help us prioritize measures for disparity reporting across quality programs.

These considerations would help guide the use of stratified measure results to provide information on healthcare disparities broadly across our quality programs. While we aim to standardize approaches where possible, disparity identification requires an understanding of the specific context and measures used by each program. To ensure that results provide the most actionable data possible, and to limit the potential for the introduction of bias, we believe decisions about how to identify and prioritize measures for possible stratification should be made at the program level.

- *Prioritize Existing Clinical Quality Measures*—When considering disparity reporting of stratified quality measures, there are several advantages to focusing on measures that we have already, through notice and comment rulemaking, adopted for one or more CMS quality programs. These measures assess the quality of care on agreed upon topics for quality measurement specific to a quality program setting. These measures have gone through an extensive development process and validation testing with significant opportunity for public input. Adapting these existing quality measures to measure disparity through stratification maintains adherence to the measurement priorities identified through expert review and validation completed through measure development and testing. The application of measure stratification to these measures would also minimize any new reporting burden on healthcare providers.
- *Prioritize Measures with Identified Disparity in Treatment or Outcomes for the Selected Social or Demographic Factor*—Candidate measures for stratification should be supported by evidence of underlying healthcare disparities in the procedure, condition, or outcome being measured. A review of peer-reviewed research studies should be conducted to identify disparities related to treatment, procedure, or outcome associated with the measure, and should carefully consider both social risk factors and patient demographics. In addition, analysis of Medicare-specific data should be done to demonstrate evidence of disparity in care among the Medicare population. In addition, consideration should also be given to conditions that have highly disproportionate prevalence in certain populations.
- *Prioritize Measures with Sufficient Sample Size to Allow for Reliable and Representative Comparisons*—Sample size holds specific significance for statistical calculations; however, it holds additional importance in the context of disparity reporting. Candidate measures for stratification will need to have sufficient cohort sample size to ensure that reported results of the disparity calculation are reliable and representative of the healthcare provider's patient population. This may be challenging if cohorts with a given social risk factor are small.

Carefully establishing reliability and representation standards for measure reporting is important for considering measures to stratify. Reliability, in this case, refers to the minimum case count needed to achieve reliable results. Metrics for reliability are used in non-stratified quality measure reporting, such as when measures require a certain number of procedures for their rates to be considered reliable. The use of a reliability standard for disparity reporting will ensure consistently reliable results are calculated.

Representation standards are also important and may involve requiring a minimum number or percent of healthcare providers or patients to be eligible to receive stratified results with reliable estimates before a measure is considered for disparity reporting. This requirement aims to ensure that meaningful comparisons can be made. As we noted previously, when only a

[727] ASPE. (2020). Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program: The Second of Two Reports Required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. Available at: *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195191/Second-IMPACT-SES-Report-to-Congress.pdf*.

[728] Obermeyer Z, Powers B, Vogeli C, Mullainathan S. Dissecting racial bias in an algorithm used to manage the health of populations. Science. 2019;366(6464):447–53.

small proportion of healthcare providers can receive statistically significant results, it may not be prudent for quality programs to pursue stratified reporting for that particular measure. Doing so can create challenges when generalizing rates of disparity for conditions or procedures when only a small proportion of a healthcare provider's results are considered. If, for example, only 10 percent of healthcare providers can report results, results must be clearly presented to ensure they are not understood to represent disparity in care for the measurement taking place in all care settings, as shown in this example, where 90 percent of them would not be included in reporting.

Quality programs may further consider measures for disparity reporting based on the size of the calculated disparity by prioritizing measures for stratification that show large differences in care between patient groups. Large differences in care for patients along social or demographic lines may indicate high potential that targeted initiatives could be effective. However, measures with disparities of smaller magnitude but with large cohorts affect many patients because they may have very large aggregate impacts on the national scale.

• *Prioritize Outcome Measures and Measures of Access and Appropriateness of Care*—Quality measurement in CMS programs often focus on outcomes of care, such as mortality or readmission. Outcomes measures remain a priority in the context of disparities measurement. However, measures that focus on access to care, when available, are also critical tools for addressing healthcare disparities. Measures that address healthcare access can counterbalance the risk of creating perverse incentives. If only differences in care between groups are measured, performance on a measure of disparity could be improved by limiting access to care for high-risk patients in the populations that are historically underserved or marginalized.

To complement stratification of measures focused on clinical outcomes, quality programs may consider prioritizing measures with a focus on access to or the appropriateness of care. These measures, when reported in tandem with clinical outcomes, would provide a broader picture of care provided by a healthcare provider, illuminate potential drivers of performance, and highlight organizations that fail to address barriers in access to care for groups that have been historically marginalized. We acknowledge that the measurement of access and appropriateness of care is a growing field, and that there are currently a limited number of developed quality measures on these topics. However, as our ability to measure these facets of healthcare improves, we expect that they will be high priority for measure stratification.

4. Principles for Social Risk Factor and Demographic Data Selection and Use

There are a wide array of non-clinical drivers of health known to impact patient outcomes, including social risk factors such as socioeconomic status, housing availability, and nutrition, as well as marked inequity in outcomes based on patient demographics such as race and ethnicity, being a member of a minority religious group, geographic location, sexual orientation and gender identity, religion, and disability status.[729] [730] [731] [732] [733] [734] [735] [736] The World Health Organization (WHO) defines social risk factors as ''non-medical factors that influence health outcomes. They are the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life.'' [737] These include factors such as income, education, job security, food security, housing, social inclusion and non-discrimination, access to affordable health services, and any others. Research has indicated that these social factors may have as much or more impact on health outcomes as clinical care itself.[738] [739] Additionally, differences in outcomes based on patient race and ethnicity have been identified as significant, persistent, and of high priority for CMS and other Federal agencies.[740]

Identifying and prioritizing specific indicators of social risk or demographic variables to consider for stratified analyses and measure reporting can be challenging due to the large number of variables identified in the literature as potential risk factors for disparities in health care and poorer health outcomes. And yet, the limited availability of data for many self-reported social risk factors and demographic factors across the healthcare sector further complicates our ability to choose effective metrics to evaluate disparity.

Disparity reporting in the Hospital IQR Program has focused on stratification by dual eligibility for Medicare and Medicaid. Dual eligibility has been used in this and other CMS quality programs as an indicator of financial risk, as the majority of Medicaid beneficiaries are eligible based on meeting thresholds for low patient income and/or assets. The use of dual eligibility is consistent with recommendations from ASPE's First Report to Congress which was required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (Pub. L. 113–185).[741] This report found that, in the context of value-based purchasing (VBP) programs, dual eligibility, as an indicator of social risk, was among the most powerful

[729] Joynt KE, Orav E, Jha AK. (2011). Thirty-day readmission rates for Medicare beneficiaries by race and site of care. JAMA, 305(7):675–681.

[730] Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income inequality and thirty-day outcomes after acute myocardial infarction, heart failure, and pneumonia: Retrospective cohort study. British Medical Journal, 346.

[731] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and equity of care in U.S. hospitals. New England Journal of Medicine, 371(24):2298–2308.

[732] Polyakova, M., et al. (2021). Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. Health Affairs, 40(2): 307–316.

[733] Rural Health Research Gateway. (2018). Rural communities: Age, income, and health status. Rural Health Research Recap. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[734] HHS Office of Minority Health (2020). 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Available at: *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[735] Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. medRxiv [Preprint]. 2020.07.21.20159327. doi: 10.1101/2020.07.21.20159327. PMID: 32743608; PMCID: PMC7386532.

[736] Milkie Vu et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6) (2016) at 58; S.B. Nadimpalli, et al., The Association between Discrimination and the Health of Sikh Asian Indians.

[737] World Health Organization. Social Determinants of Health. Available at: *https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1.*

[738] Hood, C., Gennuso K., Swain G., Catlin B. (2016). County Health Rankings: Relationships Between Determinant Factors and Health Outcomes. Am J Prev Med. 50(2):129–135. doi:10.1016/j.amepre.2015.08.024.

[739] Chepaitis, A.E., Bernacet, A., Kordomenos, C., Greene, A.M., Walsh, E.G. (2020). Addressing social determinants of health in demonstrations under the financial alignment initiative. RTI International. Available at: *https://innovation.cms.gov/data-and-reports/2021/fai-sdoh-issue-brief.*

[740] 86 FR 7009 (January 25, 2021). Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Available at: *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[741] Office of the Assistant Secretary for Planning and Evaluation. (2016). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs.*

predictors of poor health outcomes among those social risk factors that ASPE examined and tested.

Financial risk is only one metric of social risk, and stratification of quality measures by additional social risk factors and demographics (such as race, ethnicity, language, religion, sexual orientation, and gender identity) or disability, is important to provide more granular information for healthcare providers to act upon. As we consider prioritizing and expanding the variables used for measure stratification, we will carefully consider both social risk factors and patient demographics as well as other variables associated with historic disadvantage in healthcare, such as disability status.

As noted previously, a growing body of literature identifies the association between social risk factors and demographic variables with poorer health outcomes.[742] [743] [744] While social risk factors and demographic variables are both associated with worse healthcare outcomes and experiences, they are distinct constructs, and should be identified, measured, and reported as such. Patient demographic variables such as race and ethnicity are often identified as indicators of social risk driven by the differences in care received by persons who belong to minority racial and ethnic groups. The disparity in outcomes can be attributed to many factors, including discrimination in the healthcare system, challenges accessing quality healthcare, and societal inequity in other factors connected to social risk. Attributing differences in outcomes to race may inappropriately place the driver of poorer health outcomes on the patient, rather than on structural factors, such as racism in society and the healthcare system that drive the provision of lower quality care.[745] It is important, in identification of non-clinical drivers of health, to identify that race and ethnicity are not the social risk factor, but markers of exposure to other factors.

In prioritizing among social risk factors and demographic variables, disability, and other markers of disadvantage for stratified reporting, we anticipate that each individual quality program would design an approach appropriate to their care setting. We strive to operationalize our programs consistently where possible to decrease the burden on healthcare providers, however, the deeply contextual nature of this type of reporting may require the development of an approach specific to the quality programs based on care setting, patient population, and data availability.

The availability of data is a crucial consideration when examining data sources for use in stratified quality reporting. In many cases, the lack of available patient-reported data on patient social risk or demographic variables limits the ability to conduct disparity analyses. While improving the collection of patient-reported demographic information and information on social risk is an ongoing goal, other methods and data sources for estimating social risk (as described further in this section) could potentially fill in gaps in existing data sets, and could include area-based indicators or imputation techniques that use existing information about patient populations to estimate approximations about related population information. Each of these types of data sources have advantages and disadvantages.

Patient-reported data are considered to be the gold standard for evaluating care for patients with social risk factors or who belong to certain demographic groups as this is an accurate and preferred way to attribute social risk.[746] Currently, there are many efforts underway to further develop data standards for collection for self-reported patient social risk and demographic variables. Yet, given that national data sources of reliable, self-reported data are not yet available, we also intend to consider other options for social risk factor data. We note efforts to standardize the collection of demographic and social risk factor data include prior work done by both CMS and the Office of the National Coordinator for Health Information Technology (ONC) with Federal and private partners to better collect and leverage data on social risk. This work includes: (1) The development of an Inventory of Resources for Standardized Demographic and Language Data Collection; [747] [748] (2) CMS work to support specialized International Classification of Diseases, (ICD) 10th Revision, Clinical Modification (ICD–10–CM) codes for describing the socioeconomic, cultural, and environmental determinants of health; [749] and (3) the CMS sponsorship of several initiatives to statistically estimate race and ethnicity information when it is absent.[750] [751]

One example of improving sources of data come from the certified health IT utilized by hospitals to meet the requirements of the Promoting Interoperability program. This includes health IT certified to the ''demographics'' certification criterion (45 CFR 170.315(a)(5)), which provides for the capability to record race and ethnicity at a detailed level of granularity consistent with the Centers for Disease Control and Prevention's (CDC) Race & Ethnicity—CDC code system. This code system includes more than 900 concepts for race and ethnicity, which gives patients very specific options for self-identifying their demographic information. The 900 concepts are organized in a way to eventually ''roll up'' to the Office of Management and Budget's (OMB) minimum categories for race and

[742] National Academies of Sciences, Engineering, and Medicine. (2016). Accounting for social risk factors in Medicare payment: Identifying social risk factors. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21858.* Available at: *https://www.nap.edu/catalog/21858/accounting-for-social-risk-factors-in-medicare-payment-identifying-social.*

[743] Office of the Assistant Secretary For Planning and Evaluation. (2016). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs.*

[744] Office of the Assistant Secretary For Planning and Evaluation. (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.*

[745] Gee G.C., Ford C.L. (2011). Structural Racism and health inequities: Old Issues, New Directions. Du Bois Review: Social science research on race, 8(1), 115–132. Available at: *https://doi.org/10.1017/S1742058X11000130.*

[746] Jarrín OF, Nyandege AN, Grafova IB, Dong X, Lin H. (2020). Validity of race and ethnicity codes in Medicare administrative data compared with gold-standard self-reported race collected during routine home health care visits. Med Care, 58(1):e1–e8. doi: 10.1097/MLR.0000000000001216. PMID: 31688554; PMCID: PMC6904433.

[747] Centers for Medicare & Medicaid Services. (2020). Building an Organizational Response to Health Disparities Inventory of Resources for Standardized Demographic and Language Data Collection. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Collection-Resources.pdf.*

[748] The Office of the National Coordinator for Health Information Technology (ONC). Health IT Standards Bulletin. HealthIT.gov: 2021. URL: *https://www.healthit.gov/sites/default/files/page/2021-05/Standards_Bulletin_2021-2.pdf.*

[749] Centers for Medicare & Medicaid Services (2019). Utilization of Z Codes for Social Determinants of Health among Medicare Fee-for-Service Beneficiaries, 2019. Available at: *https://www.cms.gov/files/document/z-codes-data-highlight.pdf.*

[750] Centers for Medicare & Medicaid Services (2021). A New Method to Improve measurement of Race-and-Ethnicity in CMS Data and Applications to Inequities in Quality of Care. Available at: *https://www.cms.gov/files/document/new-method-improve-measurement-race-and-ethnicity-cms-data-and-applications-inequalities-quality.pptx.*

[751] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. Health Care Financing Review, 29(3), 27–42.

ethnicity,[752] which can support aggregation and reporting needs when the OMB standard is necessary. It also includes social, psychological, and behavioral standards in health IT certification criteria (80 FR 62601), providing interoperability standards (LOINC [Logical Observation Identifiers Names and Codes] and SNOMED CT [Systematized Nomenclature of Medicine—Clinical Terms]) for financial strain, education, social connection and isolation, and others. The Agency for Healthcare Research and Quality (AHRQ) has also worked with the Gravity Project which is a multistakeholder effort to expand capabilities to capture additional social determinants of health data elements, to identify and harmonize social risk factor data for interoperable electronic health information exchange for electronic health record (EHR) fields,[753] and make recommendations on the expansion of the ICD–10 (International Classification of Diseases, 10th Revision) Z-codes, the alphanumeric codes used worldwide to represent diagnoses, to include additional social risk diagnoses.[754]

We expect to continue evaluating patient-reported sources of social risk and demographic information. We are also considering three sources of social risk and demographic data that would allow us to report stratified measure results:

• *Billing and Administrative Data*—The majority of quality measurement tools used in our quality programs focus on utilizing existing claims and administrative data for Medicare beneficiaries. Using these existing data to assess disparity, for example by the use of dual enrollment for Medicare and Medicaid, allows for high impact analyses with negligible healthcare provider burden. There are, however, limitations in these data's usability for stratification analysis. CMS's current administrative race and ethnicity data have been shown to have historical inaccuracies due to limited collection classifications and attribution techniques, and are generally considered not to be accurate enough for stratification and disparity analyses.[755] International Classification of Diseases,10th Revision (ICD–10) codes for socioeconomic and psychosocial circumstances (''Z codes'' Z55 to Z65) represent an important opportunity to document patient-level social risk factors in Medicare beneficiaries, however, they are rarely used in clinical practice, limiting their usability in disparities measurement.[756] If the collection of social risk factor data improves in administrative data, we will continue to evaluate its applicability for stratified reporting in the future.

Dual eligibility is a widely used proxy for low socioeconomic status and is an exception to the previously discussed limitations, making it an effective indicator for worse outcomes due to low socioeconomic status. The use of dual eligibility in social risk factor analyses was supported by ASPE's First and Second Reports to Congress.[757] [758] These reports found that in the context of VBP programs, dual eligibility, as an indicator of social risk, was among the most powerful predictors of poor health outcomes among those social risk factors that ASPE examined and tested.

• *Area-based Indicators of Social Risk Information and Patient Demographics*—Area-based indicators pool area-level information to create approximations of patient risk or describe the neighborhood or context that a patient resides in. Popular among them are the use of the American Community Survey (ACS), which is commonly used to attribute social risk to populations at the ZIP code or Federal Information Processing Standards (FIPS) county level. Several indices, such as the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) Index,[759] Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry Social Vulnerability Index (CDC/ATSDR SVI),[760] and Health Resources and Services Administration Area Deprivation Index,[761] combine multiple indicators of social risk into a single score which can be used to provide multifaceted contextual information about an area and may be considered as an efficient way to stratify measures that include many social risk factors.

• *Imputed Sources of Social Risk Information and Patient Demographics*—Imputed data sources use statistical techniques to estimate patient-reported factors, including race and ethnicity. In the case of race and ethnicity, indirect estimation improves upon imperfect and incomplete data by drawing on information about a person's name and address and the linkage of those variables to race and ethnicity. One such tool is the Medicare Bayesian Improved Surname Geocoding (MBISG) method (currently in version 2.1), which combines information from administrative data, surname, and residential location to estimate patient race and ethnicity.[762] We have customized this tool for the Medicare population to improve our existing administrative data on race and ethnicity.

The MBISG 2.1 method does not assign a single race and ethnicity to an individual; instead, it generates a set of six probabilities, each estimating how the individual would self-identify if provided with a set of racial and ethnic groups to choose from including: American Indian or Alaska Native, Asian or Pacific Islander, Black,

[752] 62 FR 58782 (October 30, 1997). Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity. Available at: *https://www.federalregister.gov/documents/1997/10/30/97-28653/revisions-to-the-standards-for-the-classification-of-federal-data-on-race-and-ethnicity.*

[753] Gravity Project. Available at: *https://thegravityproject.net/.*

[754] Centers for Medicare and Medicaid Services. (2020). Z Codes Utilization among Medicare Fee-for-Service (FFS) Beneficiaries in 2017. Available at: *https://www.cms.gov/files/document/cms-omh-january2020-zcode-data-highlightpdf.pdf.*

[755] Jarrín OF, Nyandege AN, Grafova IB, Dong X, Lin H. (2020). Validity of race and ethnicity codes in Medicare administrative data compared with gold-standard self-reported race collected during routine home health care visits. Med Care, 58(1):e1–e8. doi: 10.1097/MLR.0000000000001216. PMID: 31688554; PMCID: PMC6904433.

[756] Centers for Medicare & Medicaid Services, Office of Minority Health. (2021). Utilization of Z codes for social determinants of health among Medicare fee-for-service beneficiaries, 2019. Available at: *https://www.cms.gov/files/document/z-codes-data-highlight.pdf.*

[757] Office of the Assistant Secretary for Planning and Evaluation. (2016). Social risk factors and performance under Medicare's value-based purchasing programs. Available at: *https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs.*

[758] Office of the Assistant Secretary For Planning and Evaluation. (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.*

[759] Bonito A., Bann C., Eicheldinger C., Carpenter L. (2008). Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare & Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality.

[760] Flanagan, B.E., Gregory, E.W., Hallisey, E.J., Heitgerd, J.L., Lewis, B. (2011). A social vulnerability index for disaster management. Journal of Homeland Security and Emergency Management, 8(1). Available at: *https://www.atsdr.cdc.gov/placeandhealth/svi/img/pdf/Flanagan_2011_SVIforDisasterManagement-508.pdf.*

[761] Center for Health Disparities Research. About the Neighborhood Atlas. Available at: *https://www.neighborhoodatlas.medicine.wisc.edu/.*

[762] Haas A., Elliott M.N., Dembosky J.W., Adams J.L., Wilson-Frederick S.M., Mallett J.S. et al. (2019). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Serv Res, 54(1):13–23. doi: 10.1111/1475–6773.13099. Epub 2018 Dec 3. PMID: 30506674; PMCID: PMC6338295. Available at: *https://pubmed.ncbi.nlm.nih.gov/30506674/.*

Hispanic, Multiracial, and White. In no case would the estimated probability be used for making inferences about a specific beneficiary; only self-reported data on race and ethnicity should be used for that purpose. However, in aggregate, these results can provide insight and accurate information at the population level, such as the patients of a given hospital, or the members of a given plan. MBISG 2.1 is currently used by our Office of Minority Health (OMH) to undertake various analyses, such as comparing scores on clinical quality of care measures from the Healthcare Effectiveness Database and Information Set (HEDIS) by race and ethnicity for Medicare Part C/D health plans, and in developing a Health Equity Summary Score (HESS) for Medicare Advantage (MA) health plans.[763]

While the use of area-based indicators and imputed data sources are not meant to replace efforts to improve patient-level data collection, we are considering how they might be used to begin population-level disparity reporting of stratified measure results while being conscientious about data limitations.

Imputed data sources, particularly when used to identify patient populations for measurement, must be carefully evaluated for their potential to negatively affect the populations being studied. For this reason, imputed data sources should only be considered after a significant validation study has been completed, including evaluation by key stakeholders for face validity, and any calculations that incorporate these methods should be continuously evaluated for the accuracy of their results and the necessity of their use. While neither imputed nor area-level geographic data should be considered a replacement for improved data collection, researchers have found their use to be a simple and cost-efficient way to make general estimations of social risk at a community level.[764] In place of patient-level information when it is not available, the combination of several sources of imputed or area-level data can provide actionable estimations of social risk of a population.

[763] Agniel D., Martino S.C., Burkhart Q., Hambarsoomian K., Orr N., Beckett M.K, et al. (2021). Incentivizing excellent care to at-risk groups with a health equity summary score. J Gen Intern Med, 36(7):1847–1857. doi: 10.1007/s11606–019–05473–x. Epub 2019 Nov 11. PMID: 31713030; PMCID: PMC8298664. Available at: *https://pubmed.ncbi.nlm.nih.gov/31713030/.*

[764] Bi, Q., He, F., Konty, K., Gould, L. H., Immerwahr, S., & Levanon Seligson, A. (2020). ZIP code-level estimates from a local health survey: Added value and limitations. Journal of Urban Health: Bulletin of the New York Academy of Medicine, 97(4), 561–567.

5. Identification of Meaningful Performance Differences

In examining potential ways to report healthcare disparity data, that is, the results of quality measure stratification, we expect to consider different approaches to identifying meaningful differences in performance. Stratified results can be presented in several ways to describe to providers how well or poorly they are performing, or how they perform when compared to other care facilities. For this reason, it is important to identify how best to present meaningful differences in performance for measures of disparity reporting. While we aim to use standardized approaches where possible, we also expect that decisions about how to identify meaningful differences in performance would ultimately be tailored to each individual program. We welcome feedback on the benefits and limitations of the possible disparity reporting approaches we have described in this RFI.

- *Statistical Differences*—When aiming to examine differences in disparities results among healthcare providers, the use of statistical testing can be helpful. There are many statistical approaches that can be used to reliably group results, such as using confidence intervals, creating cut points based on standard deviations, or using a clustering algorithm. Importantly, these approaches may result in groupings that are statistically different, but not meaningfully different depending on the distribution of results.
- *Rank Ordering and Percentiles*—Ordering healthcare providers in a ranked system is another option for reporting disparity results in a meaningful way. In this system, healthcare providers could be ranked based on their performance on disparity measures to quickly allow them to compare their performance to other similar healthcare providers. We may consider using an ordered system to report healthcare provider results by categorizing healthcare providers into groups, for example, into quintile or decile groups. This approach works well as a way for healthcare providers to easily compare their own performance against others; however, a potential drawback is that it does not identify the overall magnitude of disparity. For example, if a measure shows large disparity in care for patients based on a given factor, and that degree of disparity has very little variation between healthcare providers, the difference between the top and bottom ranked healthcare providers would be very small even if the overall disparity is large.
- *Threshold Approach*—A categorization system could also be considered for reporting disparity results. In this system, healthcare providers could be grouped based on their performance using defined metrics, such as fixed intervals of results of disparity measures, indicating different levels of performance. Using a categorized system may be more easily understood by stakeholders by giving a clear indication that outcomes are not considered equal. However, this method does not convey the degree of disparity between healthcare providers or the potential for improvement based on the performance of other healthcare providers. Furthermore, it requires a determination of what is deemed 'acceptable disparity' when developing categories.
- *Benchmarking*—Benchmarking, or comparing individual results to, for example, state or national averages, is another potential reporting strategy. This type of approach could be done, especially in combination with a ranked or threshold approach, to give healthcare providers more information about how they compare to the average care for a patient group.

Another consideration for each of these approaches is grouping similar care settings together for comparison through a peer grouping step, especially if a ranked system is used to compare healthcare providers. Some stakeholders have argued that comparisons between healthcare providers have limited meaning if the healthcare providers are not similar, and that peer grouping would improve their ability to interpret results. Overall, the value of peer grouping must be weighed against the potential to set different standards of meaningful disparity among different care settings.

6. Guiding Principles for Reporting Disparity Results

Confidential reporting for a short period that is not followed by public reporting of the same measure data is one approach we have used for newly adopted measures in a CMS quality program to give healthcare providers an opportunity to become more familiar with calculation methods and to begin improvement activities before their measure results are publicly reported. Providing early results to healthcare providers is an important way to provide healthcare providers the information they need to design impactful strategies to reduce disparity. Public reporting is a statutory requirement in all of our quality

programs. Public reporting provides all stakeholders with important information on healthcare provider quality, and in turn, relies on market forces to incentivize healthcare providers to improve and become more competitive in their markets.

Payment accountability for performance is also statutorily required in some of our quality programs. Payment accountability refers to tying payment to the results of quality measure performance, and in general rewards better performance with higher payment rates. Payment accountability allows us to reward healthcare providers for having low disparity rates and performing well for vulnerable patient groups.

We are exploring whether it would be prudent to first confidentially report all stratified measure results, where adopted into a quality reporting program, to give healthcare providers an opportunity to understand those results so they can begin to implement programs to reduce disparities before we report the results publicly.

We also believe it is important to report stratified measure data alongside overall measure results. Review of both overall measure results along with stratified results can illuminate greater levels of detail about quality of care for subgroups of patients, providing important information to drive quality improvement. Unstratified quality measure results address general differences in quality of care between healthcare providers and promote improvement for all patients, but unless stratified results are available, it may be unclear whether there are subgroups of patients that would benefit most from targeted quality improvement initiatives. Notably, even if overall quality measure scores were to improve, without identifying and measuring differences in outcomes between groups of patients, it could be impossible to track progress in reducing disparity between patients with and without heightened risk of poor outcomes due to social factors.

7. Solicitation of Comments

The goal of this RFI is to describe key considerations in determining how to develop future policies around the use of measure stratification as one quality measurement tool to address healthcare disparities and advance health equity across our quality programs. This is important as a means of setting priorities and expectations for the use of stratified measure results.

We invite general comments on the principles and approaches listed previously, as well as additional thoughts about disparity measurement or stratification guidelines suitable for overarching consideration across our quality programs. Specifically, we invite comment on:

- Overarching goals for measuring disparity that should be considered across CMS quality programs, including the importance of pairing stratified results with overall measure results to evaluate gaps in care among groups of patients attributed to a given healthcare provider and comparison of care for a subgroup of patients across healthcare providers.
- Principles to consider for prioritization of measures for disparity reporting, including prioritizing stratification for: Valid clinical quality measures; measures with established disparities in care; measures that have adequate sample size and representation among healthcare providers; and, measures that consider access and appropriateness of care.
- Principles to be considered for the selection of social risk factors and demographic data for use measuring disparities, include the importance of identifying new social risk factor and demographic variables to use to stratify measures. We also seek comment on the use of imputed and area-based social risk and demographic indicators for measure stratification when patient reported data are unavailable.
- Preferred ways that meaningful differences in disparity results can be identified or should be considered.
- Guiding principles for the use and application of the results of disparity measurement such as providing confidential reporting initially

C. Continuing To Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs—Request for Information

In the FY 2022 IPPS/LTCH PPS final rule, we stated the aim to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs (86 FR 45342). As part of this modernization of our quality measurement enterprise, we are issuing this RFI to gather broad public input on the transition to digital quality measurement. Any updates to specific program requirements related to providing data for quality measurement and reporting provisions would be addressed through future notice-and-comment rulemaking. This RFI contains five parts:

- *Background.* This part provides an overview of our goals and strategies to achieve digital quality measurement, and notes input and learnings relevant to these goals and strategies.
- *Refined definition of Digital Quality Measures (dQMs).* This part outlines potential revisions for a future definition for dQMs.
- *Data Standardization Activities to Leverage and Advance Standards for Digital Data.* This part discusses data standardization strategies and potential venues for advancing data standardization.
- *Approaches to Achieve FHIR® eCQM Reporting.* This part describes activities we are undertaking and considering to achieve FHIR-based electronic clinical quality measure (eCQM) reporting (for example, via FHIR APIs) as our initial implementation of dQMs.
- *Solicitation of Comments.* This part lists all requests for input included in the sections of this RFI.

1. Background

In the FY 2022 IPPS/LTCH PPS final rule, we noted the continued focus on use of digital data and advancements in technology and technical standards to improve interoperability of healthcare data which creates opportunity to significantly improve our quality measurement systems (86 FR 45342). In a learning health system, standardized and interoperable digital data from a single point of collection can support multiple use cases, including quality measurement, quality improvement efforts, clinical decision support, research, and public health. We believe data used for quality measurement, as well as these other use cases, should be a seamless outgrowth of data generation from routine workflows. Data sharing should be standards-based to maximize interoperability, minimize burden, and facilitate the development and use of common tooling across use cases. This approach supports data analysis, rapid-cycle feedback, and quality measurement that are aligned for continuous improvement in patient-centered care.

We are continuing to define how we can leverage existing policy to transform all CMS quality measurement to digital reporting, such as policy finalized in the ONC 21st Century Cures Act final rule (85 FR 25642). In that rule, ONC finalized a ''Standardized API for Patient and Population Services'' certification criterion (45 CFR 170.315(g)(10)) for certified health information technology (IT) requiring the use of FHIR Release 4 and several other implementation specifications. Health IT certified to this criterion will offer single patient and multiple patient services that can be accessed by third

party applications (85 FR 25742). The ONC 21st Century Cures Act final rule (85 FR 25642) also required health IT developers to update their certified health IT to support the United States Core Data for Interoperability (USCDI) standard, Version 1.[765] By aligning technology requirements for payers, healthcare providers, and health IT developers, HHS can advance an interoperable health IT infrastructure that ensures providers and patients have access to health data when and where it is needed.

In the FY 2022 IPPS/LTCH PPS final rule, we outlined actions in four areas to transition to digital quality measures: (1) Leverage and advance standards for digital data and obtain all electronic health record (EHR) data required for quality measures via provider FHIR-based application programming interfaces (APIs); (2) redesign our quality measures to be self-contained tools; (3) better support data aggregation; and (4) work to align measure requirements across our reporting programs, other Federal programs and agencies, and the private sector where appropriate (86 FR 45342). The actions are further described in CMS' Digital Quality Measurement Strategic Roadmap available at *https://ecqi.healthit.gov/dQM.* In this RFI, we focus on data standardization activities related to leveraging and advancing standards for digital data and approaches to transition to FHIR eCQM reporting in the future, as initial steps in our transition to digital quality measurement.

In the FY 2022 IPPS/LTCH PPS final rule, we also stated our goal of moving to digital quality measurement for all CMS quality reporting and value-based purchasing programs (86 FR 45342). We further clarify that we plan to transition incrementally, beginning with the uptake of FHIR API technology and shifting to eCQM reporting using FHIR standards as described subsequently in section IX.C.4. of the preamble of this proposed rule. We aim to achieve a quality measurement system fully based on digital measures. The goals of a fully digital measurement system include: Reduced burden of reporting; provision of multi-dimensional data in a timely fashion, rapid feedback, and transparent reporting of quality measures; digital measures leveraged for advanced analytics to define, measure, and predict key quality issues; and quality measures that support development of a learning health system, which uses key data that are also used for care, quality improvement, public health, research, etc.

2. Refined Definition of Digital Quality Measures (dQMs)

In the FY 2022 IPPS/LTCH PPS final rule, we sought to define a dQM as software that processes digital data to produce a measure score or measure scores (86 FR 45342). Based on feedback regarding confusion by the term ''software,'' we further clarify that dQMs are quality measures, organized as self-contained measure specifications and code packages, that use one or more sources of health information that is captured and can be transmitted electronically via interoperable systems. We continue to note data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, laboratory systems, prescription drug monitoring programs (PDMPs), instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated data such as a home blood pressure monitor, or patient-reported health data), health information exchanges (HIEs) or registries, and other sources. We are currently considering how eCQMs, which use EHR data, can be refined or repackaged to fit within the dQM umbrella. While eCQMs meet the definition for dQMs in many respects, limitations in data standards, requirements, and technology have limited their interoperability. In the current state, there are multiple standards that must be supported (for example, Health Quality Measurement Format (HQMF) [766] and Quality Reporting Document Architecture (QRDA) [767]) for eCQM data collection and reporting. Mapping EHR data can be challenging and burdensome for providers as there is often novel data collection occurring to support quality measurement. For example, eCQMs require steps to map data elements from the EHR to the appropriate format. Future dQMs would leverage interoperability standards to decrease mapping burden and align standards for quality measurement with interoperability standards used in other healthcare exchange methods.

We seek comment on this refined definition of dQMs and feedback on potential considerations or challenges related to non-EHR data sources.

3. Data Standardization Activities To Leverage and Advance Standards for Digital Data

As noted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45342), we are considering implementing eCQM quality reporting via FHIR-based APIs based on standardized, interoperable data. Advancing data standardization is a critical step for this implementation, and for long-term digital measurement strategies. Utilizing standardized data for EHR-based measurement (based on the FHIR standard) and aligning where possible with other interoperability requirements can reduce the data collection burden incurred by providers for the purpose of reporting quality measures and supports achieving the goals of transitioning to a fully digital quality measurement system identified in section IX.C.1. of the preamble of this proposed rule, including provision of timely feedback, leveraging the same data for multiple use cases, and contributing to a learning health system.

We intend to utilize standardized data for quality measurement as one-use case of digital data in a learning health system. In a learning health system, standardized digital data can support multiple use cases, including quality measurement, quality improvement efforts, clinical decision support, research, and public health. We believe that standardization across data elements and data models is necessary to ensure data are accessible across use cases and enable the transmission of data through each stage of the health system's learning process. Standardized data and FHIR APIs are important for advancing interoperability; the goal is for data to be sent and received via trusted exchanges, and for patients to have access to their data. Operations activities (for example, prior authorization) are also dependent on standardized, interoperable data. Additionally, standardization is necessary across implementation guides, or rules for how a particular interoperability standard should be used,[768] and across value sets that organize the specific terminologies and codes that define clinical concepts.[769]

Commenters on the RFI in the FY 2022 IPPS/LTCH PPS proposed rule encouraged the use of data elements for quality measurement that are consistent

[765] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[766] *https://www.hl7.org/implement/standards/product_brief.cfm?product_id=97.*

[767] *https://ecqi.healthit.gov/qrda.*

[768] Resource Implementation Guide—Content. Available at: *https://www.hl7.org/fhir/implementationguide.html.*

[769] National Library of Medicine, Value Set Authority Center. Available at: *https://vsac.nlm.nih.gov/.*

with ONC's USCDI standard,[770] where possible. We agree with this approach. To advance the use of standardized data, models, implementation guides, and value sets in quality measurement, we continue to focus on leveraging the interoperability data requirements for standardized APIs in certified health IT, set by the ONC 21st Century Cures Act final rule and any future updates made in rulemaking, as a vehicle to support modernization of CMS quality measure reporting. These API requirements are being implemented as part of a series of updates to certified health IT (85 FR 84825), and include availability of data included in the USCDI via standards-based APIs. In the CY 2021 Physician Fee Schedule final rule, we finalized that eligible clinicians and eligible hospitals and CAHs participating in the Merit-based Incentives Payment System (MIPS) and the Medicare Promoting Interoperability Program, respectively, must transition to use of certified technology updated consistent with the 2015 Edition Cures Update by 2023 (85 FR 84825). We aim to align with these standardized data requirements as the basis for data used in quality measurement.

We are collaborating with Federal agencies to define and prioritize additional data standardization needs and develop consensus with Federal partners on recommendations for future versions of the USCDI. We are also directly collaborating with ONC to build requirements to support data standardization and alignment with requirements for quality measurement. ONC recently launched the USCDI+ initiative focused on supporting identification and establishment of domain specific datasets that build on the core USCDI foundation.[771] A USCDI+ quality measurement domain currently being explored would support defining additional data specifications for quality measurement that harmonize, where possible, with other Federal agency data needs and inform supplemental standards necessary to support quality measurement.

We also received feedback on the RFI in the FY 2022 IPPS/LTCH PPS proposed rule that the use of Health Level Seven (HL7®) Implementation Guides should be foundational to FHIR measure reporting. To advance implementation of standardized data, we continue to collaborate with consensus standards-setting bodies such as HL7. We are considering how best to leverage existing implementation guides that are routinely updated and maintained by HL7 to define data standards and exchange mechanisms for FHIR-based dQMs, in a fashion that supports the learning health system and alignment across use cases, including the following existing HL7 Implementation Guides:

- US Core Implementation Guide;[772]
- Quality Improvement Core (QI Core) Implementation Guide;[773]
- Data Exchange for Quality Measures (DEQM) Implementation Guide;[774] and
- Quality Measure (QM) Implementation Guide.[775]

We are also considering what, if any, additional CMS-specific implementation guides may be necessary to support future digital quality measurement such as guidance on aggregation mechanisms for reporting.

We recognize the importance of considering how implementation guides used across quality measurement and other use cases (for example, public health reporting, clinical decision support) work together to support a learning health system. For example, the Clinical Guidelines (CPG) Implementation Guide[776] connects computable guidelines, clinical decision support, quality reporting, and case reporting. The mechanisms for reporting across use cases are also critical to consider, as each time a different mechanism for reporting is needed across different use cases, it creates more burden. We are collaborating closely with Federal partners, such as the Centers for Disease Control and Prevention (CDC), to align where possible.

We believe developing appropriately defined implementation guides will be a key component of supporting standardized FHIR APIs that enable access to standardized data elements for particular use cases, such as quality measurement.

We seek comment on the specific Implementation Guides noted previously, additional Implementation Guides we should consider, and other data and reporting components (for example, data vocabulary/terminology, alignment with other types of reporting) where standardization should be considered to advance data standardization for a learning health system.

4. Approaches To Achieve FHIR eCQM Reporting

We previously noted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45342) activities we are conducting to begin structuring and reporting eCQMs using FHIR. eCQMs are a subset of dQMs. We consider the transition to FHIR-based eCQM reporting the first step to dQM reporting, and a potential model for how future digital reporting can occur.

To support the transition, we continue to undertake and consider activities necessary for reporting of FHIR-based eCQMs and future dQMs:

- In the near term, we plan to continue to convert current Quality Data Model (QDM)-based eCQMs to the FHIR standard and test the implementation of measures respecified to FHIR and submission of data elements represented in FHIR through ongoing HL7 Connectathons.
- In the near term, we also plan to develop a unified CMS FHIR receiving system. This system would allow for a singular point of data receipt to be used for quality reporting requirements, and modernization of programmatic data receiving systems to leverage opportunities related to digital data.
- We are committed to working with implementers and partners to optimize interoperable data exchange to support FHIR-based eCQM reporting (for example, via FHIR APIs) and eventually other digital quality measures, while ensuring solutions and implementation that require patients to engage with technology also support health equity.
- In the near term, we plan to identify opportunities for the public to provide feedback on FHIR-based measure specifications prior to implementation, such as during measure development/conversion activities.
- We also plan to identify opportunities for collaboration with vendors and implementers via systems testing of FHIR-based eCQM reporting to ensure involvement in systems development.
- Finally, we are exploring venues for continued feedback on CMS future measurement direction and data aggregation approaches in anticipation of FHIR-based API reporting of eCQMs.
- To support both near term FHIR-based eCQMs and other future dQMs, as noted in section IX.C.3., we intend to continue engaging with standards development organizations to advance and maintain implementation guides to support the FHIR standard and API reporting of quality measures.

[770] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[771] USCDI+. Available at: *https://www.healthit.gov/topic/interoperability/uscdi-plus.*

[772] HL7 FHIR US Core Implementation Guide. Available at: *http://hl7.org/fhir/us/core/.*

[773] HL7 FHIR QI Core Implementation Guide. Available at: *http://hl7.org/fhir/us/qicore/.*

[774] HL7 Data Exchange For Quality Measures. Available at: *http://hl7.org/fhir/us/davinci-deqm/.*

[775] HL7 Quality Measure Implementation Guide. Available at: *http://hl7.org/fhir/us/cqfmeasures/.*

[776] HL7 FHIR Clinical Guidelines Implementation Guide. Available at: *http://hl7.org/fhir/uv/cpg/.*

• We also anticipate that prior to the implementation of any mandatory FHIR-based eCQM reporting requirements within our quality programs, it would be necessary to undertake voluntary reporting of FHIR-based eCQMs to allow time to learn and enhance systems and processes, both internally and among providers and vendors.

We also continue to consider how best to leverage the FHIR API technology implemented to meet ONC's interoperability requirements to access and electronically transmit interoperable data for quality measurement. Based on feedback on the FY 2022 IPPS/LTCH PPS proposed rule RFI, many supported the use of FHIR APIs, while others expressed concern around infrastructure readiness. We continue to explore how to leverage FHIR APIs to decrease reporting burden and support implementor readiness. We seek comment on approaches to optimize data flows for quality measurement to retrieve data from EHRs via FHIR APIs, and to combine data needed for measure score calculation for measures that require aggregating data across multiple providers (for example, risk-adjusted outcome measures) and multiple data sources (for example, hybrid claims-EHR measures). We are interested in data flows that support using the same data for measurement and to provide feedback to providers at multiple levels of accountability, such as at the individual clinician, group, accountable care organization and health plan levels, as are used for patient care and other use cases (for example public health reporting).

We seek comment on additional venues to engage with implementors during the transition to digital quality measurement, and other critical considerations during the transition. We also seek comment on data flow options to support FHIR-based eCQM reporting.

5. Solicitation of Comments

As noted previously, we seek input on the following:

• Refined potential future Definition of dQMs. We are seeking feedback on the following as described in section IX.C.2. of the preamble of this proposed rule:

++ Do you have feedback on the potential refined definition of digital quality measures (dQMs)?

++ Do you have feedback on potential considerations or challenges related to non-EHR data sources?

• Data Standardization Activities to Leverage and Advance Standards for Digital Data. We are seeking feedback on the following as described in section IX.C.3 of the preamble of this proposed rule:

++ Do you have feedback on the specific implementation guides we are considering, additional FHIR implementation guides we should consider, or other data and reporting components where standardization should be considered to advance data standardization for a learning health system?

• Approaches to Achieve FHIR eCQM Reporting. We are seeking feedback on the following as described in section IX.C.4. of the preamble of this proposed rule:

++ Are there additional venues to engage with implementors during the transition to digital quality measurement?

++ What data flow options should we consider for FHIR-based eCQM reporting, including retrieving data from EHRs via FHIR APIs and other mechanisms?

++ Are there other critical considerations during the transition?

D. Advancing the Trusted Exchange Framework and Common Agreement—Request for Information

Section 4003(b) of the 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, amended section 3001(c) of the Public Health Service Act (42 U.S.C. 300jj–11(c)), and required HHS to take steps to advance interoperability for the purposes of ensuring full network-to-network exchange of health information. Specifically, Congress directed the National Coordinator to ''develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' Since the enactment of the 21st Century Cures Act, HHS has pursued development of a Trusted Exchange Framework and Common Agreement (TEFCA). ONC's goals for TEFCA are as follows:

Goal 1: Establish a universal policy and technical floor for nationwide interoperability.

Goal 2: Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value.

Goal 3: Enable individuals to gather their health care information.[777]

On January 18, 2022, ONC announced a significant TEFCA milestone by releasing the Trusted Exchange Framework[778] and Common Agreement Version 1.[779] The Trusted Exchange Framework is a set of non-binding principles for health information exchange, and the Common Agreement for Nationwide Health Information Interoperability Version 1 (also referred to as Common Agreement) is a contract that advances those principles. The Common Agreement and the incorporated by reference Qualified Health Information Network (QHIN) Technical Framework Version 1 (QTF)[780] establish the technical infrastructure model and governing approach for different health information networks and their users to securely share clinical information with each other, all under commonly agreed to terms. The Common Agreement is a legal contract that QHINs[781] sign with the ONC Recognized Coordinating Entity (RCE),[782] a private-sector entity that implements the Common Agreement and ensures QHINs comply with its terms.

The technical and policy architecture of how exchange occurs under TEFCA follows a network-of-networks structure, which allows for connections at different levels and is inclusive of many different types of entities at those different levels, such as health information networks, care practices, hospitals, public health agencies, and Individual Access Services (IAS)[783]

[777] See *https://www.healthit.gov/buzz-blog/interoperability/321tefca-is-go-for-launch.*

[778] Trusted Exchange Framework (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf.*

[779] Common Agreement for Nationwide Health Information Interoperability Version 1 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[780] Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf.*

[781] The Common Agreement defines a QHIN as ''to the extent permitted by applicable SOP(s), a Health Information Network that is a U.S. Entity that has been Designated by the RCE and is a party to the Common Agreement countersigned by the RCE.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 10 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-.*

[782] In August 2019, ONC awarded a cooperative agreement to The Sequoia Project to serve as the initial RCE. The RCE will operationalize and enforce the Common Agreement, oversee QHIN-facilitated network operations, and ensure compliance by participating QHINs. The RCE will also engage stakeholders to create a roadmap for expanding interoperability over time. *See* ONC Awards The Sequoia Project a Cooperative Agreement for the Trusted Exchange Framework and Common Agreement to Support Advancing Nationwide Interoperability of Electronic Health Information (September 3, 2019), *https://sequoiaproject.org/onc-awards-the-sequoia-project-a-cooperative-agreement-for-the-trusted-exchange-framework-and-common-agreement-to-support-advancing-nationwide-interoperability-of-electronic-health-information.*

[783] The Common Agreement defines Individual Access Services (IAS) as ''with respect to the Exchange Purposes definition, the services

Continued

Providers.[784] QHINs connect directly to each other to facilitate nationwide interoperability, and each QHIN can connect Participants, which can connect Subparticipants.[785] Compared to most nationwide exchange today, the Common Agreement includes an expanded set of Exchange Purposes beyond Treatment to include Individual Access Services, Payment, Health Care Operations, Public Health, and Government Benefits Determination [786]—all built upon common technical and policy requirements to meet key needs of the U.S. health care system. This flexible structure allows stakeholders to participate in the way that makes most sense for them, while supporting simplified, seamless exchange.

The QTF,[787] which was developed and released by the RCE, describes the functional and technical requirements that a Health Information Network (HIN) [788] must fulfill to serve as a QHIN under the Common Agreement. The QTF specifies the technical underpinnings for QHIN-to-QHIN exchange and certain other responsibilities described in the Common Agreement. The technical and functional requirements described in the QTF enable different types of information exchange, including querying and message delivery across participating entities.

In 2022, prospective QHINs are anticipated to begin signing the Common Agreement and applying for designation. The RCE will then begin onboarding and designating QHINs to share information. In 2023, HHS expects stakeholders across the care continuum to have increasing opportunities to enable exchange under TEFCA. Specifically, this would mean such stakeholders would be: (1) Signatories to either the Common Agreement or an agreement that meets the flow-down requirements of the Common Agreement (called a Framework Agreement [789] under the Common Agreement), (2) in good standing (that is, not suspended) under that agreement, and (3) enabling secure, bi-directional exchange of information to occur, in production. TEFCA is expected to give individuals and entities easier, more efficient, access to more health information while requiring strong privacy and security protections.

We believe that exchange of health information enabled by the Common Agreement can advance CMS policy and program objectives related to care coordination, cost efficiency, and patient-centeredness in a variety of ways. We also believe that CMS policy and programs can help to accelerate nationwide connectivity through TEFCA by health care providers as well as other stakeholders.

As discussed in section IX.D. of the preamble of this proposed rule, we are proposing to add a new Enabling Exchange Under TEFCA measure in the Medicare Promoting Interoperability Program. This proposed measure would provide eligible hospitals and CAHs with the opportunity to earn credit for the Health Information Exchange objective if They: Are a signatory to a ''Framework Agreement'' as that term is defined in the Common Agreement; enable secure, bi-directional exchange of information to occur for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments; and use the functions of certified EHR technology (CEHRT) to support bi-directional exchange.

In addition to this proposal, we are considering other ways that available CMS policy and program levers can advance information exchange under TEFCA. For instance, similar to the proposal in the current rule, there may be opportunities for CMS to incentivize exchange under TEFCA through other programs that incentivize high quality care, or through program features in value-based payment models that encourage certain activities that can improve care delivery.

In addition to programs focused on providers, we are interested in opportunities to encourage exchange under TEFCA through CMS regulations for certain health care payers, including Medicare Advantage, Medicaid Managed Care, and CHIP issuers. For instance, we believe there may be opportunities to encourage information exchange under TEFCA to support recently finalized requirements for these payers to make information available to patients and to make patient information available to other payers as beneficiaries transition between plans in the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers'' final rule (85 FR 25510). Finally, we are considering future opportunities to encourage information exchange under TEFCA for payment and operations activities such as submission of clinical documentation to support claims adjudication and prior authorization processes.

We are requesting input from the public on the ideas described previously and related concepts for future exploration, as well as the following questions:

- What are the most important use cases for different stakeholder groups that could be enabled through widespread information exchange under TEFCA? What key benefits would be associated with effectively implementing these use cases, such as improved care coordination, reduced burden, or greater efficiency in care delivery?
- What are key ways that the capabilities of TEFCA can help to

provided utilizing the Connectivity Services, to the extent consistent with Applicable Law, to an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[784] The Common Agreement defines ''IAS Provider'' as: ''Each QHIN, Participant, and Subparticipant that offers Individual Access Services.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[785] For the Common Agreement definitions of QHIN, Participant, and Subparticipant, *see* Common Agreement for Nationwide Health Information Interoperability Version 1, at 8–12 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[786] For the Common Agreement definitions of Payment, Health Care Operations, Public Health, and Government Benefits Determination, *see* Common Agreement for Nationwide Health Information Interoperability Version 1, at 6–10 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[787] Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf.*

[788] ''Health Information Network'' under TEFCA has the meaning assigned to the term ''Health Information Network or Health Information Exchange'' in the information blocking regulations at 45 CFR 171.102.

[789] The Common Agreement defines ''Framework Agreement(s)'' as: ''any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.'' See Common Agreement for Nationwide Health Information Interoperability Version 1, at 6 (Jan. 2022) *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

advance the goals of CMS programs? Should CMS explore policy and program mechanisms to encourage exchange between different stakeholders, including those in rural areas, under TEFCA? In addition to the ideas discussed previously, are there other programs CMS should consider in order to advance exchange under TEFCA?

- How should CMS approach incentivizing or encouraging information exchange under TEFCA through CMS programs? Under what conditions would it be appropriate to require information exchange under TEFCA by stakeholders for specific use cases?
- What concerns do commenters have about enabling exchange under TEFCA? Could enabling exchange under TEFCA increase burden for some stakeholders? Are there other financial or technical barriers to enabling exchange under TEFCA? If so, what could CMS do to reduce these barriers?

E. Hospital Inpatient Quality Reporting (IQR) Program

1. Background and History of the Hospital IQR Program

Through the Hospital IQR Program, we strive to put patients first by ensuring they are empowered to make decisions about their own healthcare along with their clinicians by using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high-quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care, while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with CMS programs. In combination with other efforts across HHS, we believe the Hospital IQR Program incentivizes hospitals to improve healthcare quality and value, while giving patients the tools and information needed to make the best decisions for themselves.

We seek to promote higher quality and more efficient healthcare for Medicare beneficiaries. The adoption of widely agreed upon quality and cost measures supports this effort. We work with relevant stakeholders to define measures in almost every care setting and currently measure some aspect of care for almost all Medicare beneficiaries. These measures assess clinical processes, patient safety and adverse events, patient experiences with care, care coordination, and clinical outcomes, as well as cost of care. We have implemented quality measure reporting programs for multiple settings of care. To measure the quality of hospital inpatient services, we implemented the Hospital IQR Program, previously referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program. We refer readers to the following final rules for detailed discussions of the history of the Hospital IQR Program, including statutory history, and for the measures we have previously adopted for the Hospital IQR Program measure set:

- The FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861).
- The FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181).
- The FY 2012 IPPS/LTCH PPS final rule (76 FR 51605 through 61653).
- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53555).
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50775 through 50837).
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249).
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692).
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150).
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 82 FR 38348).
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609).
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509).
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58926 through 58959).
- The FY 2022 IPPS/LTCH PPS final rule (86 FR 45360 through 45426).

We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations.

2. Retention of Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513) for our finalized measure retention policy. Pursuant to this policy, when we adopt measures for the Hospital IQR Program beginning with a particular payment determination, we automatically readopt these measures for all subsequent payment determinations unless a different or more limited time period is proposed and finalized. Measures are also retained unless we propose to remove, suspend, or replace the measures. We are not proposing any changes to these policies in this proposed rule.

3. Removal Factors for Hospital IQR Program Measures

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a summary of the Hospital IQR Program's removal factors. We are not proposing any changes to these policies in this proposed rule.

4. Considerations in Expanding and Updating Quality Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the previous considerations we have used to expand and update quality measures under the Hospital IQR Program. We also refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 41148), in which we describe the Meaningful Measures Framework, our objectives under this Framework for quality measurement, and the quality topics that we have identified as high-impact measurement areas that are relevant and meaningful to both patients and providers. In 2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality, and to address a wide variety of settings, stakeholders, and measure requirements (we note that Meaningful Measures 2.0 is still under development).[790] We are not proposing any changes to these policies in this proposed rule.

We also note that the Hospital IQR Program must first adopt measures and publicly report them on the Compare tool hosted by HHS, currently available at *https://www.medicare.gov/care-compare,* or its successor website, for at least one year before the Hospital Value-Based Purchasing (VBP) Program is able to adopt them. We view the value-based purchasing programs, including the Hospital VBP Program, as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare from a passive payer of claims into an active purchaser of quality healthcare for its beneficiaries.

5. New Measures Being Proposed for the Hospital IQR Program Measure Set

In this proposed rule, we are proposing to adopt 10 new measures, including four electronic clinical quality measures (eCQMs): (1) Hospital Commitment to Health Equity measure, beginning with the CY 2023 reporting period/FY 2025 payment determination;

[790] Centers for Medicare and Medicaid Services. (2021). Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.* We note that Meaningful Measures 2.0 is still under development.

(2) Screening for Social Drivers of Health measure, beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (3) Screen Positive Rate for Social Drivers of Health measure, beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (4) Cesarean Birth eCQM, beginning with the CY 2023 reporting period/FY 2025 payment determination and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (5) Severe Obstetric Complications eCQM, beginning with the CY 2023 reporting period/FY 2025 payment determination and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (6) Hospital-Harm—Opioid-Related Adverse Events eCQM, beginning with the CY 2024 reporting period/FY 2026 payment determination; (7) Global Malnutrition Composite Score eCQM, beginning with the CY 2024 reporting period/FY 2026 payment determination; (8) Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA), beginning with two voluntary reporting periods followed by mandatory reporting for the reporting period which runs from July 1, 2025, through June 30, 2026, impacting the FY 2028 payment determination; (9) Medicare Spending Per Beneficiary (MSPB) Hospital measure beginning with the FY 2024 payment determination; and (10) Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total THA/TKA measure beginning with the FY 2024 payment determination.

We provide more details on each of these proposals in the subsequent sections.

a. Proposed Hospital Commitment to Health Equity Measure Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination and for Subsequent Years

(1) Background

Significant and persistent disparities in healthcare outcomes exist in the U.S. For example, belonging to a racial or ethnic minority group, living with a disability, being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, being a member of a religious minority, living in a rural area, or being near or below the poverty level, is often associated with worse health outcomes.[791] [792] [793] [794] [795] [796] [797] [798] [799] [800] Numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of hospital care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.[801] [802] [803] [804] [805] [806] Readmission rates in the Hospital Readmission Reduction Program have shown to be higher among Black and Hispanic Medicare beneficiaries with common conditions, including congestive heart failure and acute myocardial infarction.[807] [808] [809] [810] [811] Data indicate that, even after accounting for factors such as socioeconomic conditions, members of racial and ethnic minority groups reported experiencing lower quality of healthcare.[812] Evidence of differences in quality of care received among racial and ethnic minority groups show worse health outcomes including diabetes complications such as retinopathy.[813] Additionally, inequities in the social determinants of health affecting these groups, such as poverty and healthcare

[791] Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *JAMA,* 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

[792] Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income Inequality and thirty-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. *BMJ,* 346. Available at: *https://doi.org/10.1136/bmj.f521.*

[793] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and Equity of Care in U.S. Hospitals. *N Engl J Med,* 371(24), 2298–2308. Available at: doi: 10.1056/NEJMsa1405003.

[794] Polyakova, M, Udalova V, Kocks, G, Genadek K, Finlay K, Finkelstein AN. (2021). Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. *Health Affairs,* 40(2), 307–316. Available at: *https://doi.org/10.1377/hlthaff.2020.02142.*

[795] Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[796] HHS Office of Minority Health. (2020). Progress Report to Congress, 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Department of Health and Human Services. Available at: *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[797] Heslin KC, Hall JE. (2021). Sexual Orientation Disparities in Risk Factors for Adverse COVID–19–Related Outcomes, by Race/Ethnicity—Behavioral Risk Factor Surveillance System, United States, 2017–2019. MMWR Morb Mortal Wkly Rep, 70(5), 149. doi: 10.15585/mmwr.mm7005a1.

[798] Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. medRxiv. doi: 10.1101/2020.07.21.20159327.

[799] Vu M, Azmat A, Radejko T, Padela AI. (2016). Predictors of Delayed Healthcare Seeking Among American Muslim Women. *Journal of Women's Health,* 25(6), 586–593. doi: 10.1089/jwh.2015.5517.

[800] Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016). The Association Between Discrimination and the Health of Sikh Asian Indians. *Health Psychology,* 35(4), 351–355. *https://doi.org/10.1037/hea0000268.*

[801] CMS Office of Minority Health. (2020). Racial, Ethnic, and Gender Disparities in Healthcare in Medicare Advantage. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/files/document/2020-national-level-results-race-ethnicity-and-gender-pdf.pdf.*

[802] CMS Office of Minority Health. (Updated August 2018). Guide to Reducing Disparities in Readmissions. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[803] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. (2014). Racial Disparities in Knee and Hip Total Joint Arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis., 73(12), 2107–15. Available at: doi:10.1136/annrheumdis–2013–203494.

[804] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. (2019). Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc., 67(8), 1672–1679. Available at: *https://doi.org/10.1111/jgs.15960.*

[805] Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA, 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

[806] Tsai TC, Orav EJ, Joynt KE. (2014). Disparities in Surgical 30-day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. Ann Surg., 259(6), 1086–1090. Available at: doi: 10.1097/SLA.0000000000000326.

[807] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. (2011). Readmission Rates for Hispanic Medicare Beneficiaries with Heart Failure and Acute Myocardial Infarction. Am Heart J., 162(2), 254–261 e253. Available at: *https://doi.org/10.1016/j.ahj.2011.05.009.*

[808] Centers for Medicare & Medicaid Services. (2014). Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures. Available at: *https://www.hhs.gov/guidance/document/medicare-hospital-quality-chartbook-performance-report-outcome-measures.*

[809] CMS Office of Minority Health. (Updated August 2018). Guide to Reducing Disparities in Readmissions. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[810] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. (2013). Chronic Obstructive Pulmonary Disease Readmissions at Minority-Serving Institutions. Ann Am Thorac Soc., 10(6), 680–684. Available at: *https://doi.org/10.1513/AnnalsATS.201307-223OT.*

[811] Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA, 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

[812] Nelson AR. (2003). Unequal Treatment: Report of the Institute of Medicine on Racial and Ethnic Disparities in Healthcare. The Annals of thoracic surgery, 76(4), S1377–S1381. doi: 10.1016/s0003–4975(03)01205–0.

[813] Peek, ME, Odoms-Young, A, Quinn, MT, Gorawara-Bhat, R, Wilson, SC, & Chin, MH. (2010). Race and Shared Decision-Making: Perspectives of African-Americans with diabetes. Social science & medicine, 71(1), 1–9. Available at: doi:10.1016/j.socscimed.2010.03.014.

access, are interrelated and influence a wide range of health and quality-of-life outcomes and risks.[814]

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25592), we identified potential opportunities specific to the Hospital IQR Program by which we could leverage current measures or develop new measures to address the gap in healthcare disparities. In that rule, we sought public comment on addressing this gap, specifically requesting input on the inclusion of a structural measure to assess the degree of hospital leadership commitment to collecting and monitoring health equity performance data. We sought feedback on conceptual and measurement priorities to better illuminate organizational efforts to improve health equity, and on an appropriate measure regarding organizational commitment to health equity and accessibility for individuals with intellectual and developmental disabilities (86 FR 25593). In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45414 through 45416), we summarized the public comments we received, including support for the development and implementation of a health equity structural measure. We refer readers to the ''Closing the Health Equity Gap in CMS Quality Programs—Request for Information'' (86 FR 45349) and ''Potential Future Efforts to Address Health Equity in the Hospital IQR Program'' (86 FR 45414) in the FY 2022 IPPS/LTCH PPS final rule for more details.

We note that the Agency for Healthcare Research and Quality (AHRQ) and The Joint Commission identified that hospital leadership plays an important role in promoting a culture of quality and safety.[815] [816] AHRQ research shows that hospital boards can influence quality and safety in a variety of ways; not only through strategic initiatives, but also through more direct interactions with frontline workers.[817] Because we are working toward the goal of all patients receiving high quality healthcare when hospitalized, regardless of individual characteristics, we are committed to supporting healthcare organizations in building a culture of equity that focuses on educating and empowering their workforce to recognize and eliminate health disparities. This includes patients receiving the right care, at the right time, in the right setting for their condition(s), regardless of those characteristics.

We believe that strong and committed leadership from hospital executives and board members is essential and can play a role in shifting organizational culture and advancing equity goals. Additionally, studies demonstrate that hospital leadership can positively influence culture for better quality, patient outcomes, and experience of care.[818] [819] [820] A systematic review of 122 published studies showed that strong leadership that prioritized safety, quality, and the setting of clear guidance with measurable goals for improvement resulted in a high-performing hospital with better patient outcomes.[821] We believe leadership commitment to health equity will have a parallel effect in contributing to a reduction in health disparities.

The Institute of Healthcare Improvement's (IHI's) research of 23 health systems throughout the U.S. and Canada also shows that health equity must be a priority championed by leadership teams to improve both patient access to needed healthcare services and outcomes among disadvantaged populations.[822] This IHI study specifically identified concrete actions to make health equity a core strategy, including making health equity a leader-driven priority alongside organizational development structures and processes that support equity.[823] Based upon these findings, we believe that hospital leadership can be instrumental in setting specific, measurable, attainable, realistic, and time-based (SMART) goals to assess progress towards achieving equity priorities and ensuring high-quality care is equally accessible to all individuals. Therefore, we are proposing to adopt an attestation-based structural measure, Hospital Commitment to Health Equity, beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years.

The first pillar of our strategic priorities[824] reflects our deep commitment to improvements in healthcare equity by addressing the health disparities that underly our health system. We developed this structural measure to assess hospital commitment to health equity across five domains (see Table IX.E–01. in the subsequent section) using a suite of organizational competencies aimed at achieving health equity for racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. We believe these elements are actionable focus areas, and assessment of hospital leadership commitment to them is foundational. We also believe this measure will incentivize providers to collect and utilize data to identify critical equity gaps, implement plans to address said gaps, and ensure that resources are dedicated toward addressing healthcare equity initiatives. While many factors contribute to health equity, we believe this measure is an important step toward assessing hospital leadership commitment, and a fundamental step toward closing the gap in equitable care for all populations. We note that this measure is not intended to encourage hospitals to take action on any one given element of collected data, but instead encourages hospitals to analyze their own data to understand many factors, including race, ethnicity, and various social drivers of health, such as housing status and food security, in order to deliver more equitable care.

[814] Department of Health and Human Services. (2021). Healthy People 2020: Disparities. Available at: *www.healthypeople.gov/2020/about/foundation-health-measures/Disparities.*

[815] Agency for Healthcare Research and Quality. Leadership Role in Improving Patient Safety. Patient Safety Primer, September 2019. Available at: *https://psnet.ahrq.gov/primer/leadership-role-improving-safety.*

[816] Joint Commission on Accreditation of Healthcare Organizations, USA. Leadership Committed to Safety. Sentinel Event Alert. 2009 Aug 27;(43):1–3. PMID: 19757544.

[817] Agency for Healthcare Research and Quality. Leadership Role in Improving Patient Safety. Patient Safety Primer, September 2019: Available at: *https://psnet.ahrq.gov/primer/leadership-role-improving-safety.*

[818] Bradley EH, Brewster AL, McNatt Z, et al. (2018) How Guiding Coalitions Promote Positive Culture Change in Hospitals: A Longitudinal Mixed Methods Interventional Study. BMJ Qual Saf., 27(3), 218–225. doi:10.1136/bmjqs–2017–006574.

[819] Smith SA, Yount N, Sorra J. (2017). Exploring Relationships Between Hospital Patient Safety Culture and Consumer Reports Safety Scores. BMC Health Services Research, 17(1), 143. doi:10.1186/s12913-017-2078-6.

[820] Keroack MA, Youngberg BJ, Cerese JL, Krsek C, Prellwitz LW, Trevelyan EW. (2007). Organizational Factors Associated with High Performance in Quality and Safety in Academic Medical Centers. Acad Med., 82(12), 1178–86. doi: 10.1097/ACM.0b013e318159e1ff.

[821] Millar R, Mannion R, Freeman T, et al. (2013). Hospital Board Oversight of Quality and Patient Safety: A Narrative Review and Synthesis of Recent Empirical Research. The Milbank quarterly, 91(4), 738–70. doi:10.1111/1468–0009.12032.

[822] Mate KS and Wyatt R. (2017). Health Equity Must Be a Strategic Priority. NEJM Catalyst. Available at: *https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556.*

[823] Mate KS and Wyatt R. (2017). Health Equity Must Be a Strategic Priority. NEJM Catalyst. Available at: *https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556.*

[824] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

We believe this measure builds on current health disparities reporting, supports hospitals in quality improvement, promotes efficient and effective use of resources, and leverages available data. The five questions of the proposed structural measure are adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement.[825]

This measure also aligns with our efforts under the Meaningful Measures Framework, which identifies high-priority areas for quality measurement and improvement to assess core issues most critical to high-quality healthcare and improving patient outcomes.[826] In 2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality, and to address a wide variety of settings, stakeholders, and measure requirements.[827] We plan to address healthcare priorities and gaps with Meaningful Measures 2.0 by leveraging quality measures to promote equity and close gaps in care. The Hospital Commitment to Health Equity measure supports these efforts and is aligned with the Meaningful Measures Area of ''Equity of Care'' and the Meaningful Measures 2.0 goal to ''Leverage Quality Measures to Promote Equity and Close Gaps in Care.'' This measure also supports the Meaningful Measures 2.0 objective to ''Commit to a patient-centered approach in quality measure and value-based incentives programs to ensure that quality and safety measures address healthcare equity.''

(2) Overview of Measure

The Hospital Commitment to Health Equity measure assesses hospital commitment to health equity using a suite of equity-focused organizational competencies aimed at achieving health equity for racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. Table IX.E–01 includes the five attestation domains and the elements within each of those domains that a hospital must affirmatively attest to for the hospital to receive credit for that domain.

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[825] Centers for Medicare & Medicaid Services. (2021). Building an Organizational Response to Health Disparities [Fact Sheet]. U.S. Department of Health and Human Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf.*

[826] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

[827] Centers for Medicare & Medicaid Services. (2021). Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.* We note that Meaningful Measures 2.0 is still under development.

TABLE IX.E-01. THE HOSPITAL COMMITMENT TO HEALTH EQUITY MEASURES FIVE ATTESTATIONS

Attestation	Elements: Select all that apply (Note: Affirmative attestation of all elements within a domain would be required for the hospital to receive a point for the domain in the numerator)
Domain 1: Equity is a Strategic Priority	
Hospital commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your hospital has a strategic plan for advancing healthcare equity and that it includes all the following elements.	(A) Our hospital strategic plan identifies priority populations who currently experience health disparities. (B) Our hospital strategic plan identifies healthcare equity goals and discrete action steps to achieving these goals. (C) Our hospital strategic plan outlines specific resources which have been dedicated to achieving our equity goals. (D) Our hospital strategic plan describes our approach for engaging key stakeholders, such as community-based organizations.
Domain 2: Data Collection	
Collecting valid and reliable demographic and social determinant of health data on patients served in a hospital is an important step in identifying and eliminating health disparities. Please attest that your hospital engages in the following activities.	(A) Our hospital collects demographic information, including self-reported race and ethnicity and/or social determinant of health information on the majority of our patients. (B) Our hospital has training for staff in culturally sensitive collection of demographic and/or social determinant of health information. (C) Our hospital inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using a certified EHR technology.
Domain 3: Data Analysis	
Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your hospital engages in the following activities.	(A) Our hospital stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on hospital performance dashboards.
Domain 4: Quality Improvement	
Health disparities are evidence that high-quality care has not been delivered equally to all patients. Engagement in quality improvement activities can improve quality of care for all patients.	(A) Our hospital participates in local, regional, or national quality improvement activities focused on reducing health disparities.
Domain 5: Leadership Engagement	
Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your hospital engages in the following activities.	(A) Our hospital senior leadership, including chief executives and the entire hospital board of trustees, annually reviews our strategic plan for achieving health equity. (B) Our hospital senior leadership, including chief executives and the entire hospital board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors.

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The Hospital Commitment to Health Equity measure was included in the publicly available ''List of Measures Under Consideration for December 1, 2021'' (MUC List), a list of measures under consideration for use in various Medicare programs.[828] The National Quality Forum (NQF) Measure Applications Partnership (MAP) Rural Health Advisory Group reviewed the MUC List and the Hospital Commitment to Health Equity measure (MUC 2021–106) in detail on December 8, 2021.[829] The MAP Rural Health Workgroup initially raised concerns that this measure may cause undue burden to

[828] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96464.*

[829] National Quality Forum. (2021). Measure Applications Partnership Rural Health Advisory Group Virtual Review Meeting: Meeting Summary for December 8, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96571.*

rural hospitals that may not yet be directing resources or have available resources to dedicate toward implementing the measure. We acknowledge that for some hospitals, the implementation of this structural measure may impose additional data collection efforts. However, we believe this measure builds on hospitals' current quality improvement activities through participation in the Hospital IQR Program. Additionally, we believe the activities outlined in the previous table are foundational best practices for advancing health equity for patients and communities. The Rural Health Workgroup agreed that this is an important measure and for that reason should be added to the Hospital IQR Program measure set as the intent of the measure is to identify these gaps and make the needed investments in workforce training, leadership development, and other related areas to improve equity.[830] The MAP Rural Health Workgroup's recommendation was majority support for the Hospital Commitment to Health Equity measure.[831]

In addition, on December 9, 2021, the MAP Health Equity Advisory Group reviewed the 2021 MUC List.[832] The MAP Health Equity Advisory Group was convened at the request of CMS to provide input on the MUC List with the goal of reducing health disparities closely linked with social, economic, or environmental disadvantages.[833] The MAP Health Equity Advisory Group is charged with providing feedback related to the relative priority of each measure in advancing health equity, and input on potential data, reporting, and/or methodological concerns on reporting measures adjusting for healthcare disparities.[834] The MAP Health Equity Advisory Group provided input on potential unintended consequences or measurement gap areas related to health disparities.[835] After discussion of each measure under consideration, the Workgroup was polled on the potential impact on health disparities if the measure were to be included in a specific program. Like the MAP Rural Health Advisory Group, the MAP Health Equity Advisory Group agreed this is an important measure for advancing healthcare equity in the Hospital IQR Program and a fundamental first step toward future measure development and innovation.[836] The MAP Health Equity Advisory Group's feedback was supportive of this measure and its potential to decrease health disparities.[837]

The MUC List, including this measure (MUC2021–106), was also reviewed by the MAP Hospital Workgroup on December 15, 2021.[838] MAP stakeholders expressed concerns about whether measure data will be actionable and how improvements in clinical healthcare equity outcomes will be measured.[839] The MAP Hospital Workgroup had concerns about how this measure would be publicly reported, specifically, how it would be and interpreted by patients/consumers.[840] For these reasons, the MAP Hospital Workgroup recommended that the MAP not support the measure for rulemaking.[841] In response to this feedback, we wish to explain that we would publicly report the numerator indicating how many of the competencies hospitals attest to, and we refer readers to section IX.E.5.a.(3). for our proposed measure calculation methodology and section IX.E.5.a.(4). for the proposed public reporting. Thereafter, the MAP Coordinating Committee deliberated and ultimately voted to conditionally support this measure for rulemaking given its importance in being a first step towards the future development of outcome-based measures.[842] We agree that this measure is an important foundation of a comprehensive quality reporting program. Our approach to developing health equity measures is incremental and will evolve over time to capture healthcare equity outcomes in the Hospital IQR Program. We additionally believe this measure to be a building block that lays the groundwork for a future meaningful suite of measures that would assess progress in providing high-quality healthcare for all patients regardless of social risk factors or demographic characteristics.

We have not submitted this measure for NQF endorsement at this time. We note that under section 1866(b)(3)(B)(viii)(IX)(aa) of the Act, each measure specified by the Secretary shall be endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to a measure that has been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures on this topic, and, therefore we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

[830] National Quality Forum. (2021). Measure Applications Partnership Rural Health Advisory Group Virtual Review Meeting: Meeting Summary for December 8, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96571.*

[831] National Quality Forum. (2021). Measure Applications Partnership Rural Health Advisory Group Virtual Review Meeting: Meeting Summary for December 8, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96571.*

[832] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96464.*

[833] National Quality Forum. (2022). Measure Applications Partnership Health Equity Advisory Group Virtual Review Meeting: Meeting Summary for December 9, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96599.*

[834] National Quality Forum. (2022). Measure Applications Partnership Health Equity Advisory Group Virtual Review Meeting: Meeting Summary for December 9, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96599.*

[835] National Quality Forum. (2022). Measure Applications Partnership Health Equity Advisory Group Virtual Review Meeting: Meeting Summary for December 9, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96599.*

[836] National Quality Forum. (2022). Measure Applications Partnership Health Equity Advisory Group Virtual Review Meeting: Meeting Summary for December 9, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96599.*

[837] National Quality Forum. (2022). Measure Applications Partnership Health Equity Advisory Group Virtual Review Meeting: Meeting Summary for December 9, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96599.*

[838] National Quality Forum. (2022). Measure Applications Partnership Hospital Workgroup Web Review Meeting: Meeting Summary for December 15, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96629.*

[839] National Quality Forum. (2022). Measure Applications Partnership Hospital Workgroup Web Review Meeting: Meeting Summary for December 15, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96629.*

[840] National Quality Forum. (2022). Measure Applications Partnership Hospital Workgroup Web Review Meeting: Meeting Summary for December 15, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96629.*

[841] National Quality Forum. (2022). Measure Applications Partnership Hospital Workgroup Web Review Meeting: Meeting Summary for December 15, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96629.*

[842] National Quality Forum. (2022). Measure Applications Partnership (MAP) 2021–2022 Final Recommendations. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.*

(3) Measure Calculation

The proposed Hospital Commitment to Health Equity measure consists of five domains, and a hospital would need to evaluate and determine whether it can affirmatively attest to each domain. Some of these domains have multiple elements to which a hospital must attest. For a hospital to affirmatively attest to a domain, and receive credit for that domain, the hospital would evaluate and determine whether it engages in each of the elements that comprise the domain. We are proposing that each of the domains would be represented in the denominator as a point, for a total of 5 points (one per domain).

For example, for Domain 1 (''Hospital commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority''), a hospital would evaluate and determine whether its strategic plan meets each of the elements described in (A) through (D) (see Table IX.E–01.). If the hospital's plan meets all four of these elements, the hospital would affirmatively attest to Domain 1 and would receive a point for that attestation. A hospital would not be able to receive partial credit for a domain. In other words, if a hospital's strategic plan meets elements (A) and (B) but not (C) and (D), the hospital would not be able to affirmatively attest to Domain 1 and would not receive a point for that attestation.

The numerator would capture the total number of domain attestations that the hospital is able to affirm. For example, a hospital that affirmatively attests each element of the 5 domains would receive the maximum 5 points.

(4) Data Submission and Reporting

Specifications for the proposed measure are available on the CMS Measure Methodology page with the file name ''Hospital Commitment to Health Equity Structural Measure Specifications'' at *https://qualitynet.cms.gov/inpatient/iqr/resources.* Hospitals are required to submit information for structural measures once annually using a CMS-approved web-based data collection tool available within the Hospital Quality Reporting (HQR) System. We propose that hospitals would follow established submission and reporting requirements as previously finalized for structural measures and refer readers to section IX.E.10.i. of the preamble of this proposed rule for more details on our previously finalized data submission and deadline requirements for structural measures.

We are proposing this measure for the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. In developing this proposal, we considered proposing an incremental approach to the implementation of this measure. However, we ultimately decided to propose mandatory reporting given the importance of this measure and how it aligns with our healthcare quality goal of closing the racial and ethnic disparity gaps.

We invite public comment on this proposal.

b. Proposed Adoption of Two Social Drivers of Health Measures Beginning With Voluntary Reporting in the CY 2023 Reporting Period and Mandatory Reporting Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

Health-related social needs (HRSNs), which we have previously defined as individual-level, adverse social conditions that negatively impact a person's health or healthcare, are significant risk factors associated with worse health outcomes as well as increased healthcare utilization.[843] We believe that consistently pursuing identification of HRSNs will have two significant benefits. First, because social risk factors disproportionately impact underserved communities, promoting screening for these factors could serve as evidence-based building blocks for supporting hospitals and health systems in actualizing commitment to address disparities, improve health equity through addressing the social needs with community partners, and implement associated equity measures to track progress.[844] Second, these measures could support ongoing hospital quality improvement initiatives by providing data with which to stratify patient risk and organizational performance.

Further, we believe collecting patient-level HRSN data through screening is essential in the long-term in encouraging meaningful collaboration between healthcare providers and community-based organizations and in implementing and evaluating related innovations in health and social care delivery. We note that advancing health equity by addressing the health disparities that underlie the country's health system is one of our strategic pillars[845] and a Biden-Harris Administration priority.

As a first step towards addressing the role of HRSNs in closing the health equity gap, we have developed two evidence-based measures—Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health. These two proposed Social Drivers of Health measures will support identification of specific risk factors for inadequate healthcare access and adverse health outcomes among patients. We note that these measures would enable systematic collection of HRSN data which aligns with our other efforts, including the CY 2023 Medicare Advantage and Part D proposed rule in which we are proposing that all Special Needs Plans (SNPs) complete health risk assessments (HRAs) of enrollees that include specific standardized questions on housing stability, food security, and access to transportation (87 FR 1858).

These standardized measures would identify patients with HRSNs, who are known to experience the greatest risk of poor health outcomes, thereby improving the accuracy of high-risk prediction calculations. Improvement in risk prediction has the potential to reduce healthcare access barriers, address the disproportionate expenditures attributed to high-risk population groups, and improve the hospital's quality of care.[846] [847] [848] [849] Further, these data could guide future

[843] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.* Accessed: November 23, 2021.

[844] American Hospital Association. (2020). Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. December 2020. Accessed: January 18, 2022. Available at: *https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf.*

[845] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

[846] Baker, M.C., Alberti, P.M., Tsao, T.Y., Fluegge, K., Howland, R.E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. Health Affairs, 40(4), 645–654. Available at: *https://doi.org/10.1377/hlthaff.2020.01742.*

[847] Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290–299. Available at: *https://doi.org/10.1161/CIRCOUTCOMES.120.006752.*

[848] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://care.diabetesjournals.org/lookup/doi/10.2337/dci20-0053.*

[849] Jaffrey, J.B., Safran, G.B., Addressing Social Risk Factors in Value-Based Payment: Adjusting Payment Not Performance to Optimize Outcomes and Fairness. Health Affairs Blog, April 19, 2021. Available at: *https://www.healthaffairs.org/do/10.1377/forefront.20210414.379479/full/.*

public and private resource allocation to promote targeted collaboration between hospitals and health systems and appropriate community-based organizations and ultimately contribute to improved patient outcomes following inpatient hospitalization.

In this proposed rule, we are proposing voluntary reporting of these two measures beginning with the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We believe incremental implementation of these measures beginning with one year of voluntary reporting would allow hospitals who are not yet screening patients for HRSNs to get experience with the measure and equally allow hospitals who already undertake screening efforts to report data already being collected.

We provide further details on both proposed measures in the subsequent discussion. Additionally, consistent with our strategy to incorporate social drivers of health factors into Medicare quality reporting and payment, we refer readers to section II.D.13.(d). where we are seeking comment on how the reporting of diagnosis codes may improve our ability to advance health equity.

(1) Proposed Screening for Social Drivers of Health Measure

(a) Background

In the FY 2022 IPPS/LTCH PPS final rule, we sought feedback on the development of new measures that could address the gap in existing health disparities, focusing on social risk factors for which providers should screen (85 FR 45414). As a result, we identified the Screening for Social Drivers of Health measure, which assesses the percent of patients admitted to the hospital who are 18 years or older at time of admission and are screened for food insecurity, housing instability, transportation problems, utility difficulties, and interpersonal safety.

Health disparities manifest primarily as worse health outcomes in population groups where access to care is inequitable.[850] [851] [852] [853] [854] Such differences persist across geography and healthcare settings irrespective of improvements in quality of care over time.[855] [856] [857] Assessment of HRSNs is an essential mechanism for capturing the interaction between social, community, and environmental factors associated with health status and health outcomes.[858] [859] [860] While widespread interest in addressing HRSNs exists, action is inconsistent, with 92 percent of hospitals screening for one or more of the five HRSNs—food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety—specified in the proposed measures, but only 24 percent of hospitals screening for all five HRSNs.[861]

Growing evidence demonstrates that specific social risk factors are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality-based payment programs[862] [863] In 2017, CMS' Center for Medicare and Medicaid Innovation (CMMI) launched the Accountable Health Communities (AHC) Model to test the impact of systematically identifying and addressing the HRSNs of Medicare and Medicaid beneficiaries (through screening, referral, and community navigation on their health outcomes and related healthcare utilization and costs).[864] [865] [866] [867] Although there are models that address HRSNs, the AHC Model is one of the first Federal pilots to systematically test whether identifying and addressing core HRSNs improves healthcare costs, utilization, and outcomes.[868] It also tested the ability of hospitals and health systems to implement HRSN screening, referral, and community navigation in over 600 clinical sites in 21 states.[869] The AHC Model has a 5-year period of performance that began in May 2017

[850] Seligman, H.K., & Berkowitz, S.A. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. Annual Review of Public Health, 40(1), 319–337. Available at: *https://doi.org/10.1146/annurev-publhealth-040218–044132.*

[851] The Physicians Foundation. (2020). Survey of America's Patients, Part Three. Available at: *https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf.*

[852] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[853] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014; 371(24):2298–2308.

[854] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[855] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[856] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://care.diabetesjournals.org/lookup/doi/10.2337/dci20–0053.*

[857] Khullar, D., MD. (2020, September 8). Association Between Patient Social Risk and Physician Performance American academy of Family Physicians. Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity. Available at: *https://www.aafp.org/dam/AAFP/documents/patient_care/everyone_project/team-based-approach.pdf.*

[858] Institute of Medicine. (2014). Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/18951.*

[859] Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. (2016). Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: *https://doi.org/10.1056/NEJMp1512532.*

[860] Centers for Disease Control and Prevention. CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html.* Accessed November 17, 2021.

[861] TK Fraze, AL Brewster, VA Lewis, LB Beidler, GF Murray, CH Colla. Prevalence of screening for food insecurity, housing instability, utility needs, transportation needs, and interpersonal violence by U.S. physician practices and hospitals. JAMA Network Open 2019; 2:e1911514.10.1001/jamanetworkopen.2019.11514.31532515.

[862] Zhang Y, Li J, Yu J, Braun RT, Casalino LP. (2021). Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. JAMA Network Open. 2021;4(6):e2113212. doi:10.1001/jamanetworkopen.2021.13212.

[863] Khullar, D., Schpero, W.L., Bond, A.M., Qian, Y., & Casalino, L.P. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. JAMA, 324(10), 975–983. *https://doi.org/10.1001/jama.2020.13129.*

[864] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Accessed: November 23, 2021. Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.*

[865] Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. 2016. Accountable Health Communities–Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: *https://doi.org/10.1056/NEJMp1512532.*

[866] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[867] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Accessed November 23, 2021. Available at: *https://innovation.cms.gov/innovation-models/ahcm.*

[868] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

[869] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

and will end in April 2022, with beneficiary screening beginning in the summer of 2018 following an implementation period.[870]

While social risk factors account for 50 to 70 percent of health outcomes, the mechanisms by which this connection emerges are complex and multifaceted.[871] [872] [873] [874] The persistent interactions between individuals' HRSNs, medical providers' practices/behaviors, and community resources significantly impact healthcare access, quality, and ultimately costs, as described in the CMS Equity Plan for Improving Quality in Medicare.[875] [876] In their 2018 survey of 8,500 physicians, The Physicians Foundation found almost 90 percent of physician respondents reported their patients had a serious health problem linked to poverty or other social conditions.[877] Additionally, associations between disproportionate health risk, hospitalization, and adverse health outcomes have been highlighted and magnified by the COVID–19 pandemic.[878] [879]

In developing this measure, we identified core HRSN domains based on the following criteria: (1) The availability of high-quality scientific evidence linking a given HRSN to adverse health outcomes and increased healthcare utilization, including hospitalizations, and associated costs; (2) the HRSNs can be screened and identified in the inpatient setting prior to hospital discharge, addressed by community-based services, and potentially improve healthcare outcomes, including reduced hospital re-admission; and (3) the HRSNs are not systematically addressed by healthcare providers.[880] Based on those criteria, the following five domains were selected to screen for social risk factors in Medicare and Medicaid beneficiaries under the AHC Model: (1) Food insecurity; (2) housing instability; (3) transportation needs; (4) utility difficulties; and (5) interpersonal safety. In addition to established evidence of their association with health status, risk, and outcomes, these five domains were selected because they can be assessed across the broadest spectrum of individuals in a variety of settings.[881] [882] [883] The five core HRSN domains are described in Table IX.E–02.

[870] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

[871] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.* Accessed November 23, 2021.

[872] Khullar, D., MD. (2020, September 8). Association Between Patient Social Risk and Physician Performance American academy of Family Physicians. (2020). Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity.

[873] Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290–299. Available at: *https://doi.org/10.1161/CIRCOUTCOMES.120.006752.*

[874] The Physicians Foundation. (2021). Viewpoints: Social Determinants of Health. Available at: *https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf.* Accessed December 8, 2021.

[875] Centers for Medicare & Medicaid Services. (2021). Paving the Way to Equity: A Progress Report. Accessed January 18, 2022. Available at: *https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf.*

[876] Centers for Medicare & Medicaid Services Office of Minority Health. (2021). The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf#:~:text=The%20Centers%20for%20Medicare%20%26%20Medicaid%20Services%20%28CMS%29,evidence%20base%2C%20identifying%20opportunities%2C%20and%20gathering%20stakeholder%20input.*

[877] The Physicians Foundation. (2019). Viewpoints: Social Determinants of Health. Available at: *https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf.* Accessed December 8, 2021.

[878] Centers for Disease Control and Prevention. (2020). CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html.* Accessed November 17, 2021.

[879] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.* Accessed November 23, 2021.

[880] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[881] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[882] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Accessed November 23, 2021. Available at: *https://innovation.cms.gov/innovation-models/ahcm.*

[883] Kamyck, D., Senior Director of Marketing. (2019). CMS releases standardized screening tool for health-related social needs. Activate Care. Available at: *https://blog.activatecare.com/standardized-screening-for-health-related-social-needs-in-clinical-settings-the-accountable-health-communities-screening-tool/.*

TABLE IX.E-02. THE FIVE CORE HRSN DOMAINS TO SCREEN FOR SOCIAL DRIVERS OF HEALTH

Domain	Description
Food Insecurity	Food insecurity is defined as limited or uncertain access to adequate quality and quantity of food at the household level. It is associated with diminished mental and physical health and increased risk for chronic conditions.[884,885] Individuals experiencing food insecurity often have inadequate access to healthier food options which can impede self-management of chronic diseases like diabetes and heart disease, and require individuals to make personal trade-offs between food purchases and medical needs, including prescription medication refills and preventive health services.[886,887] Food insecurity is associated with high-cost healthcare utilization including emergency department (ED) visits and hospitalizations.[888,889,890]
Housing Instability	Housing instability encompasses multiple conditions ranging from inability to pay rent or mortgage, frequent changes in residence including temporary stays with friends and relatives, living in crowded conditions, and actual lack of sheltered housing in which an individual does not have a personal residence.[891,892] Population surveys consistently show that people from some racial and ethnic minority groups constitute the largest proportion of the U.S. population experiencing unstable housing.[893] Housing instability is associated with higher rates of chronic illnesses, injuries, and complications and more frequent utilization of high-cost healthcare services.[894,895]
Transportation Needs	Unmet transportation needs include limitations that impede transportation to destinations required for all aspects of daily living.[896] Groups disproportionately affected include older adults (aged >65 years), people with lower incomes, people with impaired mobility, residents of rural areas, and people from some racial and ethnic minority groups. Transportation needs contribute to postponement of routine medical care and preventive services which ultimately lead to chronic illness exacerbation and more frequent utilization of high-cost healthcare services including emergency medical services, EDs, and hospitalizations.[897,898,899,900]
Utility Difficulties	Inconsistent availability of electricity, water, oil, and gas services is directly associated with housing instability and food insecurity.[901] Specifically, interventions that increase or maintain access to such services have been associated with individual and population-level health improvements.[902]
Interpersonal Safety	Interpersonal safety affects individuals across the lifespan, from birth to old age, and is directly linked to mental and physical health. Assessment for this domain includes screening for exposure to intimate partner violence, child abuse, and elder abuse.[903] Exposure to violence and social isolation are reflective of individual-level social relations and living conditions that are directly associated with injury, psychological distress, and death in all age groups.[904,905]

Utilization of screening tools to identify the burden of unmet HRSNs can be a helpful first step in identifying necessary community partners and

[884] Berkowitz SA, Seligman HK, Meigs JB, Basu S. Food insecurity, healthcare utilization, and high cost: A longitudinal cohort study. Am J Managed Care. 2018 Sep;24(9):399–404. PMID: 30222918; PMCID: PMC6426124.

[885] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://care.diabetesjournals.org/lookup/doi/10.2337/dci20-0053.*

[886] Seligman, H.K., & Berkowitz, S.A. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. Annual Review of Public Health, 40(1), 319–337. Available at: *https://doi.org/10.1146/annurev-publhealth-04021044132.*

[887] National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23285.*

[888] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://care.diabetesjournals.org/lookup/doi/10.2337/dci20-0053.*

[889] Berkowitz SA, Seligman HK, Meigs JB, Basu S. Food insecurity, healthcare utilization, and high cost: a longitudinal cohort study. Am J Managed Care. 2018 Sep;24(9):399–404. PMID: 30222918; PMCID: PMC6426124.

[890] Dean, E.B., French, M.T., & Mortensen, K. (2020a). Food insecurity, health care utilization, and health care expenditures. Health Services Research, 55(S2), 883–893. Available at: *https://doi.org/10.1111/1475-6773.13283.*

[891] Larimer, M.E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: *https://doi.org/10.1001/jama.2009.414.*

[892] Hill-Briggs, F. (2021). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://care.diabetesjournals.org/lookup/doi/10.2337/dci20-0053.*

[893] Henry M., de Sousa, T., Roddey, C., Gayen, S., Bednar, T.; Abt Associates. The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness, January 2021. U.S. Department of Housing and Urban Development. Accessed November 24, 2021. Available at: *https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf.*

[894] Larimer, M.E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: *https://doi.org/10.1001/jama.2009.414.*

[895] Baxter, A., Tweed, E., Katikireddi, S., Thomson, H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness, systematic review and meta-analysis of randomized controlled trials. Journal of Epidemiology and Community Health, 73; 379–387. Available at: *jech.bmj.com/content/jech/73/5/379.full.pdf.*

connecting individuals to resources in their communities. We believe collecting data across the same five HRSN domains that were screened under the AHC Model will illuminate their impact on health outcomes and disparities and the care-cost burden for hospitals, and in particular for hospitals that serve patients with disproportionately high levels of social risk factors. Additionally, the ability of medical providers to contextualize the interaction between HRSNs and poor health outcomes could strengthen referrals to and partnerships with community-based service providers for patients with the most complex needs. This data collection could inform meaningful and sustainable solutions for other provider-types through similar collections in other quality reporting programs.[906] [907] [908] [909] [910]

For data collection of this measure, providers could use a self-selected screening tool and collect these data in multiple ways, which can vary to accommodate the population they serve and their individual needs.[911] [912] One example of such data collection is the AHC Model, which uses the standard 10-item AHC Health-Related Social Needs Screening Tool to enable providers to identify HRSNs in the five core domains (described in Table IX.E–02.) of community-dwelling Medicare, Medicaid, and dually eligible beneficiaries.[913] Since its inception, the AHC Model has been implemented across many care delivery sites in diverse geographic locations across the U.S.[914] More than one million Medicare and Medicaid beneficiaries have been screened using the AHC Health-Related Social Needs Screening Tool, which has been evaluated psychometrically and demonstrated evidence of both reliability and validity, including inter-rater reliability and concurrent and predictive validity.[915] Moreover, the screening instrument can be implemented in a variety of clinical settings, including primary care, EDs, labor and delivery units, inpatient units (including mental and behavioral health settings), and other places where patients seek healthcare.[916]

The intent of this measure is to promote adoption of HRSN screening by hospitals. We encourage hospitals to use the screening as a basis for developing their own individual action plans (which could include navigation services), as well as opportunities for initiating and improving partnerships between healthcare delivery and community-based services. This effort would yield actionable information to close the disparity gap by encouraging hospitals to identify patients with HRSNs, with a reciprocal goal of partnering with community-based organizations to connect those individuals to community support to help address those risks.

Under our Meaningful Measures Framework,[917] the Screening for Social Drivers of Health measure addresses the quality priority of ''Work with Communities to Promote Best Practices of Healthy Living'' through the Meaningful Measures Area of ''Equity of Care.'' Additionally, pursuant to Meaningful Measures 2.0, this measure addresses the ''healthcare equity'' priority area and aligns with our commitment to introduce plans to close health equity gaps and promote equity through quality measures, including to ''develop and implement measures that reflect social and economic determinants.'' [918] Development and

[896] National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23285.*

[897] National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23285.*

[898] Hill-Briggs, F. (2021, January 1), Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https:\\care.diabetesjournasl.org/lookup/doi/10.2337/dci20-0053.*

[899] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountants Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[900] Shier, G., Ginsberg, M., Howell, J., Volland, P., & Golden, R. (2013). Strong Social Support Services, Such as Transportation And Help for Caregivers, Can Lead To Lower Health Care Use And Costs. Health Affairs, 32(3), 544–551. Available at: *https://doi.org/10.31478/201705b.*

[901] Baxter, A., Tweed, E., Katikireddi, S., Thomson, H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. Journal of Epidemiology and Community Health, 73; 379–387. Available at: *https://jech.bmj.com/content/jech/73/5/379.full.pdf.*

[902] Wright, B.J., Vartanian, K.B., Li, H.F., Royal, N., & Matson, J.K. (2016). Formerly Homeless People Had Lower Overall Health Care Expenditures After Moving into Supportive Housing. Health Affairs, 35(1), 20–27. Available at: *https://doi.org/10.1377/hlthaff.2015.0393.*

[903] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[904] Henry M., de Sousa, T., Roddey, C., Gayen, S., Bednar, T.; Abt Associates. The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness, January 2021. U.S. Department of Housing and Urban Development. Accessed November 24, 2021. Available at: *https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf.*

[905] Larimer, M.E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: *https://doi.org/10.1001/jama.2009.414.*

[906] The Physicians Foundation: 2020 Survey of America's Patients, Part Three. Available at: *https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf.*

[907] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[908] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[909] Baker, M.C., Alberti, P.M., Tsao, T.Y., Fluegge, K., Howland, R.E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. Health Affairs, 40(4), 645–654. Available at: *https://doi.org/10.1377/hlthaff.2020.01742.*

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[911] Social Interventions Research & Evaluation Network. (2019). Social Needs Screening Tool Comparison Table. Available at: *https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison.* Tool. Available at: *https://www.mathematica.org/publications/a-guide-to-using-the-accountable-health-communities-health-related-social-needs-screening-tool.* Accessed January 18, 2021.

[912] Mathematica. A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool. Available at: *https://www.mathematica.org/publications/a-guide-to-using-the-accountable-health-communities-health-related-social-needs-screening-tool.* Accessed January 18, 2021.

[913] More information on the HRSN Screening Tool is available at: *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.*

[914] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

[915] Lewis C., Wellman R., Jones S., Walsh-Bailey C., Thompson E., Derus A., Paolino A., Steiner J., De Marchis E., Gottlieb L., and Sharp A. (2020). Comparing the Performance of Two Social Risk Screening Tools in a Vulnerable Subpopulation. J Family Med Prim Care. 2020 Sep; 9(9): 5026–5034. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/.*

[916] CMS. A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Accessed: November 23, 2021. Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.*

[917] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

[918] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://*

Continued

proposal of this measure also aligns with our strategic pillar to advance health equity by addressing the health disparities that underlie our health system.[919]

If finalized, this measure (alongside the proposed Screen Positive Rate for Social Drivers of Health measure) would be the first patient-level measurement of social drivers of health in the Hospital IQR Program. We believe this measure is appropriate for the measurement of the quality of care furnished by hospitals in inpatient settings. Screening during inpatient hospitalization would allow healthcare providers to identify and potentially help address HRSNs as part of discharge planning and contribute to long-term improvements in patient outcomes. This would have a direct and positive impact on hospital quality performance. Collecting baseline data via this measure would be crucial in informing design of future measures that could enable us to set appropriate performance targets for hospitals.

(b) Overview of Measure

The Screening for Social Drivers of Health measure assesses whether a hospital implements screening for all patients that are 18 years or older at time of admission for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. To report on this measure, hospitals would provide: (1) The number of inpatients admitted to the hospital who are 18 years or older at time of admission and who are screened for each of the five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety; and (2) the total number of patients who are admitted to the hospital who are 18 years or older on the date they are admitted.

The Screening for Social Drivers of Health (MUC21–136) measure was included in the publicly available ''List of Measures Under Consideration for December 1, 2021'' (MUC List).[920] The MAP Rural Health Workgroup and the Health Equity Advisory Group reviewed the measure on December 8, 2021, and December 9, 2021, respectively. Both groups indicated that screening for social risk factors would inform future efforts to expand capabilities to capture data that demonstrate the extent to which improvements in healthcare quality contribute to reductions in health disparities and the impact of serving patients at higher risk for adverse health outcomes on healthcare quality at the organization level. Although MAP stakeholders expressed concerns regarding standardization and the need to emphasize the link between the measure and better healthcare outcomes for patients, the measure developer stated that the focus at this point was to establish standard social drivers of health screening measures and not to dictate to hospitals and providers which tool they use or how to address the needs of their patients, citing that multiple CMS models have demonstrated the feasibility of implementing HRSN screening. However, we acknowledge the value and importance of tools which support the interoperability of HRSN data and encourage the use of health IT-enabled assessment instruments with coded questions. We also refer readers to section IX.E.5.b.(1).(g). of the preamble of this proposed rule where we discuss measure reporting. The MAP Health Equity Advisory Group majority voted that this measure has potential or high potential to have a positive impact by decreasing health disparities. The MAP Rural Health Workgroup majority voted agreement or strong agreement that this measure is suitable for use with rural providers.

On December 15, 2021, the MAP Hospital Workgroup reviewed the MUC List, including the Screening for Social Drivers (MUC21–136) measure. The MAP Hospital Workgroup discussion was similar to that of the MAP Health Equity Advisory Group and MAP Rural Health Workgroup, and ultimately voted to conditionally support the measure pending NQF endorsement. On January 19, 2022, the MAP Coordinating Committee reviewed the MUC List including the Screening for Social Drivers of Health (MUC21–136) measure and voted to uphold the MAP Hospital Workgroup recommendation of conditional support for rulemaking.[921]

We intend to submit this measure in future for NQF endorsement. We note that under section 1866(b)(3)(B)(viii)(IX)(aa) of the Act, each measure specified by the Secretary shall be endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures on this this topic, and, therefore we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

Measure specifications for this measure are available on the QualityNet website at *https://qualitynet.cms.gov* (or other successor CMS designated websites).

(c) Cohort

The Screening for Social Drivers of Health measure assesses the total number of patients, aged 18 years and older, screened for social risk factors (specifically, food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) during a hospital inpatient stay. The measure cohort includes patients who are admitted to an inpatient hospital stay and are 18 years or older on the date of admission.

(d) Numerator

The numerator consists of the number of patients admitted to an inpatient hospital stay who are 18 years or older on the date of admission and are screened for one or all of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety during their hospital inpatient stay.

(e) Denominator

The denominator consists of the number of patients who are admitted to a hospital inpatient stay and who are 18 years or older on the date of admission. The following patients would be excluded from the denominator: (1) Patients who opt-out of screening; and (2) patients who are themselves unable to complete the screening during their inpatient stay and have no legal guardian or caregiver able to do so on the patient's behalf during their inpatient stay.

www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization. We note that Meaningful Measures 2.0 is still under development.

[919] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

[920] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96464.*

[921] National Quality Forum. (2022). Measure Applications Partnership (MAP) 2021–2022 Final Recommendations. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.*

(f) Measure Calculation

The Screening for Social Drivers of Health measure would be calculated as the number of patients admitted to an inpatient hospital stay who are 18 years or older on the date of admission screened for one or all five HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) divided by the total number of patients 18 years or older on the date of admission admitted to the hospital.

(g) Data Submission and Reporting

We are proposing voluntary reporting of the Screening for Social Drivers of Health measure beginning with the CY 2023 reporting period, followed by mandatory reporting on an annual basis beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

Due to variability across hospital settings and the populations they serve, we are proposing to allow hospitals flexibility with selection of tools to screen patients for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Potential sources of these data could include, for example, administrative claims data, electronic clinical data, standardized patient assessments, or patient-reported data and surveys. Multiple screening tools exist and many hospitals already have screening tools integrated into their electronic health records (EHRs). We suggest hospitals refer to the Social Interventions Research and Evaluation Network (SIREN) website, for example, for comprehensive information about the most widely used HRSN screening tools.[922] [923] SIREN contains descriptions of the content and characteristics of various tools, including information about intended populations, completion time, and number of questions.

We note that providers participating in the Hospital IQR Program must use certified EHR technology (CEHRT) that has been certified to the 2015 Edition of health IT certification criteria under the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program, and extraction of structured data from a certified EHR can make the data more accessible for utilization and submission for quality measurement reporting (86 FR 45383). Use of certified health IT can also support capture of HSRN information in an interoperable fashion so that this data can be shared across the care continuum to support coordinated care. For instance, in the 2020 ONC 21st Century Cures Act final rule, ONC adopted a new framework for the core data set which certified health IT products must exchange, called the United States Core Data for Interoperability (USCDI) (85 FR 25669). Version 2 of the USCDI, published in July 2021, includes new data classes for social determinants of health (SDOH). These include standards to capture SDOH Problems/Health Concerns, SDOH Interventions, SDOH Goals, and SDOH Assessments. While adoption of USCDI v2 is not a requirement for ONC Health IT Certification, pending approval under ONC's Standards Version Advancement Process,[924] developers of certified health IT will be able to upgrade their certified health IT products to USCDI v2 to support the availability of information about social drivers of health.

Additional stakeholder efforts underway to expand capabilities to capture additional social determinants of health data elements include initiatives such as the Gravity Project [925] to identify and harmonize social risk factor data for interoperable electronic health information exchange. We note these various efforts and encourage use of tools that will meet information exchange standards and facility interoperability. We also encourage providers to identify and utilize tools that rely on standards-based approaches to data collection and utilization to support interoperability of these data.

Hospitals are required to submit information for structural measures once annually using a CMS-approved web-based data collection tool available within the HQR System. We refer readers to section IX.E.10. of the preamble of this proposed rule (Form, Manner, and Timing of Quality Data Submission) for more details on our previously finalized data submission and deadline requirements across measure types, and specifically, section IX.E.10.i. for our data and submission requirements for structural measures.

We invite public comment on this proposal.

(2) Proposed Screen Positive Rate for Social Drivers of Health Measure

(a) Background

The impact of social risk factors on health outcomes has been well-established in the literature.[926] [927] [928] [929] The Physicians Foundation reported that 73 percent of the physician respondents to their annual survey agreed that social risk factors like housing instability and food insecurity would drive health services demand in 2021.[930] As noted previously in this proposed rule, recognizing the need for a more comprehensive approach to eliminating the health equity gap, we have prioritized development and implementation of quality measures that will capture social risk factors and facilitate assessment of their impact on health outcomes and disparities and healthcare utilization and costs.[931] [932] [933] Specifically, in the inpatient setting, we aim to identify patient HRSNs as part of discharge planning with the intention of promoting linkages with relevant community-based services that will

[922] Social Interventions Research & Evaluation Network. (2019). Social Needs Screening Tool Comparison Table. Available at: *https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison.*

[923] The Social Interventions Research and Evaluation Network (SIREN) at University of California San Francisco was launched in the spring of 2016 to synthesize, disseminate, and catalyze research on the social determinants of health and healthcare delivery.

[924] Office of the National Coordinator for Health IT. (2022). Standards Version Advancement Process. Available at: *https://www.healthit.gov/topic/standards-version-advancement-process-svap.*

[925] See *https://thegravityproject.net/.*

[926] Institute of Medicine 2014. Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/18951.*

[927] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: *https://innovation.cms.gov/innovation-models/ahcm.* Accessed November 23, 2021.

[928] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.* Accessed November 23, 2021.

[929] Office of the Assistant Secretary for Planning and Evaluation (ASPE). (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[930] The Physicians Foundation. (2020) 2020 Survey of America's Patients, Part Three. Available at: *https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf.*

[931] Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. 2016. Accountable Health Communities–Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: *https://doi.org/10.1056/NEJMp1512532.*

[932] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: *https://innovation.cms.gov/innovation-models/ahcm.* Accessed November 23, 2021.

[933] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

address those needs and support improvements in health outcomes following hospitalization.

While the proposed Screening for Social Drivers of Health process measure (discussed previously in section IX.E.5.b.(1).) enables identification of individuals with HRSNs, use of the proposed Screen Positive Rate for Social Drivers of Health structural measure would allow us to estimate the impact of individual-level HRSNs on healthcare utilization, including hospitalizations, when evaluating quality of care.[934] [935] [936] The Screen Positive Rate for Social Drivers of Health structural measure would require the reporting of the resulting screen positive rates for each domain. Reporting the social drivers of health screen positive rate for each domain would inform actionable planning by hospitals towards closing health equity gaps and enable the development of individual patient action plans (including navigation and referral). We believe this effort could yield actionable information to close the health equity gap in CMS programs and policies.

In the FY 2022 IPPS/LTCH PPS final rule, we discussed ongoing consideration of potential approaches that could be implemented to address health equity through the Hospital IQR Program (85 FR 45414). As a result of the feedback we received, we identified the Screen Positive Rate for Social Drivers of Health measure to help inform efforts to address health equity. This structural measure assesses the percent of patients admitted to the hospital who are 18 years or older at time of admission who were screened for HRSNs and who screen positive for one or more of the core HRSNs, including food insecurity, housing instability, transportation problems, utility difficulties, or interpersonal safety (reported as five separate rates).[937] We refer readers to section IX.E.5.b.(1).(a). of the preamble of this proposed rule where we previously discussed the CMS identification process resulting in the selection of these five domains.

The COVID–19 pandemic underscored the overwhelming impact that these five core domains have on disparities, health risk, healthcare access, and health outcomes, including premature mortality.[938] [939] Adoption of the Screen Positive Rate for Social Drivers of Health structural measure would encourage hospitals to track prevalence of specific HRSNs among patients over time and use the data to stratify risk as part of quality performance improvement efforts. This measure may also prove helpful for patients by providing data transparency and signifying hospitals' familiarity, expertise, and commitment regarding these issues. Evaluation of AHC Model participation demonstrated positive feedback and enhanced trust among patients.[940] This measure also has the potential to reduce healthcare provider burnout by systematically acknowledging patients' social needs that contribute to adverse health outcomes and linking providers with community-based organizations to enhance patient-centered treatment and discharge planning.[941] [942] [943] Finally, we believe there is a potential further value of this measure to facilitate data-informed collaboration with community-based services and targeted community investments, and enable quality improvement activities and efforts to address disparities, including the development of pathways and infrastructure to connect patients to community resources.

Underserved communities are disproportionately impacted by HRSNs, such as food insecurity, that impact health outcomes and cost.[944] [945] Unmet HRSNs have been directly associated with healthcare utilization, including hospitalization, especially for hospitals that serve such communities.[946] In pursuit of eliminating health equity gaps, we are focused on supporting effective and sustainable collaboration between healthcare delivery and community-based services organizations to meet the unmet needs of underserved populations. Reporting data from both the Screening for Social Drivers of Health measure and the proportion of admitted patients who screen positive for HRSNs across the five domains (via this complementary measure) would enable quantification of the levels of HRSNs in local communities served by a hospital and greater visibility into the interaction between HRSNs and health status, healthcare utilization, and quality of care. These measures would harmonize, as it is important to know both if a hospital or health system is using a screening tool *and* the results from the screening. Ultimately, we believe that, together, these two social drivers of health measures could enhance collaboration to meet the needs of underserved populations by identifying high-risk individuals who would benefit from engagement with community-based service providers. As with the theory of change for the AHC Model, we would expect such collaboration, and associated increase in capacity and community investments, to yield a net reduction in costly healthcare utilization, such as ED visits and avoidable hospitalizations and promote more appropriate healthcare service consumption.[947]

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[936] Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290–299. Available at: *https://doi.org/10.1161/CIRCOUTCOMES.120.006752.*

[937] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[938] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.* Accessed November 23, 2021.

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[941] The Physicians Foundation. (2020). Survey of America's Patients, Part Three. Available at: *https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf.*

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[945] US Department of Agriculture Economic Research Service (2021). Food Security in the U.S. Accessed January 18, 2022. Available at: *https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/key-statistics-graphics.aspx.* Accessed January 18, 2022.

[946] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[947] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS

Pursuant to Meaningful Measures 2.0, this measure addresses the ''healthcare equity'' priority area and aligns with our commitment to introduce plans to close health equity gaps and promote equity through quality measures, including to ''develop and implement measures that reflect social and economic determinants.'' [948] Under CMS' Meaningful Measures Framework, the Screen Positive Rate for Social Drivers of Health structural measure addresses the quality priority of ''Work with Communities to Promote Best Practices of Healthy Living'' through the Meaningful Measures Area of ''Equity of Care.'' [949] Development and proposal of this measure also aligns with our strategic pillar to advance health equity by addressing the health disparities that underlie our health system.[950]

(b) Overview of Measure

The Screen Positive Rate for Social Drivers of Health structural measure is intended to enhance standardized data collection that can identify high-risk individuals who will benefit from connection via the hospital to targeted community-based services.[951] The measure would identify the proportion of patients who screened positive on the date of hospital admission for one or more of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. Hospitals would report this measure as five separate rates. We note that this measure is intended to provide information to hospitals on the level of unmet social needs among patients served, and not for comparison between hospitals.

The Screen Positive Rate for Social Drivers of Health (MUC21–134) measure was included in the publicly available ''List of Measures Under Consideration for December 1, 2021'' (MUC List), a list of measures under consideration for use in various Medicare and Medicaid programs.[952] The MAP Rural Health Advisory Group and the Health Equity Advisory Group reviewed the measure on December 8, 2021, and December 9, 2021, respectively. Both groups expressed concerns about standardization of the measure and operationalization approaches that will yield real solutions for patients and clinicians. We intend to prioritize consideration of potential standardization approaches in future rulemaking. The MAP Health Equity Advisory Group members emphasized the importance of explaining to patients that self-report of HRSNs will not be used to stigmatize them or reduce healthcare benefits. We recommend that hospitals incorporate inclusive language in their screening activities to address this potential concern among patient and caregiver respondents. The measure developer stated that the focus of this measure is to establish standard social drivers of health screening measures, referencing data from the AHC Model as having demonstrated the feasibility of implementing HRSN screening and how essential the screening results are to enable action. Stakeholders' support for the measure was attributed, in part, to potential for hospitals, health systems, and community-based organizations to use the data to identify and prioritize opportunities for investment in community resources to address these HRSNs. Likewise, discussants reported that screening for HRSNs has allowed payors to enhance their understanding of the scope of such challenges among their patients, target resource investments, initiate changes in benefits designs, and prioritize community partnerships. We expect that hospitals will report similar findings and use the data to enhance resource allocation that will support referrals to relevant community-based services organizations.

On December 15, 2021, the MAP Hospital Workgroup met and reviewed the MUC List, including the Screen Positive Rate for Social Drivers of Health (MUC21–134) measure. Similar concerns and support as raised during the MAP Health Equity Advisory Group and MAP Rural Health Workgroup were also discussed during the MAP Hospital Workgroup meeting. The MAP Hospital Workgroup voted to conditionally support the measure for rulemaking pending NQF endorsement. On January 19, 2022, the MAP Coordinating Committee met and reviewed the MUC List including the Screen Positive Rate for Social Drivers of Health (MUC21–134) measure. The Coordinating Committee upheld the vote of the MAP Hospital Workgroup.[953]

We intend to submit this measure in future for NQF endorsement. We note that under section 1866 (b)(3)(B)(viii)(IX)(aa) of the Act, each measure specified by the Secretary shall be endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures on this topic, and, therefore we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

If finalized, this measure (alongside the Screening for Social Drivers of Health) would be the first patient-level measurement of social drivers of health. We believe this is an important measure to include because of the connection between HRSNs and patient health. When patients are admitted to hospital for inpatient care, there is substantial opportunity to screen for HRSNs and include relevant community services referrals as part of discharge planning. Providers would be able to identify if patients have unmet health-related social needs and the rate would help gauge what percentage of the population they serve (who are screened) indicate they need help, by HRSN domain. We envision that hospitals could implement and assess their quality improvement efforts to address patients' unmet social needs such as by connecting admitted patients identified with unmet social

Innovation Center. Available at: *https://innovation.cms.gov/innovation-models/ahcm.* Accessed November 23, 2021.

[948] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.* We note that Meaningful Measures 2.0 is still under development.

[949] Centers for Medicare & Medicaid Services. (2020). CMS Measures Management System Blueprint (Blueprint v 16.0). Available at: *https://www.cms.gov/Medicare/QualityInitiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

[950] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

[951] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights (June 2021). Available at: *https://innovation.cms.gov/media/document/ahcm screeningtool-companion.* Accessed November 23, 2021.

[952] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96464.*

[953] National Quality Forum. (2022). Measure Applications Partnership (MAP) 2021–2022 Final Recommendations. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=9.*

needs to local community resources. These efforts could include referring patients to services available through the hospital or the community. The information from this structural measure may serve as a baseline in future to assess the proportion of admitted patients whose unmet social needs were addressed by the hospital during the hospital stay to support safe discharge and improved health outcomes.

Measure specifications for this measure are available on the QualityNet website at *https://qualitynet.cms.gov* (or other successor CMS designated websites).

(c) Cohort

The Screen Positive Rate for Social Drivers of Health is a structural measure that provides information on the percent of patients admitted for an inpatient hospital stay and who are 18 years or older on the date of admission, were screened for an HSRN, and who screen positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation problems, utility difficulties, or interpersonal safety.

(d) Numerator

The numerator consists of the number of patients admitted for an inpatient hospital stay who are 18 years or older on the date of admission, who were screened for an HSRN, and who *screen positive* for having a need in one or more of the following five HRSNs (calculated separately): Food insecurity, housing instability, transportation needs, utility difficulties or interpersonal safety.

(e) Denominator

The denominator consists of the number of patients admitted for an inpatient hospital stay who are 18 years or older on the date of admission and are *screened* for an HSRN (food insecurity, housing instability, transportation needs, utility difficulties and interpersonal safety) during their hospital inpatient stay. The following patients would be excluded from the denominator: (1) Patients who opt-out of screening; and (2) patients who are themselves unable to complete the screening during their inpatient stay and have no caregiver able to do so on the patient's behalf during their inpatient stay.

(f) Measure Calculation

The result of this measure would be calculated as *five separate rates.* Each rate is derived from the number of patients admitted for an inpatient hospital stay and who are 18 years or older on the date of admission, screened for an HSRN, and who screen positive for each of the five HRSNs—food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety—divided by the total number of patients 18 years or older on the date of admission screened for all five HRSNs.

(g) Data Submission and Reporting

We are proposing voluntary reporting of the Screen Positive Rate for Social Drivers of Health measure beginning with the CY 2023 reporting period, followed by mandatory reporting on an annual basis, beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

Hospitals are required to submit information for structural measures once annually using a CMS-approved web-based data collection tool available within the HQR System. We refer readers to section IX.E.10. (Form, Manner, and Timing of Quality Data Submission) of the preamble of this proposed rule for more details on our previously finalized data submission and deadline requirements across measure types, and specifically, section IX.E.10.i. for our data and submission requirements for structural measures.

We invite public comment on this proposal.

c. Proposed Cesarean Birth eCQM Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination With Mandatory Reporting Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

In this proposed rule, we are proposing to adopt the Cesarean Birth eCQM as one of the eCQMs in the Hospital IQR Program measure set that hospitals can self-select to report for the CY 2023 reporting period/FY 2025 payment determination. We are also proposing to make reporting of this eCQM mandatory beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

(1) Background

A Cesarean section (C-section) is the use of surgery to deliver a baby (or babies) in lieu of vaginal delivery. The procedure entails surgical and anesthesia risks and requires mothers to undergo several days of inpatient, post-operative recovery. A C-section may occur on an elective or nonelective basis.[954] Elective C-sections may be planned due to the presence of a complicating medical condition, abnormal positioning of the baby, or other medical indications.[955] Elective C-sections may also occur for non-medical reasons, including maternal preference (in consultation with their healthcare provider), local practice patterns, malpractice risk, or other factors.[956] [957] [958] C-sections that occur upon a mother's request are rare, but occur after consultation with a clinician.[959]

The total rate of (elective and nonelective) C-sections has risen in the U.S. since the 1990s.[960] C-sections accounted for 31.8 percent of U.S. live births in 2020,[961] and there is a considerable amount of variation in the rates based on U.S. region, state, and healthcare institution.[962] There is also substantial variability across races and ethnicities; the rate of C-sections is: 30.8 percent among Non-Hispanic White women, 36.3 percent among Black women, 28.8 percent among American Indian or Alaska Native women, 32.6 among Asian women, and 31.4 percent among Hispanic women.[963] U.S.

[954] National Quality Forum. Quality Measure PC–02 (Cesarean Birth). Available at: *https://www.qualityforum.org/QPS/0471.*

[955] Xu, X., Yan, J.Y., Chen, L.C. (2021). Risk factors and maternal-fetal outcomes of pregnancies complicated by pre-eclampsia, following cesarean section after a trial vaginal birth. Chin Med J (Engl). 2021;134(18):2249–2251. doi:10.1097/CM9.0000000000001452.

[956] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol. 2014 Mar;210(3):179–93. doi: 10.1016/j.ajog.2014.01.026.

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[958] Chen CS, Liu TC, Chen B, Lin CL. (2014). The failure of financial incentive? The seemingly inexorable rise of cesarean section. Soc Sci Med. 2014 Jan;101:47–51. doi: 10.1016/j.socscimed.2013.11.010. Epub 2013 Nov 15.

[959] Committee on Obstetric Practice. (2019) Cesarean Delivery on Maternal Request. The American College of Obstetricians and Gynecologists, 133(1). Available at: *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/01/cesarean-delivery-on-maternal-request.*

[960] Osterman, M.J.K., Martin, J.A. (2014). Trends in Low-risk Cesarean Delivery in the United States, 1990–2013. National Vital Statistics Reports, 63(6): 1–16.

[961] Hamilton, B.E., Martin, J.A., Osterman, M.J.K. (2020). Births: Provisional Data for 2020. National Vital Statistics Rapid Release, no 12. DOI: *https://doi.org/10.15620/cdc:104993.*

[962] Kozhimannil, K.B., Law, M.R. & Virnig, B.A. (2013). Cesarean delivery rates vary tenfold among US hospitals; reducing variation may address quality and cost issues. *Health Affairs,* 32(3): 527–35.

[963] Hamilton, B.E., Martin, J.A., Osterman, M.J.K. (2020). Births: Provisional Data for 2020. National

practice guidelines have not indicated an optimal rate of C-section or an appropriate variance rate; while international studies suggest a preference for a lower range than current U.S. rates.[964] [965] [966]

When medically indicated, a C-section can effectively prevent maternal and neonatal morbidity and mortality.[967] However, clinicians and consensus groups agree that increased C-section rates have not improved overall perinatal outcomes and that C-sections are overused.[968] [969] Additionally, low risk C-sections—defined as deliveries by nulliparous, term, or singleton vertex (NTSV) women—have seen an increase. ''Nulliparous'' women are those who have never given birth to a live baby but may have had a miscarriage, stillbirth, or elective abortion. They have a lower risk of maternal morbidity and mortality during vaginal birth than do women who have undergone a previous C-section.[970] [971] ''Term'' indicates a term birth (that is on or after 37 weeks' gestation), which has better outcomes than a preterm birth, and ''singleton'' refers to the birth of a single child during one delivery. Vertex presentations, which are those where the child is positioned headfirst, carry less risk than breech or transverse presentations.[972] The rate of low-risk C-section deliveries also varies by race and ethnicity; low-risk C-section births in 2020 were: 24.9 percent among NTSV Non-Hispanic White women, 30.6 percent among NTSV Non-Hispanic Black women, 23.6 percent among NTSV American Indian or Alaska Native women, 27.7 percent among NTSV Asian women, and 25.2 percent among NTSV Hispanic women.[973] A majority of which are still higher than the Centers for Disease Control and Prevention's (CDC's) Healthy People 2020 goal to reduce C-section births among NTSV women to 23.9 percent by 2020.[974]

C-sections have higher morbidity and mortality (9.2 percent) than vaginal deliveries (8.6 percent).[975] Existing literature largely does not distinguish whether inferior outcomes derive from cause (higher-risk patients undergo C-section) or effect (surgery carries inherent risks due to anesthesia, bleeding, infection, post-operative recovery, etc.).[976] However, taking an aggregate view of multiple studies over time, it appears that C-sections carry a higher risk of subsequent miscarriage, placental abnormalities, and repeat C-section.[977] The rates of transfusions, ruptured uteri, unplanned hysterectomies, and intensive care unit (ICU) admissions are higher among women who deliver via C-section for the first time than those who deliver vaginally for the first time across all races and ethnicities. However, non-Hispanic Black women who deliver via C-section for the first time had the highest rates of uterine rupture and ICU admission compared with all other races and ethnicities.[978]

In terms of neonatal outcomes, C-sections have higher respiratory morbidity (1 percent to 4 percent) than vaginal births (<1 percent).[979] Again, it is unclear whether this is because of cause (high-risk fetuses are more likely to be delivered by C-section) or effect (surgery carries inherent risks due to anesthesia, bleeding, infection, post-operative recovery, etc.). The medical indications for a C-section entail broad provider discretion because of the need to: (1) Balance any conflicting medical conditions of mother versus fetus; and (2) balance the C-section against any other competing clinical considerations or external constraints (for example, availability of operation room, personnel, and/or blood). It should also be noted that reducing the rate of C-sections does not result in worse outcomes for the mother or newborn, with newborn complications even declining in some hospitals with significant C-section reductions.[980]

Furthermore, C-sections receive higher reimbursement than vaginal deliveries (typically about 50 percent more). The prevalence of non-medically indicated C-sections carries economic impacts because C-sections are more expensive than vaginal deliveries and may be accompanied by adverse outcomes and complications, which similarly have substantial cost implications.[981]

We believe this eCQM will help further our goal of addressing maternal health outcomes in the Hospital IQR Program. Currently, the Hospital IQR Program includes two measures that address improving maternal health: The Elective Delivery measure (PC–01) (77 FR 53530) and the Maternal Morbidity Structural measure (86 FR 45361 through 45365). However, neither of these measures directly address the factors contributing to maternal mortality, such as the high rates of C-sections in the U.S. We believe adopting measures like the Cesarean Birth eCQM presents unique opportunities for large-scale quality measurement and activities that can improve the short- and long-

Vital Statistics Rapid Release, no 12. DOI: *https://doi.org/10.15620/cdc:104993.*

[964] National Collaborating Centre for Women's and Children's Health. (2011). Caesarean Section: NICE Clinical Guideline (commissioned by the United Kingdom National Institute for Health and Clinical Excellence).

[965] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[966] Keag, O.E., Norman, J.E. & Stock, S.J. (2018). Long-term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis. Plos Med, 15(1): e1002494.

[967] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[968] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[969] National Collaborating Centre for Women's and Children's Health. (2011). Caesarean Section: NICE Clinical Guideline (commissioned by the United Kingdom National Institute for Health and Clinical Excellence).

[970] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[971] National Quality Forum. (2016). Perinatal and Reproductive Health 2015–2016 Final Report. Available at: *https://www.qualityforum.org/Publications/2016/12/Perinatal_and_Reproductive_Health_2015-2016_Final_Report.aspx.*

[972] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[973] Hamilton, B.E., Martin, J.A., Osterman, M.J.K. (2020). Births: Provisional Data for 2020. National Vital Statistics Rapid Release, no 12. DOI: *https://doi.org/10.15620/cdc:104993.*

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[975] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[976] Keag, O.E., Norman, J.E. & Stock, S.J. (2018). Long-term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis. Plos Med, 15(1): e1002494.

[977] Keag, O.E., Norman, J.E. & Stock, S.J. (2018). Long-term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis. Plos Med, 15(1): e1002494.

[978] Curtin, S.C., Gregory, K.D., Korst, L.M., Uddin, S.F.G. (2015) Maternal Morbidity for Vaginal and Cesarean Deliveries, According to Previous Cesarean History: New Data from the Birth Certificate, 2013. National Vital Statistics Reports. Volume 64, Number 4. Available at: *https://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_04.pdf.*

[979] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[980] Main, E.K., Chang, S.C., Cape, V., Sakowski, C. Smith, H., Vasher, J. (2019) Safety Assessment of a Large-Scale Improvement Collaborative to Reduce Nulliparous Cesarean Delivery Rates. Obstetrics & Gynecology, 133(4):613–623. doi: 10.1097/AOG.0000000000003109.

[981] Kozhimannil, K.B., Law, M.R. & Virnig, B.A. (2013). Cesarean delivery rates vary tenfold among US hospitals; reducing variation may address quality and cost issues. Health Affairs, 32(3): 527–35. doi: 10.1377/hlthaff.2012.1030.

term health outcomes for mothers and children.[982] We also refer readers to section IX.E.5.d. of the preamble of this proposed rule, where we are also proposing the adoption of the Severe Obstetric Complications eCQM as part of the Hospital IQR Program measure set.

In response to increases in low-risk C-sections, HHS has included a goal of reducing low-risk C-sections by 25 percent in the next five years as part of the Maternal Action Plan.[983] To build on the previously established HHS Maternal Health Action Plan, the Vice President's nationwide call to action to reduce maternal morbidity and mortality, and ongoing efforts with HHS and across the Federal Government,[984] the Biden-Harris Administration seeks to use a whole-of-government approach for improving maternal health and advancing maternal health equity that reduces maternal mortality and morbidity, reduces persistent disparities, and among other activities, increases hospital participation in HHS-sponsored maternal health quality improvement initiatives. A critical focus is reducing existing disparities in maternal health outcomes across race, ethnicity, and geographic area. The Cesarean Birth eCQM is intended to facilitate safer patient care by assessing the rate of NTSV C-sections to ultimately reduce the occurrence of non-medically indicated C-sections, promoting adherence to recommended clinical guidelines, and encouraging hospitals to track and improve their practices of appropriate monitoring and care delivery for pregnant and postpartum patients. The 2020 performance measurement data for the Cesarean Birth eCQM indicates a 27.5 percent average rate of C-section birth for NTSV women (across 15 hospitals, N=933). A group of subject matter experts for NQF noted that decreasing the rate of non-medically indicated C-sections can result in increased patient safety, decreased maternal and neonatal morbidity, and substantial savings in healthcare costs.[985] Additionally, considering that Non-Hispanic Black women have the highest rate of low-risk C-sections along with the highest rates of uterine ruptures and ICU admissions as a result of C-sections, reducing low-risk C-section rates could improve maternal health outcomes for this population in particular by reducing the excess maternal morbidity they experience.[986] [987] [988]

Under CMS' Meaningful Measures Framework,[989] the Cesarean Birth eCQM addresses the quality priority of ''Make Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measures Area of ''Preventable Healthcare Harm.'' [990] Additionally, pursuant to Meaningful Measures 2.0,[991] this measure addresses the ''Safety'' priority area and aligns with our commitment to a patient-centered approach in quality measurement to ensure that patients are safe and receive the highest quality care.[992] Finally, this measure aligns with our strategic priorities including the pillar to advance health equity by addressing the health disparities that underlie our health system.[993]

Therefore, in this proposed rule, we are proposing to adopt the Cesarean Birth eCQM beginning with the CY 2023 reporting period/FY 2025 payment determination. As part of the currently finalized eCQM reporting and submission requirements, hospitals must report on three self-selected eCQMs and the Safe Use of Opioids—Concurrent Prescribing eCQM, for a total of four eCQMs (85 FR 58939). We are proposing to adopt this measure such that hospitals may choose to report it as one of the three self-selected eCQMs for the CY 2023 reporting period/FY 2025 payment determination. After which, beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years, we are proposing that the Cesarean Birth eCQM would have to be reported by all hospitals, except those hospitals that do not have an obstetrics department and do not perform deliveries. We also refer readers to section IX.E.10.e. of the preamble of this proposed rule for our proposal to modify the eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination.

(2) Overview of Measure

This measure assesses the rate of NTSV pregnancies delivered via C-section. Determining the NTSV C-section rate permits a hospital to compare its outcomes to other hospitals while focusing only on the NTSV population which can impact the rates of first time and possibly subsequent C-section rates. We note that the NQF has endorsed the chart-abstracted form of this measure (PC–02: Cesarean Birth, NQF #0471) as a voluntary consensus standard since 2008 and continuously renewed its endorsement (most recently in 2020).[994] The Rural Health Workgroup of the NQF's MAP also identified the chart-abstracted version as a measure that holds particular relevance for rural hospitals, noting how important it is to focus on best practices in obstetric care in rural areas.[995] We acknowledge that there are instances where C-sections are medically

[982] Department of Health and Human Services. (2020). Healthy Women, Healthy Pregnancies, Health Futures: Action Plan to Improve Maternal Health in America. Available at: *https://aspe.hhs.gov/sites/default/files/private/aspe-files/264076/healthy-women-healthy-pregnancies-healthy-future-action-plan_0.pdf.*

[983] Department of Health and Human Services. HHS Initiative to Improve Maternal Health. Available at: *https://aspe.hhs.gov/topics/public-health/hhs-initiative-improve-maternal-health.*

[984] Department of Health and Human Services. HHS Initiative to Improve Maternal Health. Available at: *https://aspe.hhs.gov/topics/public-health/hhs-initiative-improve-maternal-health.*

[985] National Quality Forum. (2008) Perinatal and Reproductive Health ProjectNQF #0471 PC–02 Cesarean Section: Measure Submission and Evaluation Worksheet 5.0. Available at: *https://www.qualityforum.org/Projects/n-r/Perinatal_Care_Endorsement_Maintenance_2011/0471.aspx.*

[986] Department of Health and Human Services. (2020). Healthy Women, Healthy Pregnancies, Health Futures: Action Plan to Improve Maternal Health in America. Available at: *https://aspe.hhs.gov/sites/default/files/private/aspe-files/264076/healthy-women-healthy-pregnancies-healthy-future-action-plan_0.pdf.*

[987] Curtin, S.C., Gregory, K.D., Korst, L.M., Uddin, S.F.G. (2015) Maternal Morbidity for Vaginal and Cesarean Deliveries, According to Previous Cesarean History: New Data from the Birth Certificate, 2013. National Vital Statistics Reports. Volume 64, Number 4. *https://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_04.pdf.*

[988] Debbink, M.P. Ugwu, L.G. Grobman, W.A. et al. (2022) Racial and Ethnic Inequities in Cesarean Birth and Maternal Morbidity in a Low-Risk, Nulliparous Cohort. Obstetrics & Gynecology;139(1): 73–82. doi: 10.1097/AOG.0000000000004620.

[989] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

[990] CMS' Meaningful Measures Framework can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[991] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.* We note that Meaningful Measures 2.0 is still under development.

[992] Centers for Medicare & Medicaid Services. (2021) CMS Quality Measurement Action Plan. Available at: *https://www.cms.gov/files/document/2021-cms-quality-conference-cms-quality-measurement-action-plan-march-2021.pdf.*

[993] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

[994] National Quality Forum. Quality Measure PC–02 (Cesarean Birth). Available at: *https://www.qualityforum.org/QPS/0471.*

[995] National Quality Forum, Measure Applications Partnership. (2018). A Core Set of Rural-Relevant Measures and Measuring and Improving Access to Care: 2018 Recommendations from the MAP Rural Health Workgroup. Available at: *https://www.qualityforum.org/Publications/2018/08/MAP_Rural_Health_Final_Report_-_2018.aspx.*

indicated, and we emphasize that this measure is not intended to discourage practitioners from performing C-sections when they are medically indicated. We believe that assessing the rate of NTSV C-sections may ultimately reduce the occurrence of non-medically indicated C-sections. We encourage hospitals whose measure rates are higher than rates at other hospitals to explore and evaluate differences in the clinical management of women in labor.[996] Further, this measure would help ensure that the Hospital IQR Program includes measures which are applicable to rural hospitals.

The Cesarean Birth eCQM was included in a publicly available document entitled ''List of Measures Under Consideration for December 1, 2018'' (MUC List).[997] The MAP's Final Report on February 15, 2019 conditionally supported the eCQM for rulemaking pending NQF evaluation and endorsement.[998] The MAP suggested further feasibility testing, consultation with multiple stakeholders, and examination of unintended consequences.

Given the importance of this measure, we sought stakeholder input on the potential future inclusion of this measure in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19491 through 19494). Many stakeholders supported inclusion of the measure, though some stakeholders shared similar concerns as the MAP (84 FR 42493 through 42496). Thereafter, the measure steward conducted further reliability and validity testing in 2021 and submitted the measure to the NQF for consideration of endorsement in Spring 2022. Given the additional testing performed and feedback provided, we are proposing to adopt this measure in this proposed rule.

We also note that in 2020, the measure steward introduced the Cesarean Birth eCQM as one of the available eCQMs hospitals can choose for data submission to meet The Joint Commission's ORYX® requirements.[999] The ORYX initiative integrates performance measurement data into The Joint Commission's accreditation process.[1000] Currently, we understand that The Joint Commission uses both the chart-abstracted (PC–02) and the eCQM versions. A total of 15 hospitals (representing 6 sites) submitted production data for one quarter of calendar year 2020. We note that the measure steward reached out to all 15 hospitals to recruit sites willing to participate in reliability testing on the data submitted. Seven hospitals (representing 2 sites) volunteered. One site is a system representing six hospitals. The seventh hospital is a stand-alone facility that uses a different EHR system. During the third quarter of 2021, feasibility scorecards were completed, and the feasibility rate was found to be 98 percent across the two EHR systems. Reliability and validity testing revealed the Cesarean Births eCQM to have a measure outcome agreement rate of 83.7 percent with a kappa score of .750 indicating substantial agreement. Overall, the data element agreement rate for all hospitals was 92.2 percent.

As mentioned above, the NQF has endorsed the chart-abstracted form of this measure. Additionally, the measure steward submitted the eCQM to the NQF for consideration of endorsement during Spring 2022. We note that section 1866(b)(3)(B)(viii)(IX)(aa) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and note that while the chart-abstracted version is endorsed, we were unable to identify any other NQF-endorsed measures on this topic, and, therefore we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

The measure specifications for the Cesarean Birth eCQM can be found on the eCQI Resource Center website, available at *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms.*

(3) Data Sources

The eCQM uses data collected through hospitals' EHRs. The measure is designed to be calculated by the hospitals' CEHRT using the patient-level data and then submitted by hospitals to CMS.

(4) Measure Calculation

This eCQM assesses the rate of nulliparous women with a term, singleton baby in a vertex position delivered by C-section birth.[1001] The eCQM uses one of the following: Nulliparous defined as Parity = 0, Gravidity = 0, or Preterm and Term both = 0. Parity is the number of completed pregnancies reaching 20 weeks gestation regardless of the number of fetuses or outcome of the pregnancy. Gravidity is the number of pregnancies, current and past, regardless of the pregnancy outcome. Preterm is less than 37 weeks and 0 days, and Term is greater than or equal to 37 weeks and 0 days using best Estimated Due Delivery (EDD).

(5) Outcome

The outcome of interest is the number of C-sections to NTSV women divided by all live, term (≥37 weeks gestation) singleton deliveries to NTSV women.

(6) Cohort

The cohort consists of all patients in the denominator: Nulliparous women with a singleton, vertex fetus at ≥37 weeks of gestation who deliver a liveborn infant. The cohort includes all pertinent patients regardless of payer (for example, Medicare, Medicaid, other public programs, private insurance, self-pay, or charity care) or admission source (for example, home, ED, nursing home, hospice, another hospital, or law enforcement).

(7) Numerator

The measure numerator consists of the subset of patients delivering by C-section.

[996] Centers for Medicare & Medicaid Services. (2015). Cesarean Birth (PC–02) Measure Public Comment Summary. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/PC-02-Public-Comment-Summary-Memo.pdf?msclkid=a582dfc0b52411ecbab8ba3255a5b678.*

[997] Centers for Medicare & Medicaid Services. (2018). List of Measures Under Consideration for December 1, 2018. Available at: *https://www.cms.gov/files/document/2018rmuc-listclearancerpt.pdf.*

[998] National Quality Forum. (2019). Measure Applications Partnership, MAP 2019 Considerations for Implementing Measures in Federal Programs: Hospitals Final Report. Available at: *https://www.qualityforum.org/Publications/2019/02/MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_Hospitals.aspx.*

[999] The Joint Commission. (2020). 2020 ORYX Performance Measure Reporting Requirements. Available at: *https://www.jointcommission.org/-/media/tjc/documents/measurement/oryx/cy2020-oryx-reporting-requirements_.pdf.*

[1000] The Joint Commission. Accreditation-ORYX. Available at: *https://www.jointcommission.org/measurement/reporting/accreditation-oryx/.*

[1001] The Joint Commission. (2021). eCQM Specifications 2022 Reporting Period. Available at: *https://www.jointcommission.org/-/media/tjc/documents/measurement/specification-manuals/2022-reporting-period/january-2022/ecqm_specifications_reportingperiod_2022.zip.*

(8) Denominator

The measure denominator consists of the number of nulliparous women with a singleton, vertex fetus at ≥37 weeks of gestation who deliver a liveborn infant.

(9) Exclusion Criteria

The measure excludes patients with abnormal presentations or placenta previa.

(10) Risk Adjustment

This measure is not currently risk adjusted. When developing the measure, the exclusion criteria were chosen to ensure that the focus population would be women with NTSV pregnancies. Nulliparous women are those experiencing their first birth. These women have a lower risk of maternal morbidity and mortality during a vaginal birth delivery than do women who have undergone a previous C-section.[1002] The population of women in the denominator as a result of the exclusions allow the measure to focus on a more homogeneous group of women where the greatest improvement opportunity exists as evidenced by variation in rates of NTSV C-sections, indicating clinical practice patterns may affect this rate.[1003] Lowering the C-section rate in NTSV pregnancies is important because C-sections may carry a higher risk of subsequent miscarriage, placental abnormalities, and repeat C-section.[1004] The rates of ruptured uteri, unplanned hysterectomies, and ICU admission are higher among women who deliver via C-section for the first time than those who deliver vaginally for the first time across all races and ethnicities. However, non-Hispanic Black women who deliver via C-section for the first time had the highest rates of uterine rupture and ICU admission compared with all other races.[1005] Focusing on the NTSV population aligns with the measure intent to have a significant effect on cesarean birth rates. We believe this could encourage a decrease in C-section rates in the NTSV population, which would in turn have a meaningful impact on future pregnancies and maternal health. Including a comprehensive set of maternal medical exclusions would add data collection burdens without commensurate benefit.

(11) Data Submission and Reporting

We refer readers to: Section IX.E.10.e. of the preamble of this proposed rule for a discussion of our previously finalized eCQM reporting and submission policies; and section IX.E.13.b. for the public reporting of eCQM data. Additionally, we refer readers to section IX.E.10.e.(4). where we discuss the use of the zero denominator declarations and case threshold exemption policies for hospitals.

We also refer readers to four related proposals discussed in the preamble of this proposed rule: (1) Section IX.E.10.e. where we discuss newly proposed modifications to our reporting and submission requirements for eCQMs, including a discussion of our proposal to require hospitals to report on the Cesarean Birth eCQM; (2) section IX.E.5.d. for our proposal to adopt the Severe Obstetric Complications eCQM; (3) section IX.H.10.a.(2). of the preamble of this proposed rule for a discussion of similar proposals to adopt these two perinatal eCQMs in the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs); and (4) section IX.E.8. where we are proposing to establish a publicly-reported hospital designation to capture the quality and safety of maternity care and other related activities in advancing maternal health equity.

We invite public comment on this proposal.

d. Proposed Severe Obstetric Complications eCQM Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination With Mandatory Reporting Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

In this proposed rule, we are proposing to adopt the Severe Obstetric Complications eCQM as one of the eCQMs in the Hospital IQR Program measure set on which hospitals can self-select to report for the CY 2023 reporting period/FY 2025 payment determination. We are also proposing to make reporting of this eCQM mandatory beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

(1) Background

Severe maternal morbidity (SMM) refers to unexpected outcomes due to complications at labor and delivery that result in significant consequences to a woman's health, and includes, but is not limited to, hemorrhage, embolism, severe hypertension, stroke, and other serious complications.[1006] Despite the highest rate of spending on maternity care, totaling $1.4 billion dollars in FY 2021,[1007] the U.S. ranks worse than most other developed nations in pregnancy-related deaths and the rate of SMM is continuing to steadily increase.[1008] [1009] As reported by the CDC, the overall rate of SMM increased almost 200 percent, from 49.5 per 10,000 delivery hospitalizations in 1993 to 144 per 10,000 delivery hospitalizations in 2014.[1010] [1011] [1012] Increasing rates of SMM are resulting in increased healthcare costs, longer hospitalization stays, and short- and long-term negative outcomes to women's health.[1013] [1014] [1015] [1016]

[1002] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[1003] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[1004] Keag, O.E., Norman, J.E. & Stock, S.J. (2018). Long-term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis. Plos Med, 15(1): e1002494.

[1005] Curtin, S.C., Gregory, K.D., Korst, L.M., Uddin, S.F.G. (2015) Maternal Morbidity for Vaginal and Cesarean Deliveries, According to Previous Cesarean History: New Data from the Birth Certificate, 2013. National Vital Statistics Reports, 64(4). Available at: *https://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_04.pdf.*

[1006] Centers for Disease Control and Prevention. (2021). Severe Maternal Morbidity in the United States. Available at: *https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html.*

[1007] Kaiser Family Foundation. (2021). The US Government and Global Maternal and Child Health Efforts. Available at: *https://www.kff.org/global-health-policy/fact-sheet/the-u-s-government-and-global-maternal-and-child-health-efforts/.*

[1008] Centers for Disease Control and Prevention. (2021). Severe Maternal Morbidity in the United States. Available at: *https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html.*

[1009] Maternal Health Task Force. (2015). Maternal Health in the United States. Available at: *https://www.mhtf.org/topics/maternal-health-in-the-united-states/.*

[1010] Centers for Disease Control and Prevention. (2021). Severe Maternal Morbidity in the United States. Available at: *https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html.*

[1011] Leonard SA et al. (2019). Racial and ethnic disparities in severe maternal morbidity prevalence and trends. Annals of epidemiology. 2019;33:30–36.

[1012] Petersen EE, Davis NL, Goodman D, et al. (2019). Vital signs: Pregnancy-related deaths, United States, 2011–2015, and strategies for prevention, 13 states, 2013–2017. Morbidity and Mortality Weekly Report. 68(18):423.

[1013] Vesco KK et al. (2020). Costs of Severe Maternal Morbidity During Pregnancy in US Commercially Insured and Medicaid Populations: An Observational Study. Maternal and Child Health Journal, 24(1):30–38.

[1014] Chen HY, Chauhan SP, Blackwell SC. (2018). Severe Maternal Morbidity and Hospital Cost among Hospitalized Deliveries in the United States. Am J Perinatol. 2018 Nov;35(13):1287–1296. doi: 10.1055/s–0038–1649481. Epub 2018 May 3. PMID: 29723900.

[1015] Lin, Ching-Ching Claire, et al. (2020). ''Rural-urban differences in delivery hospitalization costs by severe maternal morbidity status.'' Annals of Internal Medicine 173.11_Supplement: S59–S62.

[1016] Premier Inc. (2019). Report 2: The Added Cost of Complications During and After Delivery. Available at: *https://explore.premierinc.com/*

Without proper treatment and awareness surrounding SMM, such complications can lead to mortality.[1017] While partially attributed to changes in reporting standards, the maternal mortality rate has also risen in the U.S. from 17 deaths per 100,000 live births in 1990 to 26 deaths per 100,000 live births in 2015.[1018] Recent maternal mortality data from 2018 reveal that 658 women died from pregnancy-related complications, resulting in a rate of 17.4 deaths per 100,000 live births, with 77 percent of the deaths attributed to direct obstetric causes like hemorrhage, preeclampsia, obstetric embolism, and other complications.[1019] [1020] Researchers have found that the presence of select maternal morbidities such as chronic hypertension, preeclampsia, and sepsis were strongly associated with increased odds of mortality at the time of delivery.[1021] [1022] Similar to maternal mortality, the existing literature on maternal morbidity indicates that a significant proportion of maternal morbidity is highly preventable.[1023] Therefore, timely and appropriate treatment of maternal morbidities is imperative to prevent complications that can lead to maternal mortality.[1024]

Additionally, racial and ethnic disparities are significant; non-Hispanic Black women are at considerably higher risk for developing these maternal complications than are non-Hispanic White women.[1025] [1026] Maternal death rate data indicate wide ethnic and racial gaps exist in maternal healthcare and outcomes. The maternal death rate for Black women is more than double that of White women—37.1 deaths per 100,000 live births compared to 14.7—and almost three times the rate compared to Hispanic women—11.8 deaths per 100,000 live births.[1027]

As stated in the HHS Action Plan to Improve Maternal Health in America,[1028] we are pursuing a vision for improving maternal health by focusing on: (1) Reducing maternal mortality, including disparities by race, ethnicity, and geography, in 5 years; (2) reducing SMM, including disparities by race and ethnicity, in five years; and (3) increasing hospital participation in HHS-sponsored maternal health quality improvement initiatives. As reflected in these goals, a critical focus of our maternal health efforts is reducing existing disparities in maternal health outcomes across race, ethnicity, and geographic area. This is further reflected in the Biden-Harris Administration's first ever Presidential proclamation recognizing Black Maternal Health Week.[1029] CMS is also interested in promoting policies that ensure Americans who live in rural areas have access to high quality care, particularly in the area of maternal health where residents in rural settings have a 9 percent greater probability of SMM and mortality, compared with urban residents.[1030] Ultimately, driving the development and execution of evidence-based best practices in maternity care, improving overall maternal health, and closing the racial and ethnic disparity gaps in outcomes are among our agency's top healthcare quality and safety goals.[1031]

Currently, the Hospital IQR Program includes two measures that address improving maternal health: The Elective Delivery measure (PC–01) (77 FR 53530) and the Maternal Morbidity Structural measure (86 FR 45361 through 45365). In section IX.E.5.c. of the preamble of this proposed rule, we are proposing the adoption of the Cesarean Birth eCQM as part of the Hospital IQR Program measure set. However, there are currently no maternal morbidity or obstetric complications outcome-based measures in the Hospital IQR Program.

The Severe Obstetric Complications eCQM has been developed to focus on the high maternal morbidity and mortality rates in the U.S., which we believe will present important opportunities for large-scale quality measurement and improvement activities in the Hospital IQR Program.[1032] Statistics on preventability vary but suggest that a considerable proportion of maternal morbidity and mortality events could be prevented.[1033] [1034] This measure is intended to facilitate safer patient care by increasing awareness of the danger of obstetric complications, promoting adherence to recommended clinical guidelines, and encouraging hospitals to track and improve their practices of appropriate monitoring and care delivery for pregnant and postpartum patients.

Under CMS' Meaningful Measures Framework, the Severe Obstetric Complications eCQM addresses the quality priority of ''Make Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measures Area of ''Preventable Healthcare Harm.'' Additionally, pursuant to Meaningful Measures 2.0, this measure addresses the ''Safety'' priority area and aligns with our

Global/FileLib/Quick_Start_Cloud/19250_BudleofJoyReport_Report2_v7_digital.pdf.

[1017] Kilpatrick, S.K., Ecker, J.L. (2016). Severe Maternal Morbidity: Screening and Review. American Journal of Obstetrics and Gynecology, 215(3):B17–B22.

[1018] Maternal Health Task Force. (2015). Maternal Health in the United States. Available at: *https://www.mhtf.org/topics/maternal-health-in-the-united-states/.*

[1019] Hoyert, D.L., & Miniño, A.M. (2020). Maternal mortality in the United States: Changes in coding, publication, and data release, 2018.

[1020] St Pierre A, Zaharatos J, Goodman D, Callaghan WM. Challenges and Opportunities in Identifying, Reviewing, and Preventing Maternal Deaths. Obstet Gynecol. 2018 Jan;131(1):138–142. doi: 10.1097/AOG.0000000000002417. PMID: 29215526; PMCID: PMC6511983.

[1021] Campbell, K.H. et al. (2013). Maternal Morbidity and Risk of Death at Delivery Hospitalization. Obstetrics and Gynecology, 122(3): 627–633. Available at: *https://journals.lww.com/greenjournal/fulltext/2013/09000/Maternal_Morbidity_and_Risk_of_Death_at_Delivery.20.aspx.*

[1022] Mocumbi, A.O., Sliwa, K., & Soma-Pillay, P. (2016). Medical disease as a cause of maternal mortality: The pre-imminence of cardiovascular pathology: Review articles. Cardiovascular journal of Africa, 27(2), 84–88.

[1023] Kilpatrick, S.K., Ecker, J.L. (2016). Severe Maternal Morbidity: Screening and Review. American Journal of Obstetrics and Gynecology, 215(3): B17.

[1024] Kilpatrick, S.K., Ecker, J.L. (2016). Severe Maternal Morbidity: Screening and Review. American Journal of Obstetrics and Gynecology. 215(3): B17.

[1025] Leonard, S.A., Main, E.K., Scott, K.A., Profit, J., & Carmichael, S.L. (2019). Racial and ethnic disparities in severe maternal morbidity prevalence and trends. Annals of epidemiology, 33, 30–36.

[1026] Petersen, E.E. et al. (2019). Vital signs: Pregnancy-related deaths, United States, 2011–2015, and strategies for prevention, 13 states, 2013–2017. Morbidity and Mortality Weekly Report, 68(18), 423.

[1027] Centers for Disease Control and Prevention. (2020). First Data Released on Maternal Mortality in Over a Decade. Available at: *https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2020/202001_MMR.htm.*

[1028] US Department of Health and Human Services. Healthy Women, Healthy Pregnancies, Healthy Futures: Action Plan to Improve Maternal Health in America. Available at: *https://aspe.hhs.gov/sites/default/files/private/aspe-files/264076/healthy-women-healthy-pregnancies-healthy-future-action-plan_0.pdf.*

[1029] 86 FR 20023, April 16, 2021.). A Proclamation on Black Maternal Health Week. Available at: *https://www.federalregister.gov/documents/2021/04/16/2021-08008/black-maternal-health-week-2021.*

[1030] Kozhimannil, K.B., Interrante, J.D., Henning-Smith, C., & Admon, L.K. (2019). Rural-urban differences in severe maternal morbidity and mortality in the US, 2007–15. Health affairs, 38(12), 2077–2085.

[1031] Centers for Medicare & Medicaid Services. (2021). Evidence-based best practices for hospitals in managing obstetric emergencies and other key contributors to maternal health disparities. Available at: *https://www.cms.gov/files/document/qso-22-05-hospitals.pdf.*

[1032] National Quality Forum. (2022). Measure Applications Partnership (MAP) 2021–2022 Final Recommendations. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.*

[1033] Davis, N.L., Smoots, A.N., & Goodman, D.A. (2019). Pregnancy-Related Deaths: Data from 14 US Maternal Mortality Review Committees. Education, 40(36), 8–2.

[1034] Geller SE, Rosenberg D, Cox SM, et al. (2004). The continuum of maternal morbidity and mortality: Factors associated with severity. American journal of obstetrics and gynecology, 191(3):939–944.

commitment to a patient-centered approach in quality measurement to ensure that patients are safe and receive the highest quality care.[1035]

Therefore, in this proposed rule, we are proposing to adopt the Severe Obstetric Complications eCQM beginning with the CY 2023 reporting period/FY 2025 payment determination. We previously finalized that hospitals must report on three self-selected eCQMs and the Safe Use of Opioids—Concurrent Prescribing eCQM, for a total of four eCQMs in the CY 2023 reporting period/FY 2025 payment determination (85 FR 58939). In this proposed rule, we are proposing to include this measure as part of the measure set in the Hospital IQR Program which hospitals would be able to self-select for the CY 2023 reporting period/FY 2025 payment determination. After which, beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years, we are proposing the Severe Obstetric Complications eCQM would be reported by all hospitals except those hospitals that do not perform deliveries or have an obstetrics department. We refer readers to section IX.E.10.e. of this proposed rule for our related proposal to modify the eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination.

(2) Overview of Measure

This measure assesses the proportion of patients with severe obstetric complications which occur during the inpatient delivery hospitalization. The Severe Obstetric Complications eCQM was included in the publicly available ''List of Measures Under Consideration for December 1, 2021'' (MUC List).[1036] The MAP Rural Health Advisory Group reviewed the MUC List and the Severe Obstetric Complications eCQM (MUC 2021–104) on December 8, 2021.[1037] The MAP Rural Health Advisory Workgroup discussed questions regarding the specifications of the measure. First, there was discussion about the use of blood transfusions as an intervention and concern that blood transfusions would be excluded and/or delayed when clinical evidence indicates that patients would benefit from transfusions as an earlier intervention. The measure developer provided clarification that this measure reports two outcomes, one that includes all patients that meet the numerator criteria, and one that excludes patients whose only qualification for the numerator is a transfusion.[1038] This is as a recognition that transfusions may be necessary for a number of reasons and for less severe complications. Second, the MAP Rural Health Advisory Workgroup discussed that rural settings have high maternal morbidity and mortality and that this measure would help improve maternal health outcomes, and that since the measure is risk-adjusted for the presence of economic/housing instability the measure has a focus on accounting for potential disparities. The measure developer added that as an EHR-based measure, these data are patient-specific and the measure was tested in both rural and urban settings.[1039] The Workgroup voted majority support in agreement of the applicability of the Severe Obstetric Complications eCQM to rural health settings.[1040]

The Severe Obstetric Complications eCQM (MUC2021–104) was also reviewed by the NQF MAP Hospital Workgroup on December 15, 2021, and received conditional support pending NQF endorsement.[1041] Some MAP stakeholders expressed concerns about the minimum sample size and low case volumes as well as the risk adjustment methodology. The measure developer underscored for the MAP that this measure was tested in ten health systems which represented 28 hospitals and tested over 60,000 delivery encounters, and there was no concern about case volumes.[1042] The measure developer also clarified that testing was underway to evaluate the ideal risk adjustment methodology to determine approaches that would consider stratification based on sociodemographic factors, such as race and ethnicity, pre- and post-risk adjustment. We emphasized the importance of this measure and its role in helping hospitals to understand the disparities existent in maternal health outcomes.[1043] Ultimately, MAP Hospital Workgroup stakeholders supported this measure and recommended conditional support because it would assist in surveillance on maternal morbidity, a clinical area that needs further measurement.[1044] The MAP Coordinating Committee, which provides direction to the MAP workgroups, reviewed the Severe Obstetric Complications eCQM (MUC2021–104) on January 19, 2022, and voted to uphold the MAP Hospital Workgroup recommendation for conditional support pending NQF endorsement.[1045]

In January 2022, the Severe Obstetric Complications eCQM was submitted for endorsement by NQF, and is currently under review. We note that section 1866(b)(3)(B)(viii)(IX)(aa) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under

[1035] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.* We note that Meaningful Measures 2.0 is still under development.

[1036] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96464.*

[1037] National Quality Forum. (2022). Measure Applications Partnership Rural Health Advisory Group Virtual Review Meeting. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96571.*

[1038] National Quality Forum. (2022). Measure Applications Partnership Rural Health Advisory Group Virtual Review Meeting. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96571.*

[1039] National Quality Forum. (2022). Measure Applications Partnership Rural Health Advisory Group Virtual Review Meeting. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96571.*

[1040] National Quality Forum. (2022). Measure Applications Partnership Rural Health Advisory Group Virtual Review Meeting. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96571.*

[1041] National Quality Forum. (2022). Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care: Final Report. Available at: *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

[1042] National Quality Forum. (2022). Meeting Transcript—Virtual Review Meeting. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96632.*

[1043] National Quality Forum. (2022). Meeting Transcript—Virtual Review Meeting. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96632.*

[1044] National Quality Forum. (2022). Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care: Final Report. Available at: *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

[1045] National Quality Forum. (2022). Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care: Final Report. Available at: *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures on this topic, and, therefore, we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

To evaluate the validity, feasibility, and reliability of the measure, in 2021, the measure developer, conducted pilot testing in a total of 10 sites, consisting of 28 hospitals. The measure developer conducted alpha testing (formative testing) [1046] and beta testing (field testing) [1047] on the measure. Feasibility testing was conducted to assess data collection and accessibility, and included nine sites in the analysis, which consisted of 27 hospitals and three different EHR systems.[1048] Using NQF's eCQM Feasibility Scorecard template,[1049] the measure developer calculated results which indicated high feasibility of data elements defining the measure specifications (98 percent), clinical and documentation workflows compared to measure intent (99 percent), data element availability (95 percent) and accuracy (98 percent), and use of data standards (96 percent).

Following feasibility testing, one site representing two hospitals withdrew from the project, one site representing one hospital was unable to submit beta testing data in the timeline requested, and one site representing one hospital was added; as a result, the measure developer conducted beta testing in eight healthcare test sites and 25 hospitals, representing three different EHR systems. The measure developer pulled data for delivery hospital encounters discharged from January 1 to December 31, 2020. During measure testing, the measure score reliability was assessed, which is the degree to which repeated measurements of the same entity agree with each other.[1050] The measure developer estimated the measure score reliability using a signal-to-noise ratio to assess the values according to conventional standards. They assessed signal-to-noise reliability that describes how well the measure can distinguish the performance of one hospital from another. The signal is the proportion of the variability in measured performance that can be explained by real differences in performance. Scores can range from zero to one, where a score of zero implies that all the variability in a measure is attributable to measurement error, and a score of one implies that all the variability is attributable to real difference in performance. The reliability analysis yielded a median reliability score of 0.991 (range: 0.983–0.997) for any severe obstetric complication and 0.957 (range: 0.918–0.984) for severe obstetric complications excluding blood transfusion-only cases.

The measure developer completed validity testing on six sites representing 15 hospitals, which was a statistically relevant sample of electronically submitted inpatient encounters selected for re-abstraction for reliability testing and clinical adjudication from six of the beta testing sites. Validity testing of the measure refers to the correctness of conclusions about the quality of measured entities that can be made based on the measure scores (that is a higher score on a quality measure reflects higher quality).[1051] Overall, the data element agreement rate for all six sites was 90.4 percent. Further, validity testing of the measure showed a performance score agreement rate of 91.2 percent with a kappa score of .881 indicating good agreement. Measure score validity testing revealed a high positive predictive value (rate of agreement) of 94.7 percent, and a negative predictive value of 100 percent. Likewise, sensitivity (responsiveness to change) and specificity (accuracy) across test sites for the measure score were high, at 100 percent and 90.5 percent, respectively.

The measure developer conducted testing of the Severe Obstetric Complications eCQM and found that across 60,184 delivery encounters at 8 different sites, the current observed rate of any severe obstetric complications was 244 and the mean risk-standardized rate across test sites was 247 (per 10,000 delivery hospitalizations). The severe obstetric complications rate excluding blood transfusion-only cases was 50 for both the observed rate and the mean risk-standardized rate across test sites (per 10,000 delivery hospitalizations). Through rigorous testing, the measure developer found that the measure was feasible, reliable, and valid.

The measure specifications for the Severe Obstetric Complications eCQM can be found on the eCQI Resource Center website, available at *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms.*

(3) Data Sources

The eCQM uses data collected through hospitals' EHRs. The measure is designed to be calculated by the hospitals' CEHRT using the patient-level data and then submitted by hospitals to CMS.

(4) Outcome

The outcome of interest (numerator) for the Severe Obstetric Complications eCQM is the number of inpatient hospitalizations for patients with severe obstetric complications occurring during the delivery hospitalization, not present on admission, which include the following: Severe maternal morbidity *diagnoses* (we refer readers to the subsequent table); severe maternal morbidity *procedures,* including blood transfusion, conversion of cardiac rhythm, hysterectomy, temporary tracheostomy, and ventilation; or a discharge disposition of expired.[1052] [1053] Table IX.E–03. summarizes the severe maternal morbidity categories along with their corresponding diagnoses:

[1046] Centers for Medicare & Medicaid Services. (2018). Alpha tests include methods to determine if individual data elements are available and if the form in which they exist is consistent with the intent of the measure. Measure Testing NMS Newsletter. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Measure_Testing_MMS_Newsletter_April_2018.pdf.*

[1047] Centers for Medicare & Medicaid Services. (2018). Beta tests serve as the primary means to assess scientific acceptability and usability of a measure including gathering further information about feasibility. Measure Testing NMS Newsletter. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Measure_Testing_MMS_Newsletter_April_2018.pdf.*

[1048] Centers for Medicare & Medicaid Services. (2018). eCQM Feasibility: How Stakeholders Inform Measure Development. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/eCQM-Feasibility.pdf.*

[1049] National Quality Forum. (2022). NQF eCQM Feasibility Scorecard. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89036.*

[1050] Centers for Medicare & Medicaid Services. (2018). CMS Measures Management System (MNS) Testing Scientific Acceptability for de novo eCQMS. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/CMS–MMS-Webinar-BP101-%E2%80%93-Scientific-Acceptability-of-eCQMs.pptx.*

[1051] National Quality Forum. (2011). Guidance for Measure Testing and Evaluating Scientific Acceptability of Measure Properties. Available at: *http://www.qualitylowbar;Process/Measure_Testing_Task_Force_Final_Report.aspx#:~:text=Validity%20of%20the%20measure%20score,quality%20measure%20reflects%20higher%20quality.*

[1052] eCQI Resource Center. (2022). Eligible Hospital/Critical Access Hospital Pre-rulemaking eCQMs. Available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms.*

[1053] The Joint Commission. (2021). eCQM Specifications 2022 Reporting Period. Available at: *https://www.jointcommission.org/-/media/tjc/documents/measurement/specification-manuals/2022-reporting-period/january-2022/ecqm_specifications_reportingperiod_2022.zip.*

TABLE IX.E-03. SEVERE MATERNAL MORBIDITY DIAGNOSIS SPECIFIED IN THE NUMERATOR DEFINITION

Severe Maternal Morbidity Diagnoses Category	Severe Maternal Morbidity Diagnoses
Cardiac	Acute heart failure
	Acute myocardial infarction
	Aortic aneurysm
	Cardiac arrest/ventricular fibrillation
	Heart failure/arrest during procedure or surgery
Hemorrhage	Disseminated intravascular coagulation
	Shock
Renal	Acute renal failure
Respiratory	Adult respiratory distress syndrome
	Pulmonary edema
Sepsis	Sepsis
Other Obstetric Complications (OB)	Air and thrombotic embolism
	Amniotic fluid embolism
	Eclampsia
	Severe anesthesia complications
Other Medical Complications	Puerperal cerebrovascular disease
	Sickle cell disease with crisis

This measure is intended to report two outcomes: (1) Severe obstetric complications; and (2) severe obstetric complications but excluding delivery hospitalizations for which blood transfusion was the only numerator event.

(5) Cohort

The measure cohort (denominator) consists of inpatient hospitalizations for patients between eight years of age and less than 65 years of age admitted to the hospital for inpatient acute care who undergo a delivery procedure for a stillbirth or livebirth greater than or equal to 20 weeks' gestation, with a discharge date that ends during the measurement period. Patients with confirmed diagnosis of COVID–19 with COVID–19-related respiratory condition or patients with confirmed diagnosis of COVID–19-related respiratory procedure are excluded from the measure calculation.[1054]

(6) Risk Adjustment

The Severe Obstetric Complications eCQM is a risk-adjusted measure. The measure developer identified candidate risk variables for severe obstetric complications for consideration in the measure risk adjustment model by utilizing literature and research findings, consulting with an expert clinical consultant, and by soliciting input from a technical expert panel (TEP). Following the identification of candidate risk adjustment variables, the measure developer developed risk models for the outcomes of severe obstetric complications and severe obstetric complications excluding blood transfusion-only encounters. The measure developer then utilized the variables included in the final risk models for use as the risk adjustment variables when calculating the risk standardized severe obstetric complication rates for the two versions of the measure outcome (with and without transfusion-only encounters).

Variables included in the measure's risk adjustment are: Patient age; several preexisting conditions that are present on admission defined by ICD–10 codes (listed later in the section); pregnancy characteristics; laboratory tests and vital signs upon hospital arrival (hematocrit, white blood cell (WBC) count, heart rate, systolic blood pressure); long term anticoagulant medication use; and social risk measured by the presence of economic/housing instability.

The following preexisting conditions and pregnancy characteristics, defined by ICD–10 codes, are included in the measure's risk adjustment: Anemia, asthma, autoimmune disease, bariatric surgery, bleeding disorder, Body Mass Index (BMI), cardiac disease, gastrointestinal disease, gestational diabetes, Human Immunodeficiency Virus (HIV), Hypertension, mental health disorder, multiple pregnancy, neuromuscular disease, obstetric venous thromboembolism (VTE), other pre-eclampsia, placental accreta spectrum, placental abruption, placenta previa, preexisting diabetes, preterm birth, previous cesarean, pulmonary hypertension, renal disease, severe pre-eclampsia, substance abuse, and thyrotoxicosis.

(7) Measure Calculation

The measure is an outcome measure that assesses the risk-standardized proportion of eligible patients with severe obstetric complications, and the risk-standardized proportion of eligible patients with severe obstetric complications excluding transfusion-only hospital delivery encounters, which occur during the inpatient delivery hospitalization. The measure calculates the proportion of inpatient hospitalizations with severe obstetric complications occurring during the delivery hospitalization out of the total number of inpatient hospitalizations for patients delivering stillborn or live birth with greater than or equal to least 20 weeks and 0 days of gestation completed. The measure score will be reported as a rate per 10,000 deliveries.

(8) Data Submission and Reporting

We refer readers to: Section IX.E.10.e. of the preamble of this proposed rule for discussion of our previously finalized eCQM reporting and submission policies; and section IX.E.13.b. for the public reporting of eCQM data. Additionally, we refer readers to section IX.E.10.e.(4). where we discuss the use of the zero denominator declarations and case threshold exemption policies for hospitals.

[1054] eCQI Resource Center. (2022). Eligible Hospital/Critical Access Hospital Pre-rulemaking eCQMs. Available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms.*

We also refer readers to four related proposals discussed in the preamble of this proposed rule: (1) Section IX.E.10.e. where we discuss our newly proposed modifications to our reporting and submission requirements for eCQMs, including a discussion of our proposal to require hospitals to report on the Severe Obstetric Complications eCQM; (2) section IX.E.5.c. for our proposal to adopt the Cesarean Birth eCQM; (3) section IX.H.10.a.(2). of the preamble of this proposed rule for a discussion of similar proposals to adopt these two perinatal eCQMs in the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs; and (4) section IX.E.8. where we are proposing to establish a publicly-reported hospital designation to capture the quality and safety of maternity care and other related activities in advancing maternal health equity.

We invite public comment on this proposal.

e. Proposed Hospital-Harm—Opioid-Related Adverse Events eCQM (NQF #3501e) Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

(1) Background

Opioids are among the most frequently implicated medications in adverse drug events among hospitalized patients.[1055] The most serious opioid-related adverse events include those involving respiratory depression, which can lead to brain damage and death.[1056] [1057] [1058] Opioid-related adverse events have both a negative impact on patients and financial implications. Patients who experience adverse events due to opioid administration have been noted to have 55 percent longer lengths of stay, 47 percent higher costs, 36 percent higher risk of 30-day readmission, and 3.4 times higher payments than patients without these adverse events.[1059] While noting that data are limited, The Joint Commission suggested that opioid-induced respiratory arrest may contribute substantially to the 350,000 to 750,000 in-hospital cardiac arrests annually.[1060]

Most opioid-related adverse events are preventable.[1061] Of the opioid-related adverse drug events reported to The Joint Commission's Sentinel Event database, 47 percent were due to a wrong medication dose, 29 percent due to improper monitoring, and 11 percent due to other causes (for example, medication interactions and/or drug reactions).[1062] In addition, in a review of cases from a malpractice claims database in which there was opioid-induced respiratory depression among post-operative surgical patients, 97 percent of these adverse events were judged preventable with better monitoring and response.[1063]

While hospital quality interventions such as proper dosing, adequate monitoring, and attention to potential drug interactions that can lead to overdose are key to prevention of opioid-related adverse events, the use of these practices can vary substantially across hospitals.[1064] [1065] [1066] In addition, administration of opioids also varies widely by hospital, ranging from 5 percent in the lowest-use hospital to 72 percent in the highest-use hospital.[1067] Notably, hospitals that use opioids most frequently have increased adjusted risk of severe opioid-related adverse events.[1068] The measure developer, under contract with CMS, developed the Hospital Harm–Opioid-Related Adverse Events eCQM to assess the rates of adverse events as well as the variation in rates among hospitals.

(2) Overview of Measure

The Hospital Harm—Opioid-Related Adverse Events eCQM is an outcome measure focusing specifically on opioid-related adverse events during an admission to an acute care hospital by assessing the administration of naloxone. Naloxone is a lifesaving emergent therapy with clear and unambiguous applications in the setting of opioid overdose.[1069] [1070] [1071] [1072] Naloxone administration has also been used in a number of studies as an indicator of opioid-related adverse events to indicate harm to a patient during inpatient admission to a hospital.[1073] [1074] The intent of this measure is for hospitals to track and improve their monitoring and response to patients administered opioids during hospitalization, and to avoid harm, such as respiratory depression, which can lead to brain damage and death. This measure focuses specifically on in-hospital opioid-related adverse events,

[1055] Davies EC, Green CF, Taylor S, Williamson PR, Mottram DR, et al. (2009) Adverse Drug Reactions in Hospital In-Patients: A Prospective Analysis of 3695 Patient-Episodes. PLoS ONE 4(2): e4439. doi:10.1371/journal.pone.0004439.

[1056] Jungquist CR, Quinlan-Colwell A, Vallerand A, et al. (2020). American Society for Pain Management Nursing Guidelines on Monitoring for Opioid-Induced Advancing Sedation and Respiratory Depression: Revisions. Pain Manag Nurs.21(1):7–25. Epub 2019 Jul 31.

[1057] Ramachandran SK, Haider N, Saran KA, et al. (2011). Life-threatening critical respiratory events: A retrospective study of postoperative patients found unresponsive during analgesic therapy. Journal of Clinical Anesthesia. 23(3):207–213.

[1058] Dahan A, Aarts L, Smith TW. (2010). Incidence, Reversal, and Prevention of Opioid-induced Respiratory Depression. *Anesthesiology.* 112(1):226–238.

[1059] Kessler, E.R., Shah, M., Gruschkkus, S.K., et al. (2013). Cost and quality implications of opioid-based postsurgical pain control using administrative claims data from a large health system: Opioid-related adverse events and their impact on clinical and economic outcomes. Pharmacotherapy, 33(4): 383–91.

[1060] Overdyk, F.J. (2009). Postoperative Respiratory Depression and Opioids. Initiatives in Safe Patient Care. Available at: *https://www.initiatives-patientsafety.org/_files/ugd/ba15f5_d52da446e2f141d7be95d3a99b538a42.pdf.*

[1061] Lee LA, Caplan RA, Stephens LS, et al. Postoperative opioid-induced respiratory depression: A closed claims analysis. Anesthesiology. 2015;122(3):659–665.

[1062] The Joint Commission. (2012.) Safe Use of Opioids in Hospitals. The Joint Commission Sentinel Event Alert, 49:1–5. Available at: *https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/sea_49_opioids_8_2_12_finalpdf.pdf?db=web&hash=0135F306FCB10D919CF7572ECCC65C84.*

[1063] Lee, L.A., Caplan, R.A., Stephens, L.S., et al. (2015). Postoperative opioid-induced respiratory depression: A closed claims analysis. Anesthesiology, 122(3): 659–65.

[1064] Willens JS, Jungquist CR, Cohen A, Polomano R. (2013). ASPMN survey—nurses' practice patterns related to monitoring and preventing respiratory depression. Pain Management Nursing. 14(1):60–65.

[1065] Meisenberg B, Ness J, Rao S, Rhule J, Ley C. (2017). Implementation of solutions to reduce opioid-induced oversedation and respiratory depression. Am J Health Syst Pharm. 74:162–169.

[1066] Jungquist CR, Correll DJ, Fleisher LA, et al. (2016). Avoiding Adverse Events Secondary to Opioid-Induced Respiratory Depression: Implications for Nurse Executives and Patient Safety. Journal of Nursing Administration. 46(2):87–94.

[1067] Herzig, S.J., Rothberg, M.B., Cheung, M., et al. (2014). Opioid utilization and opioid-related adverse events in nonsurgical patients in US hospitals. Journal of Hospital Medicine, 9(2): 73–81.

[1068] *Ibid.*

[1069] Surgeon General's Advisory on Naloxone and Opioid Overdose. (2018). Available at: *https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html.*

[1070] Agency for Healthcare Research and Quality (AHRQ). (2017). Management of Suspected Opioid Overdose with Naloxone by Emergency Medical Services Personnel. Comparative Effectiveness Review No. 193. Available at: *https://effectivehealthcare.ahrq.gov/topics/emt-naloxon/systematic-review.*

[1071] Substance Abuse and Mental Health Services Administration (SAMHSA). (2018). Opioid Overdose Prevention Toolkit: Information for Prescribers. Available at: *https://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA18-4742.*

[1072] Harm Reduction Coalition. (2020). Guide To Developing and Managing Overdose Prevention and Take-Home Naloxone Projects. Available at: *https://harmreduction.org/issues/overdose-prevention/developing-overdose-prevention-and-naloxone-projects/.*

[1073] Eckstrand, J.A., Habib, A.S., Williamson, A., et al. (2009). Computerized surveillance of opioid-related adverse drug events in perioperative care: A cross-sectional study. Patient Safety Surgery, 3:18.

[1074] Nwulu, U., Nirantharakumar, K., Odesanya, R., et al. (2013). Improvement in the detections of adverse drug events by the use of electronic health and prescription records: An evaluation of two trigger tools. European Journal of Clinical Pharmacology, 69(2): 255–59.

rather than opioid overdose events that happen in the community and may bring a patient into the ED.

The goal of this measure is to incentivize hospitals to closely monitor patients who receive opioids during their hospitalization to prevent serious adverse events. The measure requires evidence of hospital opioid administration prior to the naloxone administration during the first 24 hours after hospital arrival to ensure that the harm was hospital acquired and not due to an overdose that happened outside of the hospital.[1075] This measure does not identify preventability of an individual harm instance or whether each instance of harm was an error, but rather, it assesses the overall rate of harm within a hospital by incorporating a definition of harm that is likely to be reduced as a result of hospital best practice.

The Hospital Harm—Opioid-Related Adverse Events eCQM was included as a measure undergoing field testing in the publicly available ''List of Measures Under Consideration for December 1, 2017'' (MUC List).[1076] The measure was reviewed by the NQF MAP Hospital Workgroup in December 2017, and received the recommendation to refine and resubmit with completed test results demonstrating reliability and validity prior to rulemaking, as referenced in the ''2017–2018 Spreadsheet of Final Recommendations to HHS and CMS.'' [1077]

This measure was submitted for endorsement consideration to NQF's Patient Safety Standing Committee for the Spring 2019 cycle. NQF reviewed the measure on June 21, 2019, but did not proceed with full endorsement consideration due to concerns with the performance gap criterion. In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19477), we proposed but did not finalize the adoption of the Hospital-Harm—Opioid-Related Adverse Events eCQM. Commenters provided measure suggestions and refinements, as outlined in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42459), and we decided to further assess the measure and the suggested considerations with intent to re-propose the measure. The main areas of suggestions were to better establish the connection between naloxone administration and an opioid-related event and consider narrowing the broad denominator that, as specified, may result in the calculation of very low rates of adverse events.

In response to the feedback received, the measure developer refined and retested the measure specifications. The measure developer limited the denominator to encounters where patients received at least one opioid during the hospitalization. The measure developer constrained the numerator to those patients with an opioid administration that preceded the subsequent naloxone administration by no more than a 12-hour time window, to ensure that a hospital administered opioid was the cause for the naloxone administration. The measure developer also updated the value sets to ensure that the most current codes for hospital administered opioids and naloxone are used and that the codes harmonize across other current eCQMs in our quality reporting programs. Finally, the measure was re-tested by the measure developer for feasibility at 23 hospital test sites using four different EHR vendor systems and for the scientific acceptability of the measure's properties including reliability and validity at six beta implementation test sites.[1078] Participant test sites varied by EHR vendor systems, bed size, geographic location, teaching/non-teaching status, and urban/rural representation.

The Hospital Harm—Opioid-Related Adverse Events eCQM (NQF #3501e) was then re-submitted to the NQF for the Spring 2021 review cycle and received NQF endorsement on December 7, 2021.[1079] The MAP Rural Health Advisory Group also reviewed the MUC List and Hospital Harm—Opioid-Related Adverse Events eCQM (MUC2021–084) on December 8, 2021 and voted majority support in agreement on the applicability of the eCQM to rural health settings.[1080] The refined and retested eCQM was also re-considered by the MAP Hospital Workgroup on December 15, 2021, which voted to support the measure for rulemaking.[1081] The MAP Coordinating Committee, which provides direction to the MAP workgroups, then reviewed the measure on January 19, 2022 [1082] and upheld the MAP Hospital Workgroup recommendation to support the measure for rulemaking.[1083]

We believe this measure would provide hospitals with reliable and timely measurement of their opioid-related adverse event rates, which is a high-priority measurement area. We believe implementation of this measure can lead to safer patient care by incentivizing hospitals to implement or refine clinical workflows that facilitate evidence-based use and monitoring when administering opioids. We also believe implementation of this measure may result in fewer patients experiencing adverse events associated with the administration of opioids, such as respiratory depression, which can lead to brain damage and death. This measure addresses the quality priority of ''Making Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measures Area of ''Preventable Healthcare Harm.'' [1084]

For detailed information on the Hospital Harm–Opioid-Related Adverse Events eCQM, we refer readers to the measure specifications, available at *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms.*

(3) Data Sources

The eCQM uses data collected through hospitals' EHRs. The measure is designed to be calculated by the hospitals' CEHRT using the patient-level data and then submitted by hospitals to CMS.

As with all quality measures we develop, testing was performed to confirm the feasibility of the measure,

[1075] #3501e Hospital Harm—Opioid-Related Adverse Events, Apr 02, 2021. Measure Information Form. *https://nqfappservicesstorage.blob.core.windows.net/proddocs/27/Spring/2021/measures/3501e/shared/3501e.zip.*

[1076] National Quality Forum. (2017). List of Measures Under Consideration for December 1, 2017. Available at: *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[1077] National Quality Forum. 2017–2018 Spreadsheet of Final Recommendations to HHS and CMS. Available at: *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[1078] National Quality Forum. #3501e Hospital Harm—Opioid-Related Adverse Events. Available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=3501e.*

[1079] National Quality Forum. (2021). Hospital Harm—Opioid Related Adverse Events. Available at: *https://www.qualityforum.org/QPS/3501e.*

[1080] National Quality Forum. (2022). Measure Applications Partnership Rural Health Advisory Group Virtual Review Meeting Summary, December 8, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96571.*

[1081] Measure Applications Partnership Hospital Workgroup Web Review Meeting: Meeting Summary. December 15, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96629.*

[1082] Measure Applications Partnership Coordinating Committee 2021–2022 Review Web Meeting: Meeting Summary. January 19, 2022. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96709.*

[1083] Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care Final Report. March 3, 2022. Available at: *https://www.qualityforum.org/Projects/i-/MAP/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report.aspx#onclick=%E2%80%9D_gaq.push([%E2%80%98_trackEvent%E2%80%99,%E2%80%99Download%E2%80%99,%E2%80%99PDF%E2%80%99,this.href]);%E2%80%9D.*

[1084] More information on CMS' Meaningful Measures Framework is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

data elements, and validity of the numerator, using clinical adjudicators who validated the EHR data compared with medical chart-abstracted data. Testing demonstrated no missing or erroneous data (0 percent) for all six implementation test sites. These results suggest that all critical data elements are reliably and consistently captured in patient EHRs, and that measure implementation is feasible. Testing also showed that the positive predictive value (PPV),[1085] which describes the probability that a patient with a positive result (numerator case) identified by the EHR data was also a positive result verified by review of the patient's medical record done by a clinical adjudicator, was high at all hospital testing sites (98 percent in one hospital to 100 percent in the five other hospitals). Testing was completed using output from the Measure Authoring Tool (MAT) in 23 hospitals using four different EHR systems for feasibility and six different hospitals for implementation testing for reliability and validity.

(4) Outcome

This measure assesses the proportion of inpatient hospital encounters where patients 18 years of age or older have been administered an opioid medication, subsequently suffer the harm of an opioid-related adverse event, and are administered an opioid antagonist (naloxone) within 12 hours. This measure excludes opioid antagonist (naloxone) administration occurring in the operating room setting.

(5) Cohort

This measure's cohort includes all patients ages 18 years and older at the start of the encounter, and for whom at least one opioid medication was administered during the encounter. An inpatient hospitalization includes time spent in the ED or in observation status when the patients are ultimately admitted to inpatient status.

(6) Inclusion and Exclusion Criteria

This measure excludes opioid antagonist (naloxone) administration occurring in the operating room setting. There are no denominator exclusions.

(7) Risk Adjustment

This measure is not risk adjusted for chronic opioid use, as most instances of opioid-related adverse events should be preventable for all patients regardless of prior exposure to opioids or chronic opioid use.

Generally, patient characteristics, including gender, age, race/ethnicity, reasons for hospitalization, clinical status when patients arrive at the hospital, or comorbidities can influence the risk of harm occurring during a hospitalization.[1086] Therefore, if hospitals care for patients with different degrees of risk, then it may be important to account for such case mix to compare hospital performance.[1087] However, opioid-related adverse events should be avoidable regardless of patient risk, particularly when the opioid was given after patients have arrived at the hospital.[1088] During measure development, in evaluating whether this measure needed to be risk adjusted, the measure developer considered the following in determining whether risk adjustment is warranted for this measure: Patients are at risk of the harm regardless of their demographic and clinical characteristics; most incidents of harm are linkable to care provision under the hospital control, for example, harms caused by excessive or inappropriate medication dosing; and there is evidence that the risk of harm can be largely reduced by following best care practices independent of patient inherent risks. For example, patients with multiple risk factors can still avoid the harm event when providers adhere to care guidelines.

Opioid-related adverse events should be avoidable regardless of patient risk, particularly when the opioid was given after patients have arrived at the hospital.[1089] While certain patients may require higher doses to achieve pain control or are more sensitive to opioids (depending on their age, sex, and weight), the most common cause is hospital administration of excessive doses and inadequate monitoring.[1090] Because the dosing of opioids and the intensity of patient monitoring is entirely under the control of providers in hospitals, the risk of an opioid-related adverse event can be reduced by following best practices.[1091] [1092] [1093] Therefore, the measure developer did not believe risk adjustment is warranted for this measure.

To provide supportive evidence of the clinical rationale for not risk adjusting, the measure developer examined the measure performance rate in various subgroups of population. All these analyses demonstrated no pattern in measure performance rates across subgroups.[1094] During measure development, TEP members gave feedback on whether the measure required risk adjustment and agreed with this rationale. Subsequently the NQF Scientific Methods Panel (SMP), the Patient Safety Standing Committee, and the Consensus Standards Advisory Committee (CSAC) also agreed with this approach.[1095] [1096] [1097]

(8) Measure Calculation

The Hospital Harm—Opioid-Related Adverse Events eCQM is an outcome measure that defines the indication of a harm for an opioid-related adverse event by assessing administration of an opioid antagonist (naloxone). The numerator is the number of inpatient hospitalizations where an opioid antagonist (naloxone) was administered outside of the

[1085] ''Predictive Value.'' Farlex Partner Medical Dictionary. Available at: *https://medical-dictionary.thefreedictionary.com/predictive+value.*

[1086] National Quality Forum. Glossary of Terms. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=73681.*

[1087] National Quality Forum. Developing and Testing Risk Adjustment Models for Social and Functional Status-Related Risk Within Healthcare Performance Measurement: Final Technical Guidance—Version 4. August 30, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96087.*

[1088] The Joint Commission. (2012). Safe Use of Opioids in Hospitals. The Joint Commission Sentinel Event Alert, 49:1–5. Available at: *https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/sea_49_opioids_8_2_12_finalpdf.pdf?db=web&hash=0135F306FCB10D919CF7572ECCCC65C84.*

[1089] *Ibid.*

[1090] Dahan A, Aarts L, Smith TW. Incidence, Reversal, and Prevention of Opioid-induced Respiratory Depression. Anesthesiology. 2010;112(1):226–238.

[1091] Practice Guidelines for the Prevention, Detection, and Management of Respiratory Depression Associated with Neuraxial Opioid Administration: An Updated Report by the American Society of Anesthesiologists Task Force on Neuraxial Opioids and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. 2016 Mar;124(3):535–52.

[1092] Jungquist CR, Quinlan-Colwell A, Vallerand A, et al. American Society for Pain Management Nursing Guidelines on Monitoring for Opioid-Induced Advancing Sedation and Respiratory Depression: Revisions. Pain Manag Nurs. 2020 Feb;21(1):7–25. Epub 2019 Jul 31.

[1093] Dahan A, Aarts L, Smith TW. Incidence, Reversal, and Prevention of Opioid-induced Respiratory Depression. Anesthesiology. 2010;112(1):226–238.

[1094] #3501e Hospital Harm—Opioid-Related Adverse Events, Apr 02, 2021. Measure Information Form. *https://nqfappservicesstorage.blob.core.windows.net/proddocs/27/Spring/2021/measures/3501e/shared/3501e.zip.*

[1095] National Quality Forum. Scientific Methods Panel Measure Evaluation Web Meeting—Spring 2021 Meeting Summary. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95246.*

[1096] National Quality Forum. Patient Safety Spring 2021 Cycle. Memo: Consensus Standards Approval Committee (CSAC). November 30, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96423.*

[1097] National Quality Forum. Consensus Standards Approval Committee (CSAC) Voting Results and Decisions for Spring 2021 Measures. November 30, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96528.*

operating room and within 12 hours following administration of an opioid medication. Only one numerator event is counted per encounter. The denominator includes inpatient hospitalizations for patients 18 years or older during which at least one opioid medication was administered. An inpatient hospitalization includes time spent in the ED or in observation status when the patients are ultimately admitted to inpatient status.

To calculate the hospital-level measure result, divide the total numerator events by the total number of qualifying inpatient encounters (denominator). Qualifying inpatient encounters include all patients 18 years of age or older at the start of the encounter with at least one opioid medication administered during the encounter. The measure does not include naloxone use in the operating room where it could be part of the sedation plan as administered by an anesthesiologist or nurse anesthetist. Uses of naloxone for procedures outside of the operating room (such as bone marrow biopsy) are counted in the numerator as its use would indicate the patient was over sedated.[1098] The measure numerator identifies a harm using the administration of naloxone, and purposely does not include any medications that combine naloxone with other agents.

(9) Data Submission and Reporting

We are proposing the adoption of the Hospital-Harm—Opioid-Related Adverse Events eCQM as part of the Hospital IQR Program for which hospitals can self-select beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to section IX.E.10.e. of the preamble of this proposed rule for a discussion of our previously finalized eCQM reporting and submission policies, as well as our proposal to modify these eCQM reporting and submission requirements. Additionally, we refer readers to section IX.H.10.a.(2). of the preamble of this proposed rule for a discussion of a similar proposal to adopt this measure in the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs.

We invite public comment on this proposal.

f. Proposed Global Malnutrition Composite Score eCQM (NQF #3592e) Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

(1) Background

From 1960 until the start of the COVID–19 pandemic,[1099] life expectancy for the total population in the U.S. increased by almost 10 years.[1100] While adults are living longer lives, the amount of time spent in poor health at the end of life is similarly increasing.[1101] Studies found that healthy nutrition is indeed more important for healthy aging than generally recognized.[1102] Malnutrition includes undernutrition (wasting, stunting, underweight), inadequate vitamins or minerals, overweight, and obesity, and can result in diet-related noncommunicable diseases.[1103] The developmental, economic, social, and medical impacts of the global burden of malnutrition are serious and lasting, for individuals and their families, for communities, and for countries.[1104] Malnutrition is complex and may be both associated with and exacerbated by chronic conditions, age-related cognitive or physical changes, medication side effects, and poverty.[1105] Evidence shows that healthy eating contributes to prevention and risk reduction of many common chronic health conditions prevalent in older adults including hypertension, heart disease, heart failure, diabetes, obesity, certain cancers, and osteoporosis.[1106] While it is estimated that sixty percent of older adults manage two or more chronic health conditions, many underuse preventive services, including those related to nutrition.[1107] Research indicates that preventive screening and interventions may reduce risk of malnutrition in older adults and improve quality of life, particularly for individuals with chronic conditions.[1108] While disease-related malnutrition is not limited to older adults, it is more frequent among those with higher age, and the consequences appear to be more severe in older persons due to their impaired regenerative capacity, inflammation, and other factors.[1109] Malnutrition remains a challenge for older adults in the U.S. as approximately 7.7 percent of seniors, or 5.5 million, are food insecure annually with reports of reduced quality, variety, or desirability of diet while 3.1 percent, or 2.1 million are very low food insecure with reports of multiple indications of disrupted eating patterns and reduced food intake.[1110] [1111] From late September through mid-October 2021, U.S. Census Bureau data indicates that more than 2.5 million adults ages 65 and older responded ''sometimes'' or ''often'' when asked the frequency of not having enough food to eat in the past seven days.[1112]

[1098] Nwulu, U., Nirantharakumar, K., Odesanya, R., McDowell, S.E., & Coleman, J.J. Improvement in the detection of adverse drug events by the use of electronic health and prescription records: An evaluation of two trigger tools. Eur J Clin Pharmacol. 2013;69(2), 255–259.

[1099] Islam N, Jdanov DA, Shkolnikov VM, Khunti K, Kawachi I, White M et al. (2021). Effects of covid–19 pandemic on life expectancy and premature mortality in 2020: Time series analysis in 37 countries. BMJ 375:e066768 doi:10.1136/bmj–2021–066768.

[1100] United States Census Bureau. (2020). Living Longer: Historical and Projected Life Expectancy in the United States, 1960 to 2060. Available at: *https://www.census.gov/content/dam/Census/library/publications/2020/demo/p25-1145.pdf.*

[1101] Roberts SB, Silver RE, Das SK, Fielding RA, Gilhooly CH, Jacques PF, et al. (2021) Healthy Aging-Nutrition Matters: Start Early and Screen Often. Adv Nutr. 12(4):1438–1448. doi: 10.1093/advances/nmab032.

[1102] *Ibid.*

[1103] World Health Organization. (2021). Malnutrition. Available at: *https://www.who.int/news-room/fact-sheets/detail/malnutrition.*

[1104] World Health Organization. (2021). Malnutrition. Available at: *https://www.who.int/news-room/fact-sheets/detail/malnutrition.*

[1105] Barker CA, Gout BS, et al. (2011). Hospital malnutrition prevalence, identification, and impact on patients and the healthcare system. International Journal of Environmental Research and Public Health.8:514–527.

[1106] Wright NC, Looker AC, Saag KG, et al. (2014). The recent prevalence of osteoporosis and low bone mass in the United States based on bone mineral density at the femoral neck or lumbar spine. J Bone Miner Res. 29(11):2520–2526. *https://onlinelibrary.wiley.com/doi/10.1002/jbmr.2269/epdf.*

[1107] U.S. Department of Health and Human Services. (2020). Office of Disease Prevention and Health Promotion. Older Adults: Overview. Healthy People 2020 website. Available at: *https://www.healthypeople.gov/2020/topics-objectives/topic/older-adults.*

[1108] Mangels, AR. (2018). Malnutrition in Older Adults. American Journal of Nursing. 118(3):34–41. doi: 10.1097/01.NAJ.0000530915.26091.be.

[1109] Norman K, Haß U, Pirlich M. (2021). Malnutrition in Older Adults—Recent Advances and Remaining Challenges. Nutrients. 13, 2764. Available at: *https://doi.org/10.3390/nu13082764.*

[1110] Feeding America. (2019). The State of Senior Hunger in America in 2017: An Annual Report. Available at: *https://www.feedingamerica.org/sites/default/files/2019-05/state-of-senior-hunger-2017_full-report.pdf.*

[1111] United States Department of Agriculture Economic Research Service. (2021). Definitions of Food Security. Available at: *https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/definitions-of-food-security.aspx.*

[1112] United States Census Bureau. (2021). Week 39 Household Pulse Survey: September 29–October 11. Available at: *https://www.census.gov/data/tables/2021/demo/hhp/hhp39.html.*

As our population continues to age, it is expected that 1 in 5 residents will be 65 years or older by the year 2030 [1113] and malnutrition risk among seniors is likely to increase.[1114]

One factor contributing to the burden of malnutrition is health disparity across racial and ethnic groups.[1115] Black, Hispanic, and other non-White older adult populations have higher hunger rates than White populations.[1116] Black Americans and Hispanic Americans are nearly 2.5 times and 1.4 times as likely as White Americans, respectively, to lack access to a full-service grocery store; this contributes to higher rates of food insecurity and can increase risk of malnutrition.[1117] Black, Hispanic, and other non-White Americans are also at higher risk for many chronic diseases, emphasizing the importance of addressing nutrition through both prevention and management of these conditions—especially when they cannot access healthy food.[1118]

Patients over 65 comprise more than one-third of all discharges and nearly 13 million seniors are hospitalized each year.[1119] [1120] While Federal data indicate that approximately 8 percent of all hospitalized adults have a diagnosis of malnutrition,[1121] [1122] additional research finds that malnutrition and malnutrition risk can be found in 20 to 50 percent of hospitalized adults.[1123] [1124] This indicates that between 910,000 and 6.5 million hospitalized seniors may experience malnutrition.[1125] Hospitalized adults with a diagnosis of malnutrition have a longer length of stay, higher costs, more comorbidities, five times the likelihood of death, and greater risk of infectious disease and injury compared with other adult inpatients without malnutrition.[1126] [1127] Malnutrition may also contribute to post-hospital syndrome—described as ''an acquired, transient period of vulnerability'' following hospitalization [1128]—which may dramatically increase the risk of readmission.[1129] [1130]

Partly due to the substantial impacts on clinical outcomes,[1131] malnutrition imposes a serious burden on the healthcare system.[1132] Hospitalized patients with poor nutrition have been estimated to incur approximately 300 percent higher healthcare costs than those who are adequately nourished.[1133] Reports indicate that the average cost for an individual hospital stay (including both direct and indirect costs) for a malnourished patient is $25,600 while it is only $13,900 for a well-nourished patient; [1134] further, malnutrition-associated diseases among older adults in the U.S. has been estimated to cost $51.3 billion annually.[1135]

Hospitals have an opportunity to identify malnutrition during the patient admission process and to address it efficiently and effectively with individualized interventions that could optimize outcomes including reduced readmissions and lengths of stay.[1136] Research demonstrates that there is significant room to improve identification, diagnosis, and treatment of malnutrition in hospitalized patients.[1137] [1138] Nutrition screening is the first step in optimal malnutrition care and triggers a nutrition assessment for patients found to be at risk.[1139] [1140]

We have consistently received stakeholder input requesting the addition of nutrition measures to the Hospital IQR Program measure set to address malnutrition of hospitalized patients, including comments described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51639), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53535), the

[1113] United States Census Bureau. (2018). Older People Projected to Outnumber Children for First Time in U.S. History. Available at: *https://www.census.gov/newsroom/press-releases/2018/cb18-41-population-projections.html.*

[1114] Haines J, LeVan D, Roth-Kauffman MM. (2020). Malnutrition in the Elderly: Underrecognized and Increasing in Prevalence. Clinical Advisor. Available at: *https://www.clinicaladvisor.com/home/topics/geriatrics-information-center/malnutrition-in-the-elderly-underrecognized-and-increasing-in-prevalence/.*

[1115] Betor N, Badaracco C, Mitchell K. (2022). Leveraging Inpatient Malnutrition Care to Address Health Disparities. Avalere Insights. Available at: *https://avalere.com/insights/leveraging-inpatient-malnutrition-care-to-address-health-disparities*).

[1116] United States Department of the Treasury CDFI Fund Capacity Building Initiative. (2012). A Summary of Searching for Markets: The Geography of Inequitable Access to Healthy & Affordable Food in the United States. Available at: *https://www.reinvestment.com/wp-content/uploads/2015/12/Searching_For_Markets-Summary_2011.pdf.*

[1117] *Ibid.*

[1118] Dawson MD, Blancato B. (2021). To Advance Health Equity, Measure Hospital Malnutrition Care. Health Affairs. Available at: *https://www.healthaffairs.org/do/10.1377/hblog20210930.667648/full/.*

[1119] Gorman A. (2016). Elderly Hospital Patients Arrive Sick, Often Leave Disabled. Kaiser Health Network. Available at: *https://khn.org/news/elderly-hospital-patients-arrive-sick-often-leave-disabled/.*

[1120] Mattison M. (2021). Hospital Management of Older Adults. Available at: *https://www.uptodate.com/contents/hospital-management-of-older-adults.*

[1121] Barrett ML, Bailey MK, Owens PL. (2016). Non-maternal and non-neonatal inpatient stays in the United States involving malnutrition, 2016. Available at: *https://www.hcup-us.ahrq.gov/reports/HCUPMalnutritionHospReport_083018.pdf.*

[1122] Valladares AF, McCauley SM, Khan M, D'Andrea C, Kilgore K, Mitchell K. (2021). Development and Evaluation of a Global Malnutrition Composite Score. Journal of the Academy of Nutrition and Dietetics. doi: *https://doi.org/10.1016/j.jand.2021.02.002.*

[1123] Pereira GF., Bulik CM, Weaver MA, Holland WC, Platts-Mills TF. (2015). Malnutrition among cognitively intact, noncritically ill older adults in the emergency department. Ann Emerg Med. 65: 85–91.

[1124] Barker CA, Gout BS, et al. (2011). Hospital malnutrition prevalence, identification, and impact on patients and the healthcare system. International Journal of Environmental Research and Public Health. 8:514–527.

[1125] United States Government Accountability Office. (2019). Report to Congressional Requestors. Nutrition Assistance Programs: Agencies Could Do More to Help Address the Nutritional Needs of Older Adults. Available at: *https://www.gao.gov/assets/gao-20-18.pdf.*

[1126] United States Agency for Healthcare Research and Quality. (2016). Healthcare Cost and Utilization Project: Non-maternal and Non-Neonatal Inpatient Stays in the United States Involving Malnutrition 2016. Available at: *https://www.hcup-us.ahrq.gov/reports/HCUPMalnutritionHospReport_083018.pdf.*

[1127] United States Agency for Healthcare Research and Quality. (2013). Characteristics of Hospital Stays Involving Malnutrition, 2013. HCUP Statistical Brief #210. Available at: *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb210-Malnutrition-Hospital-Stays-2013.pdf.*

[1128] Krumholz, HM. (2013). Post-hospital syndrome—an acquired, transient condition of generalized risk. New England Journal of Medicine. 368(2):100–2.

[1129] Sauer, A, Luo M. (2015) Role of Malnutrition in Increasing Risk of Hospital Readmissions. Abbott Nutrition Health Institute. Available at: *http://static.abbottnutrition.com/cms-prod/anhi.org/img/Role-Of-Malnutrition-In-Increasing-Risk-Of-Hospital-Readmissions-article.pdf.*

[1130] Guenter P, Jensen G, Patel V, Miller S, Mogensen KM, Malone A, et al. (2015). Addressing disease-related malnutrition in hospitalized patients: A call for a national goal. Joint Commission Journal on Quality and Patient Safety.41(10):469–73.

[1131] Norman K, Pichard C, Lochs H, Pirlich M. (2008). Prognostic impact of disease-related malnutrition. Clin. Nutr. 27, 5–15.

[1132] Khalatbari-Soltani S, Marques-Vida, P. (2015). The economic cost of hospital malnutrition in Europe; a narrative review. Clin. Nutr. ESPEN. 10, e89–e94.

[1133] Correia MI, Waitzberg DL. (2003). The impact of malnutrition on morbidity, mortality, length of hospital stay and costs evaluated through a multivariate model analysis. Clin Nutr. 22(3):235–9.

[1134] *Ibid.*

[1135] Snider JT, Linthicum MT, Wu Y, et al. (2014). Economic burden of community-based disease-associated malnutrition in the United States. JPEN. 38(2 Suppl):77s–85s.

[1136] *Ibid.*

[1137] Kabashneh S, Alkassis S, Shanah L, Ali H. (2020). A Complete Guide to Identify and Manage Malnutrition in Hospitalized Patients. Cureus. doi: 10.7759/cureus.8486.

[1138] Fitall E, Jones Pratt K, McCauley SM, Astrauskas G, Heck T, Hernandez B, et al. (2019). Improving Malnutrition in Hospitalized Older Adults: The Development, Optimization, and Use of a Supportive Toolkit. Journal of the Academy of Nutrition and Dietetics. 119(9):S25–S31 Available at: *https://www.sciencedirect.com/science/article/pii/S2212267219305039.*

[1139] Skipper A. (2008). Nutrition care process and model part I: the 2008 update. J Am Diet Assoc.108(7):1113–7.

[1140] Swan W, Vivanti A, Hakel-Smith NA, Trostler N, Beck Howarter N, Papoutsakis C. (2017). Nutrition Care Process and Model Update: Toward Realizing People-Centered Care and Outcomes Management. Journal of the Academy of Nutrition and Dietetics. 117(12):2003–2014.

FY 2014 IPPS/LTCH PPS final rule (78 FR 50810), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50056), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49561). In the FY 2018 IPPS/LTCH PPS proposed rule, we solicited public comments on potential future inclusion of malnutrition eCQMs in the Hospital IQR Program (82 FR 20060 through 20061), and in the FY 2018 IPPS/LTCH PPS final rule we provided a summary of these comments (82 FR 38379 through 38380). Commenters expressed support and stated that Medicare beneficiaries would benefit from the adoption of malnutrition eCQMs that support prompt malnutrition screening, assessment, diagnosis, and development of a care plan (82 FR 38379). In addition, the commenters stated that eCQMs specifically designed and tested to be used with patient data documented directly in the EHR would likely impose minimal data collection and reporting burden (82 FR 38379 through 38380). The commenters further stated that the inclusion of malnutrition eCQMs in the Hospital IQR Program measure set could help improve outcomes and quality of life for patients, especially for seniors and the disadvantaged (82 FR 38380). We believe adopting a malnutrition measure would address several priority areas identified in the CMS Equity Plan for Medicare, including evaluating impacts of disparities, integrating equity solutions across CMS programs, and increasing the ability of the healthcare workforce to meet the needs of underserved populations.[1141]

Therefore, in this proposed rule, we are proposing to adopt the Global Malnutrition Composite Score eCQM (NQF #3592e) beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. At this time, CMS quality reporting programs do not include quality measures that specifically address malnutrition. In the CY 2022 Physician Fee Schedule (PFS) final rule (86 FR 65970 through 65971), we adopted the Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols Improvement Activity (IA) as part of the Merit-based Incentives Payment System (MIPS), which incentivizes MIPS-eligible clinicians to create or improve, and then implement, protocols for identifying and providing appropriate support to: (a) Patients with or at risk for food insecurity, and (b) patients with or at risk for poor nutritional status.[1142] In conjunction with adopting the IA under MIPS, we believe adoption of the Global Malnutrition Composite Score eCQM in the Hospital IQR Program has the potential to improve care delivery in the inpatient setting and is likely to ameliorate food insecurity and malnutrition and lead to better health outcomes.

Under the CMS Meaningful Measures Framework,[1143] the Global Malnutrition Composite Score eCQM addresses the quality priority of ''Promote Effective Communication & Coordination of Care'' as well as ''Promote Effective Prevention and Treatment of Chronic Disease.'' Under the CMS Meaningful Measures 2.0 Initiative, the Global Malnutrition Composite Score eCQM addresses the quality priority of ''Affordability and Efficiency.'' [1144]

(2) Overview of Measure

The Global Malnutrition Composite Score eCQM assesses adults 65 years of age and older admitted to inpatient hospital service who received care appropriate to their level of malnutrition risk and malnutrition diagnosis, if properly identified. Best practices for malnutrition care recommend inpatients be screened for malnutrition risk, assessed to confirm findings of malnutrition if found at-risk, and have the proper severity of malnutrition indicated in their diagnosis along with a corresponding nutrition care plan that addresses the respective severity of malnutrition.[1145] [1146]

The proposed malnutrition composite measure includes four component measures, which are first scored separately, and then integrated into an overall composite score. The overall composite score is derived from averaging the individual performance scores of the following four component measures:

- Screening for malnutrition risk at admission;
- Completing a nutrition assessment for patients who screened for risk of malnutrition;
- Appropriate documentation of malnutrition diagnosis in the patient's medical record if indicated by the assessment findings; and
- Development of a nutrition care plan for malnourished patients including the recommended treatment plan.

Together, the four component measures represent the key processes of care of malnutrition associated with the risk identification, diagnosis, and treatment of malnutrition in older hospitalized adults as supported by clinical guidelines and submitted evidence.[1147]

The four component measures were initially submitted for endorsement as individual process measures in the NQF 2015–2017 Health and Well-Being Project.[1148] The NQF declined to endorse any of the individual component measures based on evidence, provider burden concern (including timing of malnutrition screening and assessment), and the unavailability of necessary data elements to report the eCQMs.[1149] The 2015–2017 Health and Well-Being Standing Committee recommended combining individual measures or all measures into a composite measure to make the measure more meaningful by including both the screening and the development of a nutrition care plan into one measure.[1150]

Based on these recommendations, the measure developer conducted additional testing. The four component measures were piloted as a single composite measure at a large hospital in

[1141] Centers for Medicare & Medicaid Services. CMS Equity Plan for Medicare. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/equity-plan.*

[1142] Centers for Medicare & Medicaid Services. Quality Payment Program. Improvement Activities Performance Category: Traditional MIPS Requirements. Available at: *https://qpp.cms.gov/mips/improvement-activities.*

[1143] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

[1144] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.* We note that Meaningful Measures 2.0 is still under development.

[1145] Nepple KG, Tobert CM, Valladares AF, Mitchell K, Yadrick M. (2019). Enhancing Identification and Management of Hospitalized Patients Who Are Malnourished: A Pilot Evaluation of Electronic Quality Improvement Measures. Journal of the Academy of Nutrition and Dietetics. 119(9):S32–S39.

[1146] McCauley SM, Barrocas A, Malone A. (2019). Hospital Nutrition Care Betters Patient Clinical Outcomes and Reduces Costs: The Malnutrition Quality Improvement Initiative Story. Journal of the Academy of Nutrition and Dietetics. 119(9):S11–S14.

[1147] Valladares AF, McCauley SM, Khan M, D'Andrea C, Kilgore K, Mitchell K. (2021). Development and Evaluation of a Global Malnutrition Composite Score. Journal of the Academy of Nutrition and Dietetics. 122(2):P251–P253.

[1148] National Quality Forum. Health and Well-Being Project 2015–2017. Available at: *https://www.qualityforum.org/ProjectDescription.aspx?projectID=80741.*

[1149] National Quality Forum. Prevention and Population Health, Fall 2020 Cycle: CDP Report. Available at: *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=86178.*

[1150] National Quality Forum. Health and Well-Being 2015–2017 Final Report. Available at: *https://www.qualityforum.org/Publications/2017/04/Health_and_Well-Being_2015-2017_Final_Report.aspx.*

the Midwest and the testing results demonstrated that the measures were usable for identifying key improvement areas in malnutrition care related to identifying risk, assessing for malnutrition, developing the appropriate care plan, and ensuring the diagnosis of malnutrition was documented to support follow-up care.[1151] Subsequently, a group of 27 hospitals adopted and reported on the use of the four component measures to guide various projects focused on improving care provided to hospitalized patients who were malnourished or at risk of malnutrition.[1152] The participating hospitals reported changes in measure performance based on implementation of cyclical quality improvement initiatives at their respective institutions. Multivariate analyses were then conducted to identify the relationships between performance on the four component measures with patient outcomes of 30-day readmission and length of stay. The study results concluded that the four component measures could be implemented in a cohort of diverse hospitals and lead to meaningful improvements in measure performance as all four components of the composite measure were significantly associated with improved outcomes for 30-day readmissions.[1153] [1154] Prior analyses also reported early nutrition interventions were associated with reduced patient length of stay.[1155] [1156] [1157] [1158] [1159]

Following measure testing, the measure developer returned to NQF with the composite eCQM for consideration in the Fall 2020 measure cycle.

The Global Malnutrition Composite Score eCQM (MUC20–0032) was included in the publicly available ''List of Measures Under Consideration for December 21, 2020'' (MUC List).[1160] The measure was voted on and approved by the Scientific Methods Panel in October 2020.[1161] The MAP Rural Health Advisory Group reviewed the measure during its January 2021 meeting and agreed that this measure was suitable for use with rural providers in the Hospital IQR Program.[1162] The MAP subsequently offered conditional support for rulemaking, pending NQF endorsement of the measure.[1163]

The composite measure was initially reviewed by the NQF Prevention and Population Health (PPH) Standing Committee for endorsement suitability during its February 2021 measure evaluation meeting [1164] and the full review of the measure was detailed in the NQF Prevention and Population Health Fall 2020 Consensus Development Process (CDP) Report.[1165] The NQF PPH Standing Committee members agreed malnutrition is a significant contributor to infections and pressure ulcers requiring treatment, especially for patients transferred to other care facilities (such as an inpatient rehabilitation hospital), and held a robust discussion with most members supporting the presented evidence and topic area importance that assigns accountability to the hospital team.[1166] Some PPH Standing Committee members questioned the lack of validated and standardized screening and assessment tools specified in the first two components. The measure developer along with the measure steward stated that objective, validated screening tools [1167] and standardized assessment tools [1168] can be implemented to capture variables from structured EHR data fields, such as BMI, dietary history, recent weight loss, illness severity, laboratory values, and age. After further discussion on performance gaps and the ability to discern differences within and between populations, many PPH Standing Committee members stated they wanted to review additional performance data for the eCQM.[1169] The measure developer submitted the requested performance data for the PPH NQF Standing Committee to review, discuss, and revote at the NQF Standing Committee post-comment meeting on June 3, 2021.[1170] At that time, the NQF PPH Standing Committee voted on the overall suitability for endorsement and the NQF Consensus Standards Approval Committee (CSAC) subsequently endorsed the measure (NQF #3592e).[1171]

[1151] Nepple KG, Tobert CM, Valladares AF, Mitchell K, Yadrick M. (2019). Enhancing identification and management of hospitalized patients who are malnourished: A pilot evaluation of electronic quality improvement measures. Journal of the Academy of Nutrition and Dietetics. 119: S32–S39.

[1152] Valladares AF, Kilgore KM, Partridge J, Sulo S, Kerr KW, McCauley S. (2021). How a malnutrition quality improvement initiative furthers malnutrition measurement and care: Results from a hospital learning collaborative. JPEN J Parenter Enteral Nutr. 45: 366–371.

[1153] *Ibid.*

[1154] Anghel S, Kerr KW, Valladares AF, Kilgore KM, Sulo S. (2021). Identifying patients with malnutrition and improving use of nutrition interventions: A quality study in four US hospitals. Nutrition. 91–92; 111360.

[1155] Silver HJ, Pratt KJ, Bruno M, Lynch J, Mitchell K, McCauley SM. (2018). Effectiveness of the malnutrition quality improvement initiative on practitioner malnutrition knowledge and screening, diagnosis, and timeliness of malnutrition-related care provided to older adults admitted to a tertiary care facility: A pilot study. Journal of the Academy of Nutrition and Dietetics. 118(1): 101–109.

[1156] Meehan A, Loose C, Bell J, Partridge J, Nelson J, Goates S. (2017). Health system quality improvement: Impact of prompt nutrition care on patient outcomes and health care costs. J Nurs Care Qual. 2016; 31(3): 217–223.

[1157] Sriram K, Sulo S, VanDerBosch G, et al. A comprehensive nutrition-focused Quality Improvement Program reduces 30-day readmissions and length of stay in hospitalized patients. JPEN J Parenter Enteral Nutr. 41(3): 384–391.

[1158] Somanchi M, Tao X, Mullin GE. (2011). The facilitated early enteral and dietary management effectiveness trial in hospitalized patients with malnutrition. JPEN J Parenter Enteral Nutr. 35(2): 209–216.

[1159] Deutz NE, Matheson EM, Matarese LE, et al. (2016). Readmission and mortality in malnourished, older, hospitalized adults treated with a specialized oral nutritional supplement: A randomized clinical trial. Clin Nutr. 35(1): 18–26.

[1160] Centers for Medicare & Medicaid Services. List of Measures Under Consideration for December 21, 2020. Available at: *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf.*

[1161] National Quality Forum. MAP 2020–2021 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital & PAC/LTC. Available at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC–LTC.aspx.*

[1162] National Quality Forum. Measure Applications Partnership Rural Health Workgroup Virtual Review Meeting Summary. January 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94656.*

[1163] National Quality Forum. MAP 2020–2021 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. March 2021. Available at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

[1164] National Quality Forum. Measure Evaluation Web Meeting #1: Prevention and Population Health. February 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94816.*

[1165] National Quality Forum. Prevention and Population Health Fall 2020 CDP Report. October 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96457.*

[1166] National Quality Forum. Measure Worksheet—3592—Fall 2020 Cycle. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95961.*

[1167] Skipper A, Coltman A, Tomesko J, Piemonte TA, Handu D, Cheng FW, et al. Position of the Academy of Nutrition and Dietetics: Malnutrition (Undernutrition) Screening Tools for All Adults. Journal of the Academy of Nutrition and Dietetics. 120(4):709–713.

[1168] White JV, Guenter P, Jensen G, Malone A, Schofield M. Consensus Statement of the Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition: Characteristics Recommended for the Identification and Documentation of Adult Malnutrition (Undernutrition). J Am Diet Assoc;112(5):730–738.

[1169] National Quality Forum. Post-Comment Web Meeting (Fall 2020 Cycle) Comments Received. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95422.*

[1170] National Quality Forum. Post-Comment Web Meeting (Fall 2020 Cycle) Memo. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95421.*

[1171] National Quality Forum. Consensus Standards Approval Committee Prevention and Population Health Fall 2020 Review. Available at:

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The measure specifications for the Global Malnutrition Composite Score eCQM can be found on the eCQI Resource Center website, available at *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms.*

(3) Data Sources

The eCQM uses data collected through hospitals' EHRs. The measure is designed to be calculated by the hospitals' CEHRT using the patient-level data and then submitted by hospitals to CMS.

(4) Measure Calculation

The Global Malnutrition Composite Score eCQM consists of four component measures, which are first scored separately.[1172] [1173] The overall composite score is derived from averaging the individual performance scores of the four component measures. The malnutrition component measures are all fully specified for use in EHRs. Table IX.E–04. outlines the data specification(s) and data sources for each of the four components.

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TABLE IX.E-04. GLOBAL MALNUTRITION COMPOSITE SCORE ECQM COMPONENTS AND DATA SOURCES

Component	Description	Data Sources
Completion of a Malnutrition Screening	Patients age 65 years and older who were screened for malnutrition	- Inpatient Admission Time - Inpatient Discharge Time - Birthdate - Completed Malnutrition Screening - Completed Malnutrition Screening Time Stamp
Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition	Patients age 65 years and older identified as at-risk for malnutrition based on a malnutrition screening who have a nutrition assessment documented in the medical record	- Inpatient Admission Time - Inpatient Discharge Time - Birthdate - Completed Malnutrition Screening - Malnutrition Screening Result - Completed Nutrition Assessment - Completed Nutrition Assessment Time Stamp
Appropriate Documentation of a Malnutrition Diagnosis	Patients age 65 years and older and found to be malnourished based on a completed nutrition assessment who have documentation of a malnutrition diagnosis	- Inpatient Admission Time - Inpatient Discharge Time - Birthdate - Completed Nutrition Assessment - Nutrition Assessment Result - Malnutrition Diagnosis
Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment	Patients age 65 years and older and found to be malnourished based on a completed nutrition assessment who have a documented nutrition care plan in the medical record.	- Inpatient Admission Time - Inpatient Discharge Time - Birthdate - Completed Nutrition Assessment - Nutrition Assessment Result - Documented Nutrition Care Plan

(5) Measure Numerator

The Global Malnutrition Composite Score eCQM numerator is comprised of the four component measures, that are individually scored for patients 65 years of age and older who are admitted to an acute inpatient hospital. Details on the numerator for each component are specified in Table IX.E–05.

TABLE IX.E-05. GLOBAL MALNUTRITION COMPOSITE SCORE ECQM COMPONENTS' NUMERATOR DESCRIPTIONS

Component	Numerator
Completion of a Malnutrition Screening	Patients in the denominator who have a malnutrition screening documented in the medical record
Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition	Patients in the denominator who have a nutrition assessment documented in the medical record
Appropriate Documentation of a Malnutrition Diagnosis	Patients in the denominator with a diagnosis of malnutrition documented in the medical record
Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment	Patients in the denominator who have a nutrition care plan documented in the medical record

https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95602.

[1172] Valladares AF, McCauley SM, Khan M, D'Andrea C, Kilgore K, Mitchell K. (2021). Development and Evaluation of a Global Malnutrition Composite Score. Journal of the Academy of Nutrition and Dietetics. Available at: *https://www.jandonline.org/article/S2212-2672(21)00075-7/fulltext.*

[1173] National Quality Forum. #3592e Global Malnutrition Composite Score. Available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=3592e.*

(6) Measure Denominator

The measure denominator is the composite, or total, of the four component measures for patients aged 65 years and older who are admitted to an acute inpatient hospital. Details on the denominator (and any exclusions) for each component are specified in Table IX.E–06.

TABLE IX.E-06. GLOBAL MALNUTRITION COMPOSITE SCORE ECQM COMPONENTS' DENOMINATOR DESCRIPTIONS AND EXCLUSIONS

Component	Denominator	Denominator Exclusions
Completion of a Malnutrition Screening	Patients age 65 years and older at time of admission who are admitted to an inpatient hospital	Patients with a length of stay of less than 24 hours
Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition	Patients age 65 years and older at time of admission who are admitted to an inpatient hospital and were identified as at-risk for malnutrition upon completing a malnutrition screening	Patients with a length of stay of less than 24 hours
Appropriate Documentation of a Malnutrition Diagnosis	Patients age 65 years and older at time of admission who are admitted to an inpatient hospital with findings of malnutrition upon completing a nutrition assessment	Patients with a length of stay of less than 24 hours
Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment	Patients age 65 years and older at time of admission who are admitted to an inpatient hospital with findings of malnutrition upon completing a nutrition assessment.	Patients with a length of stay of less than 24 hours

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Each measure component is a proportion with a possible performance score of 0 to 100 percent. After each component score is calculated individually, an unweighted average of all four scores is completed to determine the final composite score with a total score ranging from 0 to 100 percent.[1174]

(7) Data Submission and Reporting

We are proposing to adopt the Global Malnutrition Composite Score eCQM as part of the Hospital IQR Program measure set for which hospitals can self-select beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to section IX.E.10.e. of this proposed rule for our previously finalized eCQM reporting and submission requirements, as well as proposed modifications for these requirements. We also refer readers to section IX.H.10.a.(2). of the preamble of this proposed rule for discussion of a similar proposal to adopt this measure in the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs.

We invite public comment on this proposal.

g. Proposed Hospital-Level, Risk Standardized Patient-Reported Outcomes Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #3559), Beginning With Two Voluntary Reporting Periods in CYs 2025 and 2026, Followed by Mandatory Reporting for Eligible Elective Procedures Occurring July 1, 2025 Through June 30, 2026, Impacting the FY 2028 Payment Determination and for Subsequent Years

(1) Background

Approximately six million adults aged 65 or older suffer from osteoarthritis in the U.S.[1175] Osteoarthritis accounts for more than half of all arthritis-related hospitalizations,[1176] and in 2013 there were approximately 1,023,000 hospitalizations for osteoarthritis.[1177] Hip and knee osteoarthritis is one of the leading causes of disability among non-institutionalized adults,[1178] and roughly 80 percent of patients with osteoarthritis have some limitation in mobility.[1179] Elective total hip arthroplasty (THA) and total knee arthroplasty (TKA) are most commonly performed for degenerative joint disease or osteoarthritis, which affects more than 30 million Americans.[1180] THA and TKA offer significant improvement in quality of life by decreasing pain and improving function in a majority of patients, without resulting in a high risk of complications or death.[1181] [1182] [1183] [1184] However, not all

[1174] Valladares AF, McCauley SM, Khan M, D'Andrea C, Kilgore K, and Mitchell K. (2022). Development and Evaluation of a Global Malnutrition Composite Score. Journal of the Academy of Nutrition and Dietetics. 122(2): p251–253.

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[1180] Centers for Disease Control and Prevention (CDC). Osteoarthritis (OA). *https://www.cdc.gov/arthritis/basics/osteoarthritis.htm.* Accessed March 8, 2019. Available at: *https://www.cdc.gov/arthritis/basics/osteoarthritis.htm.*

[1181] Rissanen P, Aro S, Slatis P, Sintonen H, Paavolainen P. Health and quality of life before and after hip or knee arthroplasty. The Journal of arthroplasty. 1995;10(2):169–175.

[1182] Wiklund I, Romanus B. A comparison of quality of life before and after arthroplasty in

Continued

patients experience benefit from these procedures.[1185] Many patients note that their pre-operative expectations for functional improvement have not been met.[1186] [1187] [1188] [1189] In addition, clinical practice variation has been well documented in the U.S.,[1190] [1191] [1192] readmission and complication rates vary across hospitals,[1193] [1194] and international experience documents wide hospital-level variation in patient-reported outcome measure results following THA and TKA.[1195]

For example, data from the United Kingdom demonstrate that there is a greater than 15 percent difference across hospitals in the proportion of patients showing improvement after surgery.[1196] [1197]

Peri-operative care and care coordination across provider groups and specialties have important effects on clinical outcomes.[1198] [1199] The goal of a hospital-level outcome measure is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patients' health and reducing the burden of their disease. THA and TKA procedures provide a suitable environment for optimizing care, as there are many studies indicating how hospitals and providers can improve outcomes of their patients by addressing aspects of pre-, peri-, and post-operative care.[1200] [1201] [1202] [1203] [1204] [1205]

Due to the absence of large scale and uniformly collected patient-reported outcome (PRO) data available from patients undergoing elective primary THA/TKA, in November 2015 we established an incentivized, voluntary PRO data collection opportunity within the Comprehensive Care for Joint Replacement (CJR) model [1206] to support measure development. Requirements for successful submission of PRO data for eligible elective primary THA/TKA procedures were set forth in the 2015 CJR final rule (80 FR 73274). This Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) performance measure (THA/TKA PRO–PM) was developed and tested using PRO instruments and risk variable data collected and submitted by CJR participant hospitals. PRO data from the first few performance years for the CJR model revealed hospital-level variation in these outcomes across U.S. hospitals, although the full degree and extent of variation is unknown.

In October 2017, we launched the Meaningful Measures Framework to identify high priority areas for quality measurement that improve patient outcomes while also reducing burden on providers.[1207] The initiative captures the agency's vision in evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The scope of the Meaningful Measures Framework continues to evolve as the healthcare environment continues to change. Meaningful Measures 2.0 [1208] is currently underway and aims to promote better collection and integration of patients' voices by incorporating patient reported outcome measures that are embedded into the clinical workflow, are easy to use, and reduce reporting burden.[1209] The THA/TKA PRO–PM is fully developed and aligns with these future Meaningful Measures 2.0 goals, which are still under development.

Elective THA/TKAs are important, effective procedures performed on a

patients who had arthrosis of the hip joint. The Journal of bone and joint surgery. American volume. 1991;73(5):765–769.

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[1185] National Joint Registry. National Joint Registry for England and Wales 9th Annual Report 2012. available at *www.njrcentre.org.uk:* National Joint Registry;2012.

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[1192] American Academy of Orthopaedic Surgeons (AAOS). Preventing Venous Thromboembolic Disease in Patients Undergoing Elective Hip and Knee Arthroplasty: Evidence-Based Guideline and Evidence Report. 2011.

[1193] Suter LG, Grady JN, Lin Z, et al. 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/OR Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). March 2013.

[1194] Suter LG, Parzynski CS, Grady JN, et al. 2013 Measures Update and Specifications: Elective Primary Total Hip Arthroplasty (THA) AND/OR Total Knee Arthroplasty (TKA) Risk-Standardized Complication Measure (Version 2.0). March 2013; Available at: *https://qualitynet.org/.*

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[1196] National Health System: Provisional Patient Reported Outcome Measures (PROMs) in England—for Hip and Knee Replacement Procedures (April 2020 to March 2021): Score Comparison Tool. *https://digital.nhs.uk/data-and-information/publications/statistical/patient-reported-outcome-measures-proms/hip-and-knee-replacement-procedures-april-2020-to-march-2021#resources.*

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[1202] Choong PF, Dowsey MM, Stoney JD. Does accurate anatomical alignment result in better function and quality of life? Comparing conventional and computer-assisted total knee arthroplasty. The Journal of arthroplasty. 2009;24(4):560–569.

[1203] Galea MP, Levinger P, Lythgo N, et al. A targeted home- and center-based exercise program for people after total hip replacement: A randomized clinical trial. Archives of physical medicine and rehabilitation. 2008;89(8):1442–1447.

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[1206] Centers for Medicare & Medicaid Services. Comprehensive Care for Joint Replacement Model. Available at: *https://innovation.cms.gov/innovation-models/cjr.*

[1207] CMS' Meaningful Measures Framework can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[1208] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.* We note that Meaningful Measures 2.0 is still under development.

[1209] *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

broad population, and the patient outcomes for these procedures (such as pain, mobility, and quality of life) can be measured in a scientifically sound way,[1210] [1211] [1212] [1213] [1214] [1215] [1216] [1217] [1218] [1219] [1220] [1221] [1222] are influenced by a range of improvements in care,[1223] [1224] [1225] [1226] [1227] [1228] [1229] [1230] and demonstrate hospital-level variation even after patient case mix adjustment.[1231] [1232] Further, THA/TKA procedures are specifically intended to improve function and reduce pain, making patient reported outcomes a meaningful outcome metric to assess.[1233]

Several stakeholder groups were engaged throughout the development process of the THA/TKA PRO–PM, as recommended in the Measures Management System (MMS) Blueprint,[1234] including a Technical Advisory Group (TAG), a Patient Working Group, and a national, multi-stakeholder TEP consisting of a diverse set of stakeholders, including providers and patients. These groups were convened by the measure developer under contract with CMS and provided feedback on the measure concept, outcome, cohort, risk model variables, reporting results, and data collection. We received feedback from patients and providers that they had a desire for a flexible data collection approach. For example, providers wanted the option to choose to collect their own data or have data collected through an external entity, such as a vendor. Patients wanted to choose from multiple modes of data collection, such as telephone, paper, and/or electronic. We also received feedback from patients and providers that they would like to utilize their patient reported outcome results as part of the shared decision-making process. Patients were more willing to report data if they knew the survey was from their provider, they understood the importance and use of the survey, and they had access to their own survey responses. In response to this feedback, we are not proposing a specific mode for data collection for the THA/TKA PRO–PM. Rather, we are proposing that hospitals may determine a data collection mode that accommodates their clinical workflow. We also received multiple public comments as summarized in the 2015 CJR final rule (80 FR 73274) that we used to support the development of this measure.

The THA/TKA PRO–PM (MUC20–0003) was included in the publicly available ''2020 Measures Under Consideration List.'' [1235] The MAP Coordinating Committee supported the measure, as referenced in the 2020–2021 Final Recommendations report to HHS and CMS.[1236] The NQF endorsed the THA/TKA PRO–PM (NQF #3559) in November 2020.[1237]

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25588 through 25592), we requested public comment on the potential future inclusion of the THA/TKA PRO–PM in the Hospital IQR Program. Many commenters expressed support for the measure, with many commending joint-specific PRO–PMs as an effective way to provide insights to quality improvement opportunities, PRO–PMs for assessing results of surgery as interpreted by patients, and describing the measure as essential for value-based payment models (86 FR 45411 through 45414). Many commenters recommended that the measure be implemented in a phased approach, with voluntary reporting occurring prior to public reporting (86 FR 45411 through 45414). In response to these comments, we are proposing a phased implementation approach, with

[1210] Alviar MJ, Olver J, Brand C, Hale T, Khan F. Do patient-reported outcome measures used in assessing outcomes in rehabilitation after hip and knee arthroplasty capture issues relevant to patients? Results of a systematic review and ICF linking process. J Rehabil Med. 2011;43(5):374–381.

[1211] Alviar MJ, Olver J, Brand C, et al. Do patient-reported outcome measures in hip and knee arthroplasty rehabilitation have robust measurement attributes? A systematic review. J Rehabil Med. 2011;43(7):572–583.

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[1213] Collins NJ, Roos EM. Patient-reported outcomes for total hip and knee arthroplasty: Commonly used instruments and attributes of a ''good'' measure. Clin Geriatr Med. 2012;28(3):367–394.

[1214] Jones CA, Beaupre LA, Johnston DW, Suarez-Almazor ME. Total joint arthroplasties: Current concepts of patient outcomes after surgery. Rheum Dis Clin North Am. 2007;33(1):71–86.

[1215] Lau RL, Gandhi R, Mahomed S, Mahomed N. Patient satisfaction after total knee and hip arthroplasty. Clin Geriatr Med. 2012;28(3):349–365.

[1216] Liebs TR, Herzberg W, Ruther W, Russlies M, Hassenpflug J, Multicenter Arthroplasty Aftercare Project M. Quality-adjusted life years gained by hip and knee replacement surgery and its aftercare. Archives of physical medicine and rehabilitation. 2016;97(5):691–700.

[1217] Montin L, Leino-Kilpi H, Suominen T, Lepisto J. A systematic review of empirical studies between 1966 and 2005 of patient outcomes of total hip arthroplasty and related factors. J Clin Nurs. 2008;17(1):40–45.

[1218] Papalia R, Del Buono A, Zampogna B, Maffulli N, Denaro V. Sport activity following joint arthroplasty: A systematic review. Br Med Bull. 2012;101:81–103.

[1219] Rolfson O, Rothwell A, Sedrakyan A, et al. Use of patient-reported outcomes in the context of different levels of data. J Bone Joint Surg Am. 2011;93 Suppl 3:66–71.

[1220] Suter LG, Potteiger J, Cohen DB, Lin Z, Drye EE, Bernheim SM. Environmental Scan/Literature Review: Total Hip and Total Knee Arthroplasty Patient-Reported Outcome Measure. Report prepared for Centers for Medicare & Medicaid Services. 2012.

[1221] Thorborg K, Roos EM, Bartels EM, Petersen J, Holmich P. Validity, reliability and responsiveness of patient-reported outcome questionnaires when assessing hip and groin disability: A systematic review. BJSM online. 2010;44(16):1186–1196.

[1222] White D, Master H. Patient Reported Measures of Physical Function in Knee Osteoarthritis. Rheum Dis Clin North Am. 2016;42(2):239–252.

[1223] Brown K, Topp R, Brosky JA, Lajoie AS. Prehabilitation and quality of life three months after total knee arthroplasty: A pilot study. Perceptual and motor skills. 2012;115(3):765–774.

[1224] Choong PF, Dowsey MM, Stoney JD. Does accurate anatomical alignment result in better function and quality of life? Comparing conventional and computer-assisted total knee arthroplasty. The Journal of arthroplasty. 2009;24(4):560–569.

[1225] Galea MP, Levinger P, Lythgo N, et al. A targeted home- and center-based exercise program for people after total hip replacement: A randomized clinical trial. Arch Phys Med Rehabil. 2008;89(8):1442–1447.

[1226] Kim K, Anoushiravani A, Chen K, et al. Perioperative Orthopedic Surgical Home: Optimizing Total Joint Arthroplasty Candidates and Preventing Readmission. Journal of Arthroplasty. 2019;34(7):S91–S96.

[1227] McGregor AH, Rylands H, Owen A, Dore CJ, Hughes SP. Does preoperative hip rehabilitation advice improve recovery and patient satisfaction? The Journal of arthroplasty. 2004;19(4):464–468.

[1228] Moffet H, Collet JP, Shapiro SH, Paradis G, Marquis F, Roy L. Effectiveness of intensive rehabilitation on functional ability and quality of life after first total knee arthroplasty: A single-blind randomized controlled trial. Arch Phys Med Rehabil. 2004;85(4):546–556.

[1229] Monticone M, Ferrante S, Rocca B, et al. Home-based functional exercises aimed at managing kinesiophobia contribute to improving disability and quality of life of patients undergoing total knee arthroplasty: A randomized controlled trial. Arch Phys Med Rehabil. 2013;94(2):231–239.

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[1231] Bozic KJ, Grosso LM, Lin Z, et al. Variation in hospital-level risk-standardized complication rates following elective primary total hip and knee arthroplasty. JBJS. 2014;96(8):640–647.

[1232] Mäkelä KT, Peltola M, Sund R, Malmivaara A, Hakkinen U, Remes V. Regional and hospital variance in performance of total hip and knee replacements: A national population-based study. Annals of medicine. 2011;43(sup1):S31–S38.

[1233] Liebs T, Herzberg W, Gluth J, et al. Using the patient's perspective to develop function short forms specific to total hip and knee replacement based on WOMAC function items. Bone Joint J. 2013;95(B):239–243.

[1234] CMS Measures Management System Blueprint (Blueprint v 17.0). CMS. 2020. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

[1235] 2020 Measures Under Consideration List. Available at *https://www.cms.gov/media/492911.*

[1236] MAP 2020–2021 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. NQF. 2021. Available at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

[1237] NQF Quality Positioning System. Available at *https://www.qualityforum.org/QPS.*

two voluntary reporting periods in CY 2025 and 2026 reporting periods prior to mandatory reporting beginning with the CY 2027 reporting period/FY 2028 payment determination, as described in further detail in our discussion on data submission in section IX.E.5.g.(9) of the preamble of this proposed rule.

Furthermore, many commenters recommended that we offer multiple options for data submission, including through the hospital directly or by an external vendor engaged by a hospital for this purpose, to ensure hospitals have the flexibility needed to implement the measure (86 FR 45411 through 45414). In response to those comments, in this proposed rule, we are proposing flexible options for data submission as discussed in more detail in subsequent section. For a more detailed description of the public comments received, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45411 through 45414).

Additionally, we note that many hospitals have already incorporated PRO data collection into their workflows. While we are not proposing to require how hospitals collect data, hospitals new to collecting PRO data have multiple options for when and how they would collect this data and can best determine the mode of data collection that works for their patient population.

(2) Overview of Measure

The THA/TKA PRO–PM reports the hospital-level risk-standardized improvement rate (RSIR) in patient reported outcomes following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older.

Substantial clinical improvement would be measured by achieving a pre-defined improvement in score on joint-specific PRO instruments measuring hip or knee pain and functioning, from the pre-operative assessment (data collected 90 to 0 days before surgery) to the post-operative assessment (data collected 300 to 425 days following surgery). For additional details regarding the measure specifications, we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.*

(3) Data Sources

The THA/TKA PRO–PM uses four sources of data for the calculation of the measure: (1) PRO data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. The measure uses PRO data collected by hospitals pre-operatively and post-operatively (described in section IX.E.5.g.(9).) and limited patient-level risk factor data collected with PRO data and identified in claims. The measure includes PRO data collected with several PRO instruments, among them are two joint-specific PRO instruments—the Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) [1238] for completion by THA recipients and the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) [1239] for completion by TKA recipients—from which scores are used to assess substantial clinical improvement. For risk adjustment by pre-operative mental health score, hospitals would submit one of two additional PRO instruments, either all of the items in the Patient-Reported Outcomes Measurement Information System (PROMIS)-Global Mental Health subscale or all of the items in the Veterans RAND 12-Item Health Survey (VR–12) Mental Health subscale.[1240] [1241] The risk model also includes a one-question patient-reported assessment of health literacy—the Single Item Literacy Screener questionnaire.

Furthermore, the following data are collected for identification of the measure cohort, outcome and for risk adjustment purposes. Claims data are used to identify eligible elective primary THA/TKA procedures for the measure cohort to which submitted PRO data can be matched, and to identify additional variables for risk adjustment and in the statistical approach to accounting for response bias, including patient demographics and clinical comorbidities up to 12 months prior to surgery. The Medicare Enrollment Database (EDB) identifies Medicare FFS enrollment and race, and the Master Beneficiary Summary File allows for determination of Medicare and Medicaid dual eligibility enrollment status. Demographic information from the U.S. Census Bureau's American Community Survey [1242] allows for derivation of the AHRQ SES Index score. Race, dual eligibility, and AHRQ SES Index score are used in the statistical approach to accounting for non-response bias. We refer readers to section IX.E.5.g.(9). for further details regarding the variables required for data collection and submission.

(4) Outcome

The measure outcome (numerator) is the risk-standardized proportion of patients undergoing elective primary THA/TKA who meet or exceed a substantial clinical improvement threshold between pre-operative and post-operative assessments on two joint-specific PRO instruments. The measure outcome will assess patient improvement in PROs using the HOOS, JR following elective primary THA and the KOOS, JR following elective primary TKA. PRO data would be collected 90 to zero days prior to surgery and 300 to 425 days following surgery. These PRO collection periods align with typical patient visits prior to and following surgery.

The measure outcome defines patient improvement as a binary outcome (''Yes''/''No'') of meeting or exceeding the pre-defined improvement threshold between pre-operative and post-operative assessments on the joint-specific PRO instruments: Specifically, for THA patients, meeting or exceeding the threshold of 22 points on the HOOS, JR and, for TKA patients, meeting or exceeding the threshold of 20 points on the KOOS, JR.

(5) Cohort

The measure cohort (denominator) is Medicare FFS beneficiaries aged 65 years and older undergoing elective primary THA/TKA procedures as inpatients in acute care hospitals. We are aware that elective primary THA/TKA procedures are increasingly occurring in hospital outpatient and ambulatory surgical center settings and we will be evaluating options to address measurement of those procedures and settings.

For additional details regarding the measure cohort, we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—

[1238] Lyman S, Lee Y-Y, Franklin PD, Li W, Mayman DJ, Padgett DE. Validation of the HOOS, JR: A Short-form Hip Replacement Survey. *Clinical Orthopaedics and Related Research.*® 2016;474(6):1472–1482.

[1239] Lyman S, Lee Y-Y, Franklin PD, Li W, Cross MB, Padgett DE. Validation of the KOOS, JR: A Short-form Knee Arthroplasty Outcomes Survey. *Clinical Orthopaedics and Related Research.*® 2016;474(6):1461–1471.

[1240] National Institutes of Health (NIH). (Patient Reported Outcomes Measurement Information Systems) PROMIS Instrument Details. Available at: *https://www.nihpromis.org/measures/instrumentdetails.*

[1241] Iqbal US, Rogers W, Selim A, et al. The Veterans Rand 12 Item Health Survey (VR–12): What It Is and How It Is Used. *https://www.hosonline.org/globalassets/hos-online/publications/veterans_rand_12_item_health_survey_vr-12_2007.pdf.*

[1242] American Community Survey, available at: *https://www.census.gov/programs-surveys/acs.*

Measure Methodology Report, available in Hip and Knee Arthroplasty Patient-Reported Outcomes folder at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.*

(6) Inclusion and Exclusion Criteria

The THA/TKA PRO–PM includes patients who are—

- Enrolled in Medicare FFS Part A and Part B for the 12 months prior to the date of the index admission and enrolled in Part A during the index admission;
- Aged 65 or older; and
- Discharged alive from a non-Federal short-term acute care hospital.

The measure includes only elective primary THA/TKA procedures (patients with fractures and revisions are not included). The measure excludes patients with staged procedures, defined as more than one elective primary THA or TKA performed on the same patient during distinct hospitalizations during the measurement period, and patients who leave the hospital against medical advice following the procedure.

(7) Risk Adjustment

The risk model was developed with clinically relevant risk variables identified by public comment in the 2015 CJR final rule (80 FR 73274), the TEP, and expert orthopedic consultants, and supported by empirical analyses. The risk model includes some of the same risk variables collected with PRO data by hospitals in the CJR model as well as risk variables identified in claims. The pre-operative score of the Mental Health subscale from one of two global PRO instruments (the PROMIS-Global or the VR–12) is included as a risk variable. In addition, the risk model includes a validated, one-question patient-reported assessment of health literacy—the Single Item Literacy Screener questionnaire.

Furthermore, poorly or incompletely collected PRO data may be asymmetrically distributed across lower socioeconomic or disadvantaged populations, potentially affecting measure scores. Research on PRO–PM response has indicated that patients of non-White race, patients of lower socio-economic status, and patients with Medicare and Medicaid coverage have lower response rates.[1243] [1244] [1245] Therefore, the measure developer used empirical analyses and stakeholder input to develop an approach to account for response bias in the measure calculation. The approach uses comorbidities, social drivers of health, and demographic variables (such as non-White individuals, dual eligibility, and AHRQ SES index lowest quartile) to predict response to the PRO survey. Weighting the responders based on their likelihood of response (given their patient characteristics) helps reduce non-response bias when calculating the RSIR.

For additional details regarding the approach to risk adjustment and the full risk model, we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available in Hip and Knee Arthroplasty Patient-Reported Outcomes folder at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.*

(8) Measure Calculation

The hospital-level THA/TKA PRO–PM measure result is calculated by aggregating all patient-level results across the hospital. At the hospital level, this measure would be calculated and presented as a RSIR, producing a performance measure per hospital which accounts for patient case mix, addresses potential non-response bias, and represents a measure of quality of care following elective primary THA and TKA. Response rates for PRO data would be calculated as the percentage of elective primary THA or TKA procedures for which complete and matched pre-operative and post-operative PRO data have been submitted divided by the total number of eligible THA or TKA procedures performed at each hospital.

(9) Data Submission

Comments submitted on a request for information in the FY 2022 IPPS/LTCH PPS proposed rule and summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45411 through 45414) recommended CMS provide multiple options for data submission mechanisms to ensure flexibility, including through qualified clinical data registries, as well as through the hospital.

In response to ongoing stakeholder feedback and public comments in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45411through 45414), we are proposing to adopt the THA/TKA PRO–PM in the Hospital IQR Program utilizing multiple submission approaches. For example, hospitals may choose to: (1) Send their data to CMS for measure calculation directly; or (2) utilize an external entity, such as through a vendor or registry, to submit data on behalf of the hospital to CMS for measure calculation. Furthermore, hospitals or vendors would use the HQR System as part of data submission for the THA/TKA PRO–PM. Use of the HQR System leverages existing CMS infrastructure already utilized for other quality measures (such as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey). The HQR System allows for data submission using multiple file formats (such as CSV, XML) and a manual data entry option, allowing hospitals and vendors additional flexibility in data submission. We would provide hospitals with more detailed instructions and information regarding data submission through CMS' existing website QualityNet, and through list servs. This data submission approach is consistent with stakeholder input received by the measure developer during measure development and comments as summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45411 through 45414) which recommended CMS provide multiple options for data submission mechanisms to ensure flexibility.

Hospitals would submit the following pre-operative assessment variables collected between 90 and zero days prior to the THA/TKA procedure: Medicare provider number, Medicare health insurance claim (HIC) number/Medicare beneficiary identifier (MBI), date of birth, date of procedure, date of PRO data collection, procedure type, mode of collection, person completing the survey, date of admission to anchor hospitalization, generic patient reported outcome measure version, PROMIS-Global (mental health subscale items) or VR–12 (mental health subscale items), HOOS, JR (for THA patients), KOOS, JR (for TKA patients), Single-Item Health Literacy Screening (SILS2) questionnaire, BMI or weight (kg)/height (cm), chronic (≥90 day) narcotic use, total painful joint count (patient-reported in non-operative lower extremity joint), and quantified spinal

[1243] Hutchings A, Neuburger J, Frie K, Black N, van der Meulen J. Factors associated with nonresponse in routine use of patient reported outcome measures after elective surgery in England. Health and Quality of Life Outcomes. 2012;10(34).

[1244] Schamber E, Takemoto S, Chenok K, Bozic K. Barriers to completion of patient reported outcome measures. The Journal of arthroplasty. 2013;28:1449–1453.

[1245] Patel J, Lee J, Zhongmin L, SooHoo N, Bozic K, Huddleston J. Predictors of low patient-reported outcomes response rates in the California Joint Replacement Registry. The Journal of arthroplasty. 2015;30:2071–2075.

pain (patient-reported back pain, Oswestry index question [1246] [1247]).

Hospitals would submit the following post-operative assessment variables collected between 300 and 425 days following the THA/TKA procedure: Medicare provider number, Medicare health insurance claim number/ Medicare beneficiary identifier, date of birth, procedure date, date of PRO data collection, procedure type, mode of collection, person completing the survey, date of admission to anchor hospitalization, KOOS, JR (TKA patients), and HOOS, JR (THA patients). The data submission period for the THA/TKA PRO–PM would also serve as the review and correction period. Data would not be able to be corrected following the submission deadline.

For additional details we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available in Hip and Knee Arthroplasty Patient-Reported Outcomes folder at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.*

(a) Voluntary Reporting Period

We are proposing a phased implementation approach for adoption of this measure to the Hospital IQR Program, with two voluntary reporting periods prior to mandatory reporting in the Hospital IQR Program. Voluntary reporting prior to mandatory reporting would allow time for hospitals to incorporate the THA/TKA PRO–PM data collection into their clinical workflows and is responsive to stakeholder comments as summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45411through 45414). For each voluntary and subsequent mandatory reporting period, we would collect data on the THA/TKA PRO–PM in accordance with, and to the extent permitted by, the HIPAA Privacy and Security Rules (45 CFR parts 160 and 164, subparts A, C, and E), and other applicable law.

The first voluntary reporting period proposed for CY 2025 would include pre-operative PRO data collection from October 3, 2022 through June 30, 2023 (for eligible elective primary THA/TKA procedures performed from January 1, 2023 through June 30, 2023) and post-operative PRO data collection from October 28, 2023 to August 28, 2024. Hospitals would submit comm data in 2023 and post-operative data in 2024, and we intend to provide hospitals with their results in confidential feedback reports in 2025. We refer readers to section IX.E.10.k., where we propose the form, manner, and timing for PRO–PMs, including submission deadlines.

The second voluntary reporting period proposed for CY 2026 would include pre-operative PRO data collection from April 2, 2023 through June 30, 2024 (for eligible elective primary THA/TKA procedures performed from July 1, 2023 through June 30, 2024) and post-operative PRO data collection from April 26, 2024 to August 29, 2025. Hospitals would submit pre-operative data in 2024 and post-operative data in 2025, and we intend to provide hospitals with their results in confidential feedback reports in 2026. We refer readers to section IX.E.10.k., where we propose the form, manner, and timing for PRO–PMs, including submission deadlines.

Hospitals that voluntarily submit data for this measure would receive confidential feedback reports that detail submission results from the reporting period. If feasible, we would calculate and provide each participating hospital with their risk-standardized improvement rate as part of the confidential feedback reports. This would provide each hospital with an indication of their performance relative to the other hospitals that participate in the voluntary reporting period. We refer readers to Table IX.E–07. for an overview of the pre- and post-operative performance periods, data collection windows, and data submission deadlines during voluntary reporting.

TABLE IX.E-07. PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO-PM FOR VOLUNTARY REPORTING

Reporting Period	*Performance Period*	*Pre-operative Data Collection Window*	*Pre-operative Data Submission Deadline*	*Post-operative Data Collection Window*	*Post-operative Data Submission Deadline*
Voluntary Reporting 1 (2025)	January 1, 2023 through June 30, 2023	October 3, 2022 through June 30, 2023	October 2, 2023	October 28, 2023 to August 28, 2024	September 30, 2024
Voluntary Reporting 2 (2026)	July 1, 2023 through June 30, 2024	April 2, 2023 through June 30, 2024	September 30, 2024	April 26, 2024 to August 29, 2025	September 30, 2025

(b) Mandatory Reporting

Following the two voluntary reporting periods, we are proposing that mandatory reporting of the THA/TKA PRO–PM would begin with eligible elective primary THA/TKA procedures from July 1, 2024, through June 30, 2025 with affecting the FY 2028 payment determination. Hospitals' data reporting requirements would be based on pre-operative PRO data collection from April 2, 2024, through June 30, 2025 (for eligible elective THA/TKA procedures from July 1, 2024 through June 30, 2025) and post-operative PRO data collection from April 27, 2025, to August 29, 2026. Pre-operative data submission would occur in 2025 and post-data submission in 2026 and we intend to provide hospitals with their results in 2027 before publicly reporting results on the Compare tool hosted by HHS, currently available at *https://www.medicare.gov/care-compare,* or its successor website. For this first mandatory reporting period, hospitals that fail to timely meet the reporting requirements would receive a reduction of their Annual Payment Update (APU) in FY 2028. We refer readers to the section IX.E.10.k.,

[1246] Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine (Phila Pa 1976). 2000 Nov 15;25(22):2940–52; discussion 2952. doi: 10.1097/00007632–200011150–00017. PMID: 11074683.

[1247] The Oswestry Disability Index is in the public domain and available for all hospitals to use.

where we propose the form, manner, and timing for PRO–PMs, including submission deadlines. We refer readers to Table IX.E–08. for an overview of the pre- and post-operative performance periods, data collection windows, and data submission deadlines during mandatory reporting.

TABLE IX.E-08. PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO-PM FOR MANDATORY REPORTING

Reporting Period	*Performance Period*	*Pre-operative Data Collection Window*	*Pre-operative Data Submission Deadline*	*Post-operative Data Collection Window*	*Post-operative Data Submission Deadline*
Mandatory Reporting (2027)	July 1, 2024 through June 30, 2025	April 2, 2024 through June 30, 2025	September 30, 2025	April 27, 2025 to August 29, 2026	September 30, 2026

(10) Public Reporting

(a) Proposed Voluntary Reporting Periods

We are proposing to provide hospitals with their THA/TKA PRO–PM results in confidential feedback reports during the two voluntary reporting periods occurring in 2025 and 2026. While we do not propose to publicly report voluntary THA/TKA PRO–PM hospital-level risk-standardized improvement rates (RSIR) during this period, to acknowledge the efforts of stakeholders who choose to participate in voluntary reporting, and to support their efforts to improve quality in this important area, we are proposing to publicly report which hospitals choose to participate in voluntary reporting and/or the percent of pre-operative data submitted by participating hospitals for the first voluntary reporting period, and their percent of pre-operative and post-operative matched PRO data submitted for subsequent voluntary reporting periods. For example, if out of 100 eligible procedures a hospital submits 45 pre-operative cases that match to post-operative cases, then we would report that hospital submitted 45% of matched pre-operative and post-operative PRO surveys during voluntary reporting

(b) Mandatory Reporting

The THA/TKA PRO–PM results and response rates would be publicly reported on the Compare tool hosted by HHS, currently available at *https://www.medicare.gov/care-compare,* or its successor website, beginning with the first mandatory reporting period for the FY 2028 payment determination. Reporting would be based on pre-operative PRO data April 2, 2024, through June 30, 2025 (for eligible elective THA/TKA procedures from July 1, 2024, through June 30, 2025) and post-operative PRO data collection from April 27, 2025, to August 29, 2026. Hospitals would receive confidential feedback reports prior to public reporting that detail results from the reporting period. If feasible, confidential feedback reports would include the risk-standardized improvement rate as well as other results that support understanding of their performance.

We invite public comment on this proposal.

h. Proposed Medicare Spending per Beneficiary (MSPB) Hospital Measure (NQF #2158) Beginning With the FY 2024 Payment Determination

For the purpose of continuing to assess hospitals' efficiency and resource use and to meet statutory requirements under section 1886(o)(2)(B)(ii) of the Act, we are proposing the adoption of the re-evaluated version of the MSPB Hospital measure in the Hospital IQR Program. We plan to subsequently propose this for the Hospital VPB Program measure set under the Efficiency and Cost Reduction Domain sometime in the future.

(1) Background

In the FY 2012 IPPS/LTCH PPS final rule, we adopted a prior version of the MSPB Hospital measure in both the Hospital IQR Program (76 FR 51618) and the Hospital VPB Program (under the Efficiency and Cost Reduction Domain) (76 FR 51654). The original MSPB Hospital measure was subsequently removed from the Hospital IQR Program beginning with the FY 2020 payment determination, under the proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program (83 FR 41559). The original version of the MSPB Hospital measure that was removed from the Hospital IQR Program was identical to the version that was concurrently, and continues to be used in the Hospital VBP Program. For more information on the removal of the original MSPB Hospital measure from the Hospital IQR Program, please see section VIII.A.4.b of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544). We note that adding the updated MSPB Hospital measure with the refinements outlined above to the Hospital IQR Program would follow the process associated with adopting new measures into the Hospital VBP Program, as specified under section 1889(o)(2)(C)(i) of the Act, and provide beneficiaries, hospitals, and other stakeholders with an opportunity to familiarize themselves with this updated version of the measure before we propose to replace the original MSPB Hospital measure in the Hospital VBP Program and calculate incentive payment adjustments for eligible hospitals. Given that the proposed updated MSPB Hospital measure is different from the original MSPB Hospital measure currently in use in the Hospital VBP Program, we believe that including the updated MSPB Hospital measure in the Hospital IQR program will not incur costs that justified the removal of the original MSPB Hospital measure from the Hospital IQR program in the FY 2019 IPPS/LTCH PPS final rule.

The original MSPB Hospital measure evaluated hospitals' efficiency relative to the efficiency of the national median hospital. Specifically, it assessed the cost to Medicare during an episode of care, which is composed of the period three days prior to an IPPS hospital admission through 30 days after discharge. The measure included Medicare Part A and B payments for services provided to a Medicare beneficiary during an episode. The costs included in this measure were payment standardized to remove sources of variation not directly related to hospitals' care decisions, such as geographic differences in practice expenses. The measure was risk-adjusted to account for factors outside of hospitals' influence. The details of the original MSPB Hospital episode construction and measure calculation can be found in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51627).

As part of our measure maintenance process (as required in section 8 of the Blueprint for the CMS Measures Management System Version 17.0 available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*), we comprehensively re-evaluated the original MSPB Hospital measure in 2020, after it was removed from the Hospital IQR Program beginning with the FY 2020 payment determination period. The re-evaluation was informed by feedback received on this measure through prior public comment periods [1248] and the literature. Specifically, regarding the all-cost nature of the measure, some stakeholders raised concerns that an all-cost approach may result in the measure capturing services that are not under the influence of the facilities or practitioners, while others noted that there is a need for all-cost/condition measures such as the MSPB Hospital measure to promote broad incentives for care coordination. Regarding readmissions triggering new episodes, commenters noted that potentially high cost services occurring after an inpatient readmission are not fully captured under the current methodology that does not allow readmissions to initiate new episodes, and that the correlation between the MSPB Hospital measure and the Hospital Readmission Reduction Program's readmission measures is weak. Finally, some commenters suggested potential need for social risk factor (SRF) adjustments.[1249] Relatedly, the literature has identified dual enrollment in Medicare and Medicaid as a potentially meaningful SRF to adjust for in the VBP programs.[1250]

In the process of evaluating this feedback, the TEP reviewed four main topics to explore as potential changes to the specifications, including—

- Narrowing the all-cost approach through service inclusion and exclusion rules;
- Including SRFs in the measure's risk adjustment model;
- Allowing readmissions to trigger a new episode and include an indicator variable in the risk adjustment model for whether there was an inpatient stay in the 30 days prior to episode start date; and
- Changing the measure calculation from the sum of observed costs divided by the sum of expected costs to the mean of observed costs divided by expected costs.

After reviewing the analyses prepared by the measure development contractor and discussed during the February 2020 meeting, the TEP members provided feedback on each of the potential refinements during the process of re-evaluation. In brief, the TEP believed that the current all-cost methodology approach appropriately reflected the broad scope of a hospital's responsibility of care, and that this was needed to promote broad incentive for care coordination. TEP members highlighted the need for further testing around the impact of including SRF variables in the risk adjustment model. The TEP supported the refinement to allow readmissions to trigger new episodes, as they believed it was clinically appropriate to hold the hospital responsible for these costs. The members also agreed that the slight change to the measure calculation would reduce the impact of outliers on the final measure scores. The summary of the TEP's discussions of the MSBP Hospital measure is in the February 2020 Physician Cost Measures and Patient Relationship Codes TEP Summary Report.[1251]

Through the re-evaluation process and the feedback that was provided by the TEP, we identified three refinements to the measure which would ensure a more comprehensive and consistent reflection of hospital performance by capturing more episodes and adjusting the measure calculation. First, we refined the measure to include all readmissions to trigger new episodes to account for episodes and costs that are currently not included in the measure but that could be within the hospital's reasonable influence. Second, we added an indicator variable in the risk adjustment model for whether there was an inpatient stay in the 30 days prior to episode start date. And third, we revised the measure to change one step in the measure calculation from the sum of observed costs divided by the sum of expected costs (ratio of sums) to the mean of observed costs divided by expected costs (mean of ratios). Based on our measure development contractor's recommendations, informed by the guidance from the TEP and the additional testing of the potential refinements suggested by the TEP, we believe that these changes would benefit the MSPB Hospital measure's relevance and statistical stability as well as ensure a more comprehensive and consistent reflection of hospital performance by capturing more episodes and adjusting the measure calculation. We describe these changes in a summary of the measure re-evaluation on the CMS QualityNet website posted in July 2020.[1252]

We are proposing the updated MSPB Hospital measure for the Hospital IQR Program that incorporates the three changes, which are detailed in the subsequent discussion. We note that aside from these three described refinements, all other aspects of the updated measure are the same as compared to the original measure.

(a) Update To Allow Readmissions To Trigger New Episodes

First, we refined the measure to allow readmissions to trigger new episodes to account for episodes and costs that are currently not included in the measure but that could be within the hospital's reasonable influence. It is clinically appropriate to hold the hospital responsible for the costs that are associated with the readmissions (that is, from 3 days prior to the readmission through 30 days post-discharge) to encourage care transitions and coordination in improving patient care and reducing unnecessary readmissions. Under the previously adopted measure methodology, the measure only included episodes that are triggered by initial hospital admissions, and inpatient readmissions occurring in the 30-day post-discharge period of an existing episode are excluded from initiating new episodes (76 FR 51620 through 51624). Allowing readmissions to trigger new episodes would increase the number of episodes for which a provider can be scored and align the incentives of the measure during readmissions, by encouraging hospitals to provide cost efficient care and improve care coordination not only during initial hospitalizations, but also during readmissions. This refinement would also ensure that the measure captures potentially high-cost services that would otherwise be excluded.

[1248] We received feedback during the public comment periods of the FY 2012 and FY 2013 IPPS/LTCH PPS proposed rules. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51619 through 51627) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53584 through 53592) for a summary of the comments received.

[1249] FY 2012 IPPS/LTCH PPS final rule (76 FR 51624 through 51625) and FY 2013 IPPS/LTCH PPS final rule (77 FR 53586 through 53587).

[1250] Johnston, K.J., & Maddox, K.E.J. (2019). The Role of Social, Cognitive, And Functional Risk Factors In Medicare Spending For Dual And Nondual Enrollees.

[1251] Physician Cost Measures and Patient Relationship Codes TEP Summary Report. (2020). Available at: *https://www.cms.gov/files/zip/physician-cost-measures-and-patient-relationship-codes-pcmp.zip.*

[1252] Medicare Spending Per Beneficiary (MSPB) Measure Methodology. Available at: *https://qualitynet.cms.gov/inpatient/measures/mspb/methodology.*

To illustrate this refinement, take for example a beneficiary who is admitted to an inpatient hospital for a spinal procedure with major complication or comorbidity (MS–DRG 028). This hospital admission triggers an episode (Episode 1), where the episode window starts three days prior to the admission date and ends 30 days after discharge. Episode 1 is attributed to the hospital where the inpatient stay occurs. Fifteen days after being discharged from the hospital, the beneficiary needs to receive additional inpatient hospital care for pneumonia (MS–DRG 194). This readmission occurs within the 30-day post-discharge period of Episode 1 (that is, the episode triggered by the initial hospitalization), and would trigger a new episode (Episode 2). Episode 2's window would start three days prior to this readmission and end 30 days after discharge. Episode 2 would be attributed to the hospital managing this readmission. Under the previous methodology, the readmission would not be calculated under the measure as a new episode because it occurred during the 30-day post-discharge period of Episode 1. However, under the proposed new methodology, the readmission would trigger a new episode (Episode 2), and the episode would be included in the MSPB rate for the hospital managing the readmission. Episode 2 would include the costs in the post-discharge period of the readmission that would not be previously captured. Additionally, the costs where Episode 1 and Episode 2 overlap would be counted towards each episode. We note that the services being assigned to these episodes would only be counted once per episode. In other words, costs would not be double-counted. The revised measure calculation compares each hospital's observed episode costs to predicted episode costs among their peers for patients with the same observable characteristics, rather than to a pre-defined standard. By comparing hospitals to other hospitals that are all attributed in the same way, we expect this comparison to be fair. This also helps to maintain care coordination incentives of the MSPB Hospital measure.

(b) New Indicator Variable in the Risk Adjustment Model

Additionally, to account for the differences in expected costs for episodes that are triggered by readmissions, the updated methodology includes an indicator variable in the risk adjustment model showing whether there was an inpatient stay in the 30 days prior to episode start date. The previous methodology does not include this indicator variable, given that all episodes with an inpatient stay in the 30 days prior to the episode start date (that is, episodes that are based on a hospital readmission) are excluded from the measure calculation (76 FR 51620 through 51624). Continuing with the example used earlier, given that Episode 2 is based on a hospital readmission and there was an inpatient stay within 30 days prior to its episode start date, the risk adjustor indicator would be turned on for Episode 2. This means that when we calculate predicted spending for Episode 2, the risk adjustment model would take into account the fact that this episode was triggered by a readmission, and not an initial admission. This would ensure that the hospital is not unfairly penalized for providing care to the patient during the episode that could be more high cost due to its readmission status.

An illustration of this refinement that compares the previously adopted methodology where a readmission does not trigger a new episode and the proposed new methodology where a readmission does trigger a new episode, is available in Appendix B of the Measure Information Form (MIF) document available at *https://qualitynet.cms.gov/files/5f1b3bd12bd4670021abc1b4?filename=MSPB_Hospital_MIF_2020.pdf.*

(c) Updated MSPB Amount Calculation Methodology

The third refinement changes one step in the measure calculation from the sum of observed costs divided by the sum of expected costs (ratio of sums) to the mean of observed costs divided by expected costs (mean of ratios). Under the previously adopted methodology, we calculated the MSPB Amount as follows: ((Sum of Observed Costs//# of Attributed Episodes)/(Sum of Expected Costs/# of Attributed Episodes)) * Average Observed Cost Nationally (76 FR 51626). The revised methodology calculates the MSPB Amount instead as follows: (Sum (Observed Costs/Expected Costs)/# of Attributed Episodes) * Average Observed Cost Nationally. Under this refinement, changing the measure calculation would: (a) Slightly increase measure reliability with minimal score changes; and (b) evenly weight attributed episodes in the final performance score, where previously good or poor performance on more expensive episodes would have more weight in the provider's final score. Specifically, by changing the measure calculation, the impact of outlier episodes on a measure score would be reduced (under the previously adopted calculation methodology, most costly episodes are weighted proportionately, which would make the measure slightly more sensitive to outlier episodes).

Additionally, the updated MSPB Hospital measure would further align with MSPB cost measures in other settings, including the MSPB Clinician measure in MIPS (84 FR 62974 through 62977), and the MSPB-Post Acute Care (PAC) measures, including MSPB–PAC for Inpatient Rehabilitation Facilities (81 FR 52087 through 52095), Long-Term Care Hospitals (81 FR 57199 through 57207), Skilled Nursing Facilities (81 FR 52014 through 52021), and Home Health Agencies (81 FR 76757 through 76765). The updated MSPB Hospital measure would also align with the acute inpatient medical condition episode-based cost measures in MIPS (83 FR 59767 through 59773, 84 FR 62962 through 62968. and 86 FR 65446 through 65453). We note that while the scope of care is different for clinician, hospital, and post-acute care level measures, we believe aligning these measures would help to ensure consistent care coordination incentives between the hospital, post-acute care facility, and the clinician(s) providing care in those settings.

(2) NQF Re-Endorsement

This original MSPB Hospital measure was first endorsed by the NQF in 2013 [1253] and then again in 2017.[1254] We presented the updated MSPB Hospital measure (NQF ID #2158) with these three refinements to NQF in the Fall 2020 cycle for measure re-endorsement. During the Fall 2020 NQF endorsement cycle, the updated MSPB Hospital measure was reviewed by the Scientific Methods Panel (SMP), Cost and Efficiency Standing Committee, and Consensus Standards Approval Committee (CSAC) during the 11-month endorsement process.[1255] The updated measure passed on the reliability and validity criteria when reviewed by the SMP. The Cost and Efficiency Standing Committee reviewed each aspect of the updated measure in detail across three meetings. They also closely reviewed

[1253] The NQF Cost and Resource Use—Phase 3 Final Report is available at: *https://www.qualityforum.org/Publications/2015/02/Cost_and_Resource_Use_-_Phase_3_Final_Report.aspx,* and the 2013 NQF measure evaluation form is available at: *https://www.qualityforum.org/Projects/c-d/Cost_and_Resource_Project/2158.aspx.*

[1254] NQF. (2017). Cost and Resource Use 2016–2017 Final Technical Report. Available at: *https://www.qualityforum.org/Publications/2017/08/Cost_and_Resource_Use_2016-2017_Final_Technical_Report.aspx.*

[1255] The submission materials, including the testing results, are available at: *https://www.qualityforum.org/ProjectMeasures.aspx?projectID=86056&cycleNo=2&cycleYear=2020.*

our testing around the impact of social risk factors. Specifically, we had tested whether the inclusion of sex, dual eligibility status, race/ethnicity, the AHRQ SES index, components of the AHRQ SES index, and the Area Deprivation Index could meaningfully be incorporated into the measure, so as not to penalize the hospital for the patients they treat, while also not setting a lower standard of care for hospitals with patients that have social risk factors. Results showed that the inclusion of these social risk factors had a limited and inconsistent effect on measure scores, and some of the variation that was captured by tested covariates was attributable to the hospital in which the episodes were initiated. Therefore, social risk factors continue to not be included in the measure's risk adjustment model. The CSAC approved the Standing Committee's endorsement recommendation unanimously, meaning that the updated MSPB Hospital measure (NQF #2158) was re-endorsed in June 2021 with the three refinements we are proposing.[1256]

(3) Measure Applications Partnership Review

Following NQF re-endorsement, the updated measure was included in CMS's ''List of Measures Under Consideration for December 1, 2021.'' [1257] The updated MSPB Hospital measure (MUC2021–131) underwent MAP review during the 2021–2022 cycle. On December 15, 2021, the MAP Hospital Workgroup supported the updated measure for rulemaking. On January 19, 2022, the MAP Coordinating Committee upheld the MAP Hospital Workgroup's preliminary recommendation to support the updated measure for rulemaking. More detail on the discussion is available in the MAP's final report.[1258]

In this proposed rule, we are proposing the updated MSPB Hospital measure (NQF #2158) for the Hospital IQR Program beginning with the FY 2024 payment determination and for subsequent years. This will allow us to assess hospitals' efficiency and resource use and meet statutory requirements for future adoption in the Hospital VBP Program.[1259]

We invite public comment on this proposal.

i. Proposed Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Measure (NQF #1550) Beginning With the FY 2024 Payment Determination

(1) Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53516 through 53521) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50062 through 50063), we adopted the Hospital-Level RSCR Following Elective Primary THA/TKA (hereinafter referred to as the THA/TKA Complication measure) for use in both the Hospital IQR and Hospital VBP Programs, respectively. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49674) for information on the previously adopted measure specifications. Although the measure is still included in the Hospital VBP Program and measure results are still publicly reported, in the FY 2018 IPPS/LTCH PPS final rule (83 FR 41150) we finalized the removal of the measure from the Hospital IQR Program as part of agency-wide efforts to reduce provider burden since the measure was also being reported under the Hospital VBP Program. We, however, believe it is important to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures. In this proposed rule, we are proposing to adopt the re-evaluated form of the THA/TKA Complication measure with an expanded measure outcome. Since the measure was removed from the Hospital IQR Program, it has been revised to include 26 additional mechanical complication ICD–10 codes which were identified during measure maintenance. The statutory requirements of the Hospital VBP Program are set forth in section 1886(o) of the Act. As noted at 42 CFR 412.164(b) measures must be publicly reported for one year prior to the beginning of the performance period in the Hospital VBP Program. Therefore, we are proposing to adopt this measure into the Hospital IQR Program with the intention to eventually propose the updated measure into the Hospital VBP Program after the required year of public reporting in Hospital IQR Program.

THA and TKA are commonly performed procedures for the Medicare population that improve quality of life. From 2016 to 2019, there were 1,012,190 THA and TKA procedures performed on Medicare fee-for-service (FFS) patients 65 years and older.[1260] The number of procedures being performed has steadily increased over the last decade and is projected to reach over four million by 2030.[1261] [1262] While these procedures can dramatically improve a person's quality of life, they are costly. Based on projections of the annual demand for THA and TKA procedures, researchers estimate that Medicare expenditures on Total Joint Arthroplasty (TJA) could climb from $3.95 billion and $7.42 billion for both primary THA and TKA, respectively, in 2005,[1263] to $50 billion by 2030.[1264] Complications following elective THA and TKA procedures are rare, but the results can be devastating. Evidence shows that periprosthetic joint infection rates following THA and TKA range from 0.7 percent to 1.6 percent depending upon the population.[1265] [1266] Reported 30- and 90-day death rates following THA range from 0.4 percent to 0.7 percent.[1267] Rates for pulmonary embolism following THA range from 0.5 percent to 1.22 percent[1268] and range

[1256] NQF. (2020). Cost and Efficiency Final Report—Fall 2020 Cycle. Available at: *https://www.qualityforum.org/Publications/2021/09/Cost_and_Efficiency_Final_Report_-_Fall_2020_Cycle.aspx.*

[1257] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96464.*

[1258] National Quality Forum, (2022) Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care (*https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*)

[1259] Sections 1886(o)(2)(B)(ii) and 1886(o)(2)(C)(i) of the Social Security Act (*https://www.ssa.gov/OP_Home/ssact/title18/1886.htm*).

[1260] Triche, E., J.N. Grady, and J.e.a. Debuhr, Procedure Specific Complication Measure Updates and Specifications Report: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Risk-Standardized Complication Measure (Version 9.0). 2020.

[1261] Kurtz, S., et al., Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am, 2007. 89(4): p. 780–5.

[1262] Kurtz, S.M., et al., Impact of the economic downturn on total joint replacement demand in the United States: updated projections to 2021. J Bone Joint Surg Am, 2014. 96(8): p. 624–30.

[1263] Kurtz, S.M., et al., Future clinical and economic impact of revision total hip and knee arthroplasty. J Bone Joint Surg Am, 2007. 89 Suppl 3: p. 144–51.

[1264] Wilson, N.A., et al., Hip and knee implants: current trends and policy considerations. Health Aff (Millwood), 2008. 27(6): p. 1587–98.

[1265] Kurtz S, Ong K, Lau E, Bozic K, Berry D, Parvizi J. Prosthetic joint infection risk after TKA in the Medicare population. Clin Orthop Relat Res. 2010; 468:5.

[1266] Bozic KJ, Grosso LM, Lin Z, et al. Variation in hospital-level risk-standardized complication rates following elective primary total hip and knee arthroplasty. J Bone Joint Surg Am. 2014;96(8):640–647. doi:10.2106/JBJS.L.01639.

[1267] Soohoo NF, Farng E, Lieberman JR, Chambers L, Zingmond DS. Factors That Predict Short-term Complication Rates After Total Hip Arthroplasty. Clin Orthop Relat Res. Sep 2010;468(9):2363–2371.

[1268] Arshi A, Leong NL, Wang C, Buser Z, Wang JC, SooHoo NF. Outpatient total hip arthroplasty in the United States: A population-based comparative analysis of complication rates. J Am Acad Orthop Surg. 2019;27(2):61–7.

from 0.5 percent to 0.9 percent[1269] following TKA. Rates for wound infection in Medicare population-based studies vary between 0.21 percent and 1.0 percent.[1270] Rates for sepsis/septicemia range from 0.09 percent during the index admission to 0.3 percent 90 days following discharge for primary TKA. Rates for bleeding and hematoma following TKA range from 0.94 percent to 1.7 percent.[1271]

The updated THA/TKA Complication measure was listed in the publicly available document entitled ''List of Measures Under Consideration for December 1, 2021'' [1272] (MUC List) with identification number MUC2021–118. The MAP reviewed the updated measure and voted to conditionally support the measure for rulemaking for use in the Hospital IQR Program pending NQF review and endorsement of the measure update. The MAP Rural Health Advisory Group reviewed this updated measure on December 8, 2021 and voted to majority support the measure given that there would be no undue consequences for rural hospitals.[1273]

The NQF re-endorsed the original measure in July of 2021; and we intend to submit the updated measure to NQF for endorsement in Fall 2024.[1274] We note that section 1866(b)(3)(B)(viii)(IX)(aa) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures on this topic, and, therefore, we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

(2) Overview of Measure

The original THA/TKA Complication measure (NQF #1550) was previously removed from the Hospital IQR Program, but is currently implemented in the Hospital VBP Program (79 FR 50062 through 50063). We are proposing to adopt the newly refined version of this measure into the Hospital IQR Program that would expand the measure outcome to include 26 additional mechanical complication ICD–10 codes. We note that aside from the additional ICD–10 codes, measure specifications would align with the version of the measure currently in use in the Hospital VBP Program.

(3) Data Sources

The proposed updated THA/TKA Complication measure uses index admission diagnoses and in-hospital comorbidity data from Medicare Part A claims. Additional comorbidities prior to the index admission are assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to index (initial) admission. Enrollment status is obtained from the Medicare Enrollment Database which contains beneficiary demographic, benefit/coverage, and vital status information. We are proposing to use claims data with admission dates beginning from April 1, 2019–March 31, 2022 (excluding data from the period covered by the ECE granted by CMS related to the COVID–19 Public Health Emergency (PHE)) that is associated with the FY 2024 payment determination. As a claims-based measure, hospitals would not be required to submit additional data for calculating the measure.

(4) Outcome

The outcome for the proposed updated THA/TKA Complication measure is any complication occurring during the index admission (not coded as present on admission (POA)) to 90 days post-date of the index admission. Complications are counted in the measure only if they occur during the index hospital admission or during a readmission. The complication outcome is a dichotomous (yes/no) outcome. If a patient experiences one or more of these complications in the applicable time period, the complication outcome for that patient is counted in the measure as a ''yes.''

The proposed updated measure includes the following 26 additional clinically vetted mechanical complication ICD–10 codes:

- M96.65 Fracture of pelvis following insertion of orthopedic implant, joint prosthesis, or bone plate.
- M96.661 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, right leg.
- M96.662 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, left leg.
- M96.669 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, unspecified leg.
- M96.671 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, right leg.
- M96.672 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, left leg.
- M96.679 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, unspecified leg.
- M97.01XA Periprosthetic fracture around internal prosthetic right hip joint, initial encounter.
- M97.01XD Periprosthetic fracture around internal prosthetic right hip joint, subsequent encounter.
- M97.01XS Periprosthetic fracture around internal prosthetic right hip joint, sequela.
- M97.02XA Periprosthetic fracture around internal prosthetic left hip joint, initial encounter.
- M97.02XD Periprosthetic fracture around internal prosthetic left hip joint, subsequent encounter.
- M97.02XS Periprosthetic fracture around internal prosthetic left hip joint, sequela.
- M97.11XA Periprosthetic fracture around internal prosthetic right knee joint, initial encounter.
- M97.11XD Periprosthetic fracture around internal prosthetic right knee joint, subsequent encounter.
- M97.11XS Periprosthetic fracture around internal prosthetic right knee joint, sequela.
- M97.12XA Periprosthetic fracture around internal prosthetic left knee joint, initial encounter.

[1269] Khatod M, Inacio M, Paxton EW, et al. Knee replacement: epidemiology, outcomes, and trends in Southern California: 17,080 replacements from 1995 through 2004. Acta Orthop. Dec 2008;79(6):812–819.

[1270] Browne J, Cook C, Hofmann A, Bolognesi M. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. Mar 2010;17(2):152–156.

[1271] Huddleston JI, Maloney WJ, Wang Y, Verzier N, Hunt DR, Herndon JH. Adverse Events After Total Knee Arthroplasty: A National Medicare Study. The Journal of Arthroplasty. 2009;24(6, Supplement 1):95–100.

[1272] *https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf.*

[1273] *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

[1274] National Quality Forum. Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) Measure Specifications. 2021. *https://www.qualityforum.org/QPS/1550.*

- M97.12XD Periprosthetic fracture around internal prosthetic left knee joint, subsequent encounter.
- M97.12XS Periprosthetic fracture around internal prosthetic left knee joint, sequela.
- M97.8XXA Periprosthetic fracture around other internal prosthetic joint, initial encounter.
- M97.8XXD Periprosthetic fracture around other internal prosthetic joint, subsequent encounter.
- M97.8XXS Periprosthetic fracture around other internal prosthetic joint, sequela.
- M97.9XXA Periprosthetic fracture around unspecified internal prosthetic joint, initial encounter.
- M97.9XXD Periprosthetic fracture around unspecified internal prosthetic joint, subsequent encounter.
- M97.9XXS Periprosthetic fracture around unspecified internal prosthetic joint, sequela.
- M96.69 Fracture of other bone following insertion of orthopedic implant, joint prosthesis, or bone plate.

During routine measure maintenance, our analyses showed the addition of these clinically relevant codes contributed to an increase in the THA/TKA national observed complication rate. Findings demonstrated an increase of approximately 0.5 percent (from 2.42 percent to 2.93 percent) in the THA/TKA national observed complication rate when evaluated for the FY 2021 performance period (April 1, 2016 through March 30, 2019). These findings suggest that the expanded outcome will allow the updated THA/TKA Complication measure to capture a more complete outcome.

The updated THA/TKA Complication measure as with the version of measure currently implemented in the Hospital VBP Program (86 FR 45279 through 45281), excludes admissions with a principal or secondary COVID–19 diagnosis, POA, from the measure outcome, as outcomes for patients with COVID–19 who are receiving THA/TKA surgery may differ from patients without COVID–19. The four medical complication outcomes that this applies to are: (1) Acute myocardial infarction (AMI) during a subsequent inpatient admission that occurs within 7 days from the start of the index admission; (2) pneumonia or other acute respiratory complication during a subsequent inpatient admission that occurs within 7 days from the start of the index admission; (3) sepsis/septicemia/shock during a subsequent inpatient admission that occurs within 7 days from the start of the index admission; and (4) pulmonary embolism during the index admission or a subsequent inpatient admission within 30 days from the start of the index admission. In these cases, readmissions with a principal or secondary diagnosis POA of COVID–19 (U07.1) will be removed from the numerator.

We refer readers to the Hip and Knee Arthroplasty Complications (ZIP) folder on the *CMS.gov* Measure Methodology website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology* for measure specification details on this newly restructured measure.

(5) Cohort

The proposed updated THA/TKA Complication measure continues to include Medicare FFS beneficiaries, aged 65 years or older, having a qualifying elective primary THA or TKA procedure during the index admission. Beneficiaries must be enrolled in Medicare FFS Part A and Part B for the 12 months prior to the date of admission and enrolled in Part A during the index admission. We also note that the updated THA/TKA Complication measure excludes admissions with a principal or secondary COVID–19 diagnosis, POA, from the measure cohort.

(6) Risk Adjustment

The proposed updated THA/TKA Complication measure is risk adjusted using clinically relevant risk variables identified from inpatient and outpatient claims in the 12 months prior to the procedure. We would also include a covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission.

(7) Measure Calculation

The updated THA/TKA Complication measure would be calculated using a hospital risk-standardized complication rate by producing a ratio of the number of ''predicted'' complications (that is, the adjusted number of complications at a specific hospital based on its patient population) to the number of ''expected'' complications (that is, the number of complications if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national observed complication rate. For each hospital, the numerator of the ratio is the number of complications within the specified time period (up to 90 days) predicted on the basis of the hospital's performance with its observed case mix, and the denominator is the number of complications expected based on the nation's performance with that hospital's case mix. This approach is analogous to a ratio of ''observed'' to ''expected'' used in other types of statistical analyses. It conceptually allows for a comparison of a particular hospital's performance given its case mix to an average hospital's performance with the same case mix.

We are proposing to adopt the newly restructured version of the THA/TKA Complication measure beginning with admission dates from April 1, 2019–March 31, 2022 (excluding data from the period covered by the ECE granted by CMS related to the COVID–19 Public Health Emergency (PHE)) affecting the FY 2024 payment determination.

(8) Public Reporting

If finalized as proposed, we would also publicly report the updated THA/TKA Complication measure on the Compare tool hosted by HHS, currently available at *https://www.medicare.gov/care-compare,* or its successor website, beginning in 2023.

We invite public comment on this proposal.

6. Proposed Refinements to Current Measures in the Hospital IQR Program Measure Set

In this proposed rule, we are proposing refinements to two measures currently in the Hospital IQR Program measure set—Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA and/or TKA and Excess Days in Acute Care (EDAC) After Hospitalization for Acute Myocardial Infarction (AMI)—beginning with the FY 2024 payment determination. We provide more details on our proposals in the subsequent discussion.

a. Proposed Refinement of the Hospital-Level, Risk-Standardized Payment Associated With an Episode of Care for Primary Elective Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Measure (NQF #3474) Beginning With the FY 2024 Payment Determination and for Subsequent Years

(1) Background

In this proposed rule, we are proposing a refinement to the Hospital-Level, Risk-Standardized Payment Associated with an Episode of Care for Primary Elective THA and/or TKA Measure (NQF #3474) (hereinafter referred to as the THA/TKA Payment measure), which expands the measure outcome to include 26 clinically vetted mechanism complication ICD–10 codes, for the FY 2024 payment determination and subsequent years. For the purposes of describing the refinement of this measure, we note that the ''outcome'' is defined as hospital-level, risk-

standardized payment associated with a 90-day episode-of-care for primary elective THA and/or TKA.

The THA/TKA Payment measure was first adopted into the Hospital IQR Program in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49680) for the FY 2018 payment determination and subsequent years. Prior to adopting the measure, the MAP conditionally supported it on December 10, 2014, pending a timely review by the NQF Cost and Resource Use Standing Committee.[1275] The MAP recommended harmonizing and determining the most parsimonious approach to measure the costs of hip and knee replacements to minimize the burden and confusion of competing methodologies.[1276] The original measure was initially NQF endorsed in June 2019 and will be submitted for the first re-endorsement in Fall 2022.[1277]

The proposed refined measure was included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2021'' [1278] (MUC List) with identification number MUC2021–120. The refined measure was reviewed by the MAP and conditionally supported for rulemaking pending NQF review and endorsement of the measure update.[1279]

As noted earlier, we intend to submit the revised measure for the first NQF re-endorsement in the Fall of 2022. We note that section 1866(b)(3)(B)(viii)(IX)(aa) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures on this topic, and, therefore, we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

(2) Overview of Measure

The proposed measure refinement would expand the measure outcome to include 26 mechanical complication ICD–10 codes to the outcome. This refinement is in alignment with the refinement of the updated THA/TKA Complication measure proposed in section IX.E.5.i. of the preamble of this proposed rule. The data sources, cohort, inclusion and exclusion criteria, and risk adjustment remain substantively unchanged. We are proposing this measure refinement for the FY 2024 payment determination and subsequent years, reflecting data collected beginning from April 1, 2019 through March 31, 2022 admissions (excluding data from the period covered by the ECE granted by CMS related to the COVID–19 PHE).

(3) Data Sources

We are not proposing any changes to the data sources for the THA/TKA Payment measure. The measure uses Part A and Part B Medicare administrative claims data that contain payments for Medicare FFS beneficiaries who were hospitalized and underwent an elective THA/TKA. This measure uses three years of data.

(4) Outcome

The primary outcome of this measure is the hospital-level risk-standardized payment for an elective primary THA/TKA episode-of-care. This measure captures payments for Medicare FFS patients across multiple care settings, services, and supplies (inpatient, outpatient, skilled nursing facility, home health, hospice, physician/clinical laboratory/ambulance services, and durable medical equipment, prosthetics/orthotics, and supplies). This measure includes patient copayments as well as payments from coinsurance.

This measure uses the index admission for an elective primary THA/TKA to 90 days postadmission. The measurement includes all payments for the first 30 days after admission and only certain payments based on a pre-defined set of care settings and services for days 31–90. Payments in the 31–90-day window include readmissions for complications as defined in the THA/TKA Complication measure (Mechanical Complications and Periprosthetic Joint Infection/Wound Infection and Other Wound Complications) (see section IX.E.5.i. of this proposed rule for discussion on this measure), therefore, the expansion of the definition of mechanical complications impacts this measure as well.

As we are proposing no changes besides the addition of the 26 mechanical complication codes, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49674) for information on the previously adopted measure specifications. We refer readers to Hip and Knee Arthroplasty Payment (ZIP) folder on the *CMS.gov* Methodology website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology* for updated specifications on this measure.

The proposed additional 26 mechanical complication ICD–10 codes are the following:

- M96.65 Fracture of pelvis following insertion of orthopedic implant, joint prosthesis, or bone plate.
- M96.661 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, right leg.
- M96.662 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, left leg.
- M96.669 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, unspecified leg.
- M96.671 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, right leg.
- M96.672 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, left leg.
- M96.679 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, unspecified leg.
- M97.01XA Periprosthetic fracture around internal prosthetic right hip joint, initial encounter.
- M97.01XD Periprosthetic fracture around internal prosthetic right hip joint, subsequent encounter.
- M97.01XS Periprosthetic fracture around internal prosthetic right hip joint, sequela.
- M97.02XA Periprosthetic fracture around internal prosthetic left hip joint, initial encounter.
- M97.02XD Periprosthetic fracture around internal prosthetic left hip joint, subsequent encounter.
- M97.02XS Periprosthetic fracture around internal prosthetic left hip joint, sequela.

[1275] *https://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx.*

[1276] *https://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx.*

[1277] *https://www.qualityforum.org/QPS/QPSTool.aspx.*

[1278] *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

- M97.11XA Periprosthetic fracture around internal prosthetic right knee joint, initial encounter.
- M97.11XD Periprosthetic fracture around internal prosthetic right knee joint, subsequent encounter.
- M97.11XS Periprosthetic fracture around internal prosthetic right knee joint, sequela.
- M97.12XA Periprosthetic fracture around internal prosthetic left knee joint, initial encounter.
- M97.12XD Periprosthetic fracture around internal prosthetic left knee joint, subsequent encounter.
- M97.12XS Periprosthetic fracture around internal prosthetic left knee joint, sequela.
- M97.8XXA Periprosthetic fracture around other internal prosthetic joint, initial encounter.
- M97.8XXD Periprosthetic fracture around other internal prosthetic joint, subsequent encounter.
- M97.8XXS Periprosthetic fracture around other internal prosthetic joint, sequela.
- M97.9XXA Periprosthetic fracture around unspecified internal prosthetic joint, initial encounter.
- M97.9XXD Periprosthetic fracture around unspecified internal prosthetic joint, subsequent encounter.
- M97.9XXS Periprosthetic fracture around unspecified internal prosthetic joint, sequela.
- M96.69 Fracture of other bone following insertion of orthopedic implant, joint prosthesis, or bone plate.

We are proposing the addition of these codes as proposed refinements to the THA/TKA Payment measure in response to recent analyses during routine measure maintenance showing that the addition of these codes would increase the national observed complication rate within the proposed THA/TKA Complication measure (NQF #1550) discussed earlier in this proposed rule. This demonstrates that the exclusion of these codes could result in missed complications. A number of clinicians in the field of orthopedics vetted the proposed addition of the new ICD–10 codes to identify the complications of care. As described in section IX.E.5.i. of the preamble of this proposed rule, we anticipate the inclusion of these additional complication codes would increase the national observed complication rate and therefore may impact payments. Payments in the 31–90-day window are included readmissions for complications as defined in the proposed THA/TKA Complication measure (Mechanical Complications and Periprosthetic Joint Infection/Wound Infection and Other Wound Complications), therefore, the expansion of the definition of mechanical complications impacts the THA/TKA Payment measure as well. Since the payment measure uses these codes for payment included in the post-30-day window, we would also anticipate an increase in total payments.

If finalized as proposed, these refinements to the measure would be effective for admissions from April 1, 2019 through March 31, 2022 (excluding data from the period covered by the ECE granted by CMS related to the COVID–19 PHE) and impacting the FY 2024 payment determination and subsequent years.

We invite public comment on this proposal.

b. Proposed Refinement of the Excess Days in Acute Care (EDAC) After Hospitalization for Acute Myocardial Infarction (AMI) Measure (NQF #2881) Beginning With the FY 2024 Payment Determination and for Subsequent Years

(1) Background

The EDAC After Hospitalization for AMI (hereinafter referred to as AMI EDAC) measure was initially adopted in the Hospital IQR Program in the FY 2016 IPPS/LTCH PPS final rule (FR 80 49660 through 49690) beginning with the FY 2018 payment determination. The measure is intended to capture the quality-of-care transitions provided to discharged patients hospitalized with AMI by collectively measuring a set of adverse acute care outcomes that can occur post-discharge: (1) ED visits, (2) observation stays, and (3) unplanned readmissions at any time during the 30 days post-discharge. Safely transitioning patients from hospital to home requires a complex series of tasks including timely and effective communication between providers, prevention of and response to complications, patient education about post-discharge care and self-management, timely follow-up, and more. Suboptimal transitions contribute to a variety of adverse events post-discharge, including ED evaluation, need for observation, and readmission. Within the Hospital IQR Program's measure set, the AMI EDAC measure illuminates post-discharge outcomes that are important to patients, better informs consumers about care quality, and incentivizes improvement in transitional care.

(2) Overview of Measure

We are proposing to refine this measure by increasing the minimum case count for reporting. The NQF Scientific Methods Panel Committee and stakeholder feedback indicated that the measure's reliability was not adequate. Therefore, we are proposing to increase the reporting threshold to 50 cases in an effort to balance the need to include as many hospitals as possible while maintaining acceptable measure reliability.[1280] The remainder of the AMI EDAC measure specifications, including the data sources, outcome, cohort, exclusion criteria, risk adjustment approach, and measure calculation would remain unchanged as compared to what is currently adopted in the Hospital IQR Program.

For more detailed measure specifications, we refer readers to the ''2017 Condition-Specific Measures Updates and Specifications Report Hospital-Level 30-Day Risk-Standardized Excess Days in Acute Care Measures: Acute Myocardial Infarction—Version 2.0'' available in the AMI, HF Excess Days in Acute Care folder on the *CMS.gov* Measure Methodology website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology* and the *CMS.gov* QualityNet website at *https://qualitynet.cms.gov/inpatient/measures/complication/methodology.*

(3) Proposed Update to Minimum Case Count

In this proposed rule, we are proposing a refinement to the currently adopted version of the AMI EDAC measure to increase the minimum case count of 25 to a minimum case count of 50 during the measurement period. The increase to the minimum case count would improve the measure's reliability. Based on internal analyses using the reporting period July 1, 2016 through June 30, 2019, the split-sample intraclass correlation (ICC) with Spearman Brown Adjustment increased when we increased the minimum case count from .384 with 25 admissions to .402 with 50 admissions. Based on our analysis, the mean performance rate for all hospitals was 3.6 excess days per 100 discharges, with a standard deviation of 26.3. For hospitals with at least 50 admissions in the same performance period, the mean performance rate was 6.9 per 100 discharges, with a standard deviation of 22. Additionally, 1,805 hospitals of 4,074 hospitals (or 44.3 percent) meet the minimum case count of 50 admissions for the same performance period.

[1280] National Quality Forum. Scientific Methods Panel: Spring 2021 Measure Evaluation Meeting Transcript. March 30, 2021. *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95191.*

Based on this improvement in reliability, we are proposing to increase the AMI EDAC measure's minimum case count reporting threshold from 25 to 50 beginning with the FY 2024 payment determination using the reporting period July 1, 2019 through June 30, 2022 (excluding data from the period covered by the ECE granted by CMS related to the COVID–19 PHE), for which public display of the measure results would occur as part of a 2023 Compare website refresh (or as soon as operationally feasible thereafter), and for subsequent years. We are proposing that hospitals with fewer than 50 cases for the AMI EDAC measure would continue to receive confidential feedback reports containing measure results to understand their performance. Public reporting of measure results on the Compare tool hosted by HHS, currently available at *https://www.medicare.gov/care-compare,* or its successor website, would only occur for hospitals meeting the 50 minimum cases required for reporting. Hospitals would not need to submit additional data as the AMI EDAC measure is calculated using administrative claims submitted to CMS for payment purposes.

We invite public comment on this proposal.

7. Summary of Previously Finalized and Proposed Hospital IQR Program Measures

a. Summary of Previously Finalized and Proposed Hospital IQR Program Measures for the FY 2024 Payment Determination

This table summarizes the previously finalized and newly proposed Hospital IQR Program measure set for the FY 2024 payment determination:

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TABLE IX.E-09. MEASURES FOR THE FY 2024 PAYMENT DETERMINATION

Short Name	Measure Name	NQF #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Outcome Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE*	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
READM-30-HWR**	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days***	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment***	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	3474
MSPB****	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158
Claims and Electronic Data Measures		
Hybrid HWR**	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* In this proposed rule, we are proposing adoption of a refined Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA measure beginning with the FY 2024 payment determination and for subsequent years. We refer readers to section IX.E.5.i. for more detailed discussion.

** In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid HWR measure (NQF #2879), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

*** In this proposed rule, we are proposing refinements to two current Hospital IQR Program measures—Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA and Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction (AMI)—beginning with the FY 2024 payment determination. We refer readers to sections IX.E.6.a. and IX.E.6.b, respectively, for more detailed discussion.

**** In this proposed rule, we are proposing adoption of a refined the MSPB Hospital measure beginning with the FY 2024 payment determination. We refer readers to section IX.E.5.h. for more detailed discussion.

b. Summary of Previously Finalized and Proposed Hospital IQR Program Measures for the FY 2025 Payment Determination

This table summarizes the previously finalized and newly proposed Hospital IQR Program measure set for the FY 2025 payment determination:

TABLE IX.E-10. MEASURES FOR THE FY 2025 PAYMENT DETERMINATION

Short Name	Measure Name	NQF #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality/Complications Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE*	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
READM-30-HWR**	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days***	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment***	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	3474
MSPB****	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158
Claims and Electronic Data Measures		
Hybrid HWR**	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Hybrid HWM*****	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
HCHE******	Hospital Commitment to Health Equity	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
ePC-02*******	Cesarean Birth	N/A
ePC-07/SMM*******	Severe Obstetric Complications	N/A
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)
Process Measures		
SDOH-1********	Screening for Social Drivers of Health	N/A
SDOH-2********	Screen Positive Rate for Social Drivers of Health	N/A

* In this proposed rule, we are proposing adoption of a refined Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA measure beginning with the FY 2024 payment determination and for subsequent years. We refer readers to section IX.E.5.i. for more detailed discussion.
** In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid HWR measure (NQF #2879), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.
*** In this proposed rule, we are proposing refinements to two current Hospital IQR Program measures—Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA and Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction (AMI)—beginning with the FY 2024 payment determination. We refer readers to sections IX.E.6.a. and IX.E.6.b, respectively, for more detailed discussion.
**** In this proposed rule, we are proposing adoption of a refined MSPB Hospital measure beginning with the FY 2024 payment determination. We refer readers to section IX.E.5.h. for more detailed discussion.
***** In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45365), we finalized adoption of the Hybrid HWM measure beginning with one voluntary reporting period (July 1, 2023-June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023- June 30, 2024 reporting period, impacting the FY 2026 payment determination.
****** In this proposed rule, we are proposing the adoption of the Hospital Commitment to Health Equity measure beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. We refer readers to section IX.E.5.a. for more detailed discussion.
******* In this proposed rule, we are proposing two eCQMs beginning with the CY 2023 reporting period/FY 2025 payment determination: Cesarean Birth and Severe Obstetric Complications. We are proposing mandatory reporting of these two measures beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to sections IX.E.5.c. and IX.E.5.d., respectively, for more detailed discussion. We also refer readers to section IX.E.10.e. for proposed changes to our eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.
******** In this proposed rule, we are proposing adoption of the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting in the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to sections IX.E.5.b.(1). and IX.E.5.b.(2), respectively, for more detailed discussion.

c. Summary of Previously Finalized and Proposed Hospital IQR Program Measures for the FY 2026 Payment Determination

This table summarizes the previously finalized and newly proposed Hospital IQR Program measure set for the FY 2026 payment determination:

TABLE IX.E-11. MEASURES FOR THE FY 2026 PAYMENT DETERMINATION

Short Name	Measure Name	NQF #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality/Complications Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE*	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
AMI Excess Days**	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment**	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	3474
MSPB***	Medicare Spending Per Beneficiary (MSPB)—Hospital Measure	2158
Claims and Electronic Data Measures		
Hybrid HWM****	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502
Hybrid HWR*****	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
HCHE******	Hospital Commitment to Health Equity	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
ePC-02*******	Cesarean Birth	N/A
ePC-07/SMM*******	Severe Obstetric Complications	N/A
HH-ORAE********	Hospital-Harm—Opioid Related Adverse Events	3501e
GMCS********	Global Malnutrition Composite Score	3592e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)
Patient-Reported Outcome Performance Measures		
THA/TKA PRO-PM*********	Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO-PM)	3559
Process Measures		
SDOH-1**********	Screening for Social Drivers of Health	N/A

Short Name	Measure Name	NQF #
SDOH-2*********	Screen Positive Rate for Social Drivers of Health	N/A

* In this proposed rule, we are proposing adoption of a refined Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA measure beginning with FY 2024 payment determination and for subsequent years. We refer readers to section IX.E.5.i. for more detailed discussion.
** In this proposed rule, we are proposing refinements to two current Hospital IQR Program measures—Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA and Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction (AMI)—beginning with the FY 2024 payment determination. We refer readers to sections IX.E.6.a. and IX.E.6.b, respectively, for more detailed discussion.
*** In this proposed rule, we are proposing adoption of a refined MSPB Hospital measure beginning with the FY 2024 payment determination. We refer readers to section IX.E.5.h. for more detailed discussion.
**** In the FY 2022 IPPS/LTCH PPS final rule 86 FR 45365, we finalized adoption of the Hybrid HWM measure beginning with one voluntary reporting period (July 1, 2023-June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023- June 30, 2024 reporting period, impacting the FY 2026 payment determination.
***** In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid HWR measure (NQF #2879), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.
****** In this proposed rule, we are proposing the adoption of the Hospital Commitment to Health Equity measure beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. We refer readers to section IX.E.5.a. for more detailed discussion.
******* In this proposed rule, we are proposing two eCQMs beginning with the CY 2023 reporting period/FY 2025 payment determination: Cesarean Birth and Severe Obstetric Complications. We are proposing mandatory reporting of these two measures beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to sections IX.E.5.c. and IX.E.5.d., respectively, for more detailed discussion. We also refer readers to section IX.E.10.e. for proposed changes to our eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.
******** In this proposed rule, we are proposing the adoption of two eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years: Hospital-Harm—Opioid-Related Adverse Events and Global Malnutrition Composite Score. We refer readers to sections IX.E.5.e. and IX.E.5.f., respectively for more detailed discussion. We also refer readers to section IX.E.10.e. for proposed changes to our eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.
********* In this proposed rule, we are proposing adoption of the Hospital-Level THA/TKA PRO-PM measure. We are proposing voluntary reporting of the measure across two periods—July 1, 2023 through June 30, 2024 and July 1, 2024 through June 30, 2025—followed by mandatory reporting for the reporting period which runs from July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination and for subsequent years. We refer readers to section IX.E.5.g. for more detailed discussion.
********** In this proposed rule, we are proposing adoption of the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting in the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to sections IX.E.5.b.(1). and IX.E.5.b.(2)., respectively, for more detailed discussion.

d. Summary of Previously Finalized and Proposed Hospital IQR Program Measures for the FY 2027 Payment Determination

This table summarizes the previously finalized and newly proposed Hospital IQR Program measure set for the FY 2027 payment determination:

TABLE IX.E-12. MEASURES FOR THE FY 2027 PAYMENT DETERMINATION

Short Name	Measure Name	NQF #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality/Complications Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE*	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
AMI Excess Days**	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment**	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	3474
MSPB***	Medicare Spending Per Beneficiary (MSPB)—Hospital Measure	2158
Claims and Electronic Data Measures		
Hybrid HWM****	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502
Hybrid HWR*****	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
HCHE******	Hospital Commitment to Health Equity	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435

Short Name	Measure Name	NQF #
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
ePC-02*******	Cesarean Birth	N/A
ePC-07/SMM*******	Severe Obstetric Complications	N/A
HH-ORAE********	Hospital-Harm—Opioid Related Adverse Events	3501e
GMCS********	Global Malnutrition Composite Score	3592e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)
Patient-Reported Outcome Performance Measures		
THA/TKA PRO-PM*********	Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO-PM)	3559
Process Measures		
SDOH-1**********	Screening for Social Drivers of Health	N/A
SDOH-2**********	Screen Positive Rate for Social Drivers of Health	N/A

* In this proposed rule, we are proposing adoption of the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA measure beginning with the FY 2024 payment determination and for subsequent years. We refer readers to section IX.E.5.i. for more detailed discussion.

** In this proposed rule, we are proposing refinements to two current Hospital IQR Program measures—Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA and Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction (AMI)—beginning with the FY 2024 payment determination. We refer readers to sections IX.E.6.a. and IX.E.6.b, respectively, for more detailed discussion.

*** In this proposed rule, we are proposing adoption of a refined MSPB-Hospital measure beginning with the FY 2024 payment determination. We refer readers to section IX.E.5.h. for more detailed discussion.

**** In the FY 2022 IPPS/LTCH PPS final rule 86 FR 45365, we finalized adoption of the Hybrid HWM measure beginning with one voluntary reporting period (July 1, 2023-June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023- June 30, 2024 reporting period, impacting the FY 2026 payment determination.

***** In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid HWR measure (NQF #2879), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

****** In this proposed rule, we are proposing the adoption of the Hospital Commitment to Health Equity measure beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. We refer readers to section IX.E.5.a. for more detailed discussion.

******* In this proposed rule, we are proposing two eCQMs beginning with the CY 2023 reporting period/FY 2025 payment determination: Cesarean Birth and Severe Obstetric Complications. We are proposing mandatory reporting of these two measures beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to sections IX.E.5.c. and IX.E.5.d., respectively, for more detailed discussion. We also refer readers to section IX.E.10.e. for proposed changes to our eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

******** In this proposed rule, we are proposing the adoption of two eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years: Hospital-Harm—Opioid-Related Adverse Events and Global Malnutrition Composite Score. We refer readers to sections IX.E.5.e. and IX.E.5.f., respectively for more detailed discussion. We also refer readers to section IX.E.10.e. for proposed changes to our eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years

********* In this proposed rule, we are proposing adoption of the Hospital-Level THA/TKA PRO-PM measure. We are proposing voluntary reporting of the measure across two periods—July 1, 2023 through June 30, 2024 and July 1, 2024 through June 30, 2025—followed by mandatory reporting for the reporting period which runs from July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination and for subsequent years. We refer readers to section IX.E.5.g. for more detailed discussion.

********** In this proposed rule, we are proposing adoption of the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting in the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to sections IX.E.5.b.(1) and IX.E.5.b.(2)., respectively, for more detailed discussion.

e. Summary of Previously Finalized and Proposed Hospital IQR Program Measures for the FY 2028 Payment Determination and for Subsequent Years

This table summarizes the previously finalized and newly proposed Hospital IQR Program measure set for the FY 2028 payment determination and for subsequent years:

TABLE IX.E-13. MEASURES FOR THE FY 2028 PAYMENT DETERMINATION AND FOR SUBSEQUENT YEARS

Short Name	Measure Name	NQF #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality/Complications Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE*	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
AMI Excess Days**	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment**	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	3474
MSPB***	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158
Claims and Electronic Data Measures		
Hybrid HWM****	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	N/A
Hybrid HWR*****	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
HCHE******	Hospital Commitment to Health Equity	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
ePC-02*******	Cesarean Birth	N/A
ePC-07/SMM*******	Severe Obstetric Complications	N/A
HH-ORAE********	Hospital-Harm—Opioid Related Adverse Events	3501e
GMCS********	Global Malnutrition Composite Score	3592e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)
Patient-Reported Outcome Performance Measures		
THA/TKA PRO-PM*********	Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO-PM)	3559
Process Measures		
SDOH-1**********	Screening for Social Drivers of Health	N/A
SDOH-2**********	Screen Positive Rate for Social Drivers of Health	N/A

* In this proposed rule, we are proposing adoption of a refined Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA measure beginning with the CY 2022 reporting period/FY 2024 payment determination. We refer readers to section IX.E.5.i. for more detailed discussion.

** In this proposed rule, we are proposing refinements to two current Hospital IQR Program measures—Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA and Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction (AMI)—beginning with the FY 2024 payment determination. We refer readers to sections IX.E.6.a. and IX.E.6.b, respectively, for more detailed discussion.
*** In this proposed rule, we are proposing adoption of a refined MSPB Hospital measure beginning with the /FY 2024 payment determination. We refer readers to section IX.E.5.h. for more detailed discussion.
**** In the FY 2022 IPPS/LTCH PPS final rule 86 FR 45365, we finalized adoption of the Hybrid HWM measure beginning with one voluntary reporting period (July 1, 2023-June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023- June 30, 2024 reporting period, impacting the FY 2026 payment determination.
***** In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid HWR measure (NQF #2879), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.
****** In this proposed rule, we are proposing the adoption of the Hospital Commitment to Health Equity measure beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. We refer readers to section IX.E.5.a. for more detailed discussion.
******* In this proposed rule, we are proposing two eCQMs beginning with the CY 2023 reporting period/FY 2025 payment determination: Cesarean Birth and Severe Obstetric Complications. We are proposing mandatory reporting of these two measures beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to sections IX.E.5.c and IX.E.5.d, respectively, for more detailed discussion. We also refer readers to section IX.E.10.e. for proposed changes to our eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.
******** In this proposed rule, we are proposing the adoption of two eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years: Hospital-Harm—Opioid-Related Adverse Events and Global Malnutrition Composite Score. We refer readers to sections IX.E.5.e. and IX.E.5.f., respectively for more detailed discussion. We also refer readers to section IX.E.10.e. for proposed changes to our eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.
********* In this proposed rule, we are proposing adoption of the Hospital-Level THA/TKA PRO-PM measure. We are proposing voluntary reporting of the measure across two periods—July 1, 2023 through June 30, 2024 and July 1, 2024 through June 30, 2025—, followed by mandatory reporting for the reporting period which runs from July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination and for subsequent years We refer readers to section IX.E.5.g. for more detailed discussion.
********** In this proposed rule, we are proposing adoption of the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure beginning with a voluntary reporting in the CY 2023 reporting period and mandatory reporting in the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to sections IX.E.5.b.(1). and IX.E.5.b.(2)., respectively, for more detailed discussion.

BILLING CODE 4120–01–C

8. Proposed Establishment of a Publicly-Reported Hospital Designation To Capture the Quality and Safety of Maternity Care

In this proposed rule, we are proposing to establish a hospital quality designation that we would publicly report on a CMS website beginning Fall 2023. This designation would be awarded to hospitals based on their attestation of submission of the Maternal Morbidity Structural measure, which we believe would reflect their commitment to the quality and safety of maternity care they furnish. This would be the first-ever hospital quality designation by HHS or CMS that specifically focuses on maternal health. We are proposing this policy in conjunction with Vice President Harris' ''Maternal Health Day of Action'' announcement [1281] which also signaled CMS' intent to establish this proposed ''birthing-friendly'' hospital designation.

Additionally, we are requesting feedback on potential additional activities that we could undertake to advance maternal health equity.

a. The U.S. Maternal Health Crisis

Despite the highest rate of spending on maternity care, maternal mortality rates in the U.S. are among the highest in the developed world. Every year, approximately 700 women die of complications related to pregnancy and childbirth, and over 25,000 women experience severe complications of pregnancy (severe maternal morbidity).[1282] [1283] Approximately one-third of all pregnancy-related deaths occur at the time of delivery and immediately postpartum, with nearly 20 percent occurring between one and six days postpartum.[1284] Yet, three out of five pregnancy-related deaths are considered preventable.[1285]

Racial, ethnic, and geographic disparities intensify the U.S. maternal health crisis. Adverse maternal health outcomes vary considerably by race and ethnicity, and are highest among Black and American Indian/Alaskan Native women, regardless of their income or education levels.[1286] [1287] Black and American Indian/Alaskan Native women die from pregnancy-related causes at a rate two to three times higher [1288] and experience severe

[1281] The White House. (2021). Fact Sheet: Vice President Kamala Harris Announces Call to Action to Reduce Maternal Mortality and Morbidity. Accessed January 26, 2022. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/07/fact-sheet-vice-president-kamala-harris-announces-call-to-action-to-reduce-maternal-mortality-and-morbidity/.*

[1282] Petersen EE et al. Vital Signs: Pregnancy-Related Deaths, United States, 2011–2015, and Strategies for Prevention, 13 States, 2013–2017. MMWR Morbidity and Mortality Weekly Report 2019;68:423–29.

[1283] Maternal and Child Health Bureau. Federally Available Data (FAD) Resource Document. Health Resources and Services Administration. Available at: *https://mchb.tvisdata.hrsa.gov/Admin/FileUpload/DownloadContent?fileName=FadResourceDocument.pdf&isForDownload=False.*

[1284] Davis N.L., Smoots A.N., and Goodman D.A. (2019). Pregnancy-Related Deaths: Data from 14 U.S. Maternal Mortality Review Committees, 2008–2017. Available at: *https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/MMR-Data-Brief_2019-h.pdf.*

[1285] The Centers for Disease Control and Prevention. Pregnancy-Related Deaths in the United States. September 2021. Available at: *https://www.cdc.gov/hearher/pregnancy-related-deaths/index.html.*

[1286] Hoyert DL and Miniño AM. Maternal Mortality in the United States: Changes in Coding, Publication, and Data Release. National Vital Statistics Report. Vol 69, No. 2 (Jan. 2020): 1–18.

[1287] Centers for Disease Control and Prevention. Racial/Ethnic Disparities in Pregnancy-Related Deaths—United States, 2007–2016. September 6, 2019. Vol. 68, No. 35. Available at: *https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6835a3-H.pdf.*

[1288] Centers for Disease Control and Prevention. Pregnancy Mortality Surveillance System. Available at: *https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm.* Accessed November 10, 2021.

maternal morbidity at a rate nearly two times higher than their white, Asian Pacific Islander, and Hispanic counterparts.[1289] The COVID–19 pandemic in the U.S. has exacerbated such racial and ethnic disparities in maternal outcomes, likely associated with Black and Hispanic women facing higher rates of economic hardship and reporting higher rates of mental health concerns compared to their White counterparts.[1290] [1291] [1292] [1293] Finally, geographic disparities in maternal outcomes also exist. Pregnant women who live in rural communities are at higher risk for severe maternal morbidity and about 60 percent more likely to die before, during, or after delivery than those living in urban settings.[1294]

b. HHS Focus on Improving Maternal Health in the U.S.

To build on the previously established HHS Maternal Health Action Plan, the Vice President's nationwide call to action to reduce maternal morbidity and mortality, and ongoing efforts with HHS and across the Federal Government,[1295] the Administration seeks to use a whole-of-government approach for improving maternal health and advancing maternal health equity that reduces maternal mortality and morbidity, reduces persistent disparities, and among other activities, increases hospital participation in HHS-sponsored maternal health quality improvement initiatives. A critical focus is reducing existing disparities in maternal health outcomes across race, ethnicity, and geographic area. This targeted strategy is further embodied by other efforts spearheaded by the Biden-Harris Administration, including the first-ever Presidential Proclamation in recognition of Black Maternal Health Week in April 2021, as well as the first-ever Federal ''Maternal Health Day of Action'' on December 7, 2021.[1296] [1297]

As part of the ''Day of Action,'' Vice President Harris issued a nationwide call to action to reduce maternal mortality and morbidity and made several key announcements, including CMS' intention to establish the proposed hospital designation.[1298] Additionally, we released a quality, safety, and oversight memorandum (QSO–22–05–Hospitals) to state survey agencies. In that memorandum, we encourage hospitals to consider implementation of evidence-based best practices for the management of obstetric emergencies, along with interventions to address other key contributors to maternal health disparities, to support the delivery of equitable, high-quality care for all pregnant and postpartum individuals.[1299] Such best practices include participation in local/regional perinatal quality collaboratives, application of early warning sign tools, and the use of patient safety ''bundles.'' We encourage hospitals to review the guidance and resources provided in the memorandum to assess their own capacity to provide optimal management of obstetric emergencies and to combat maternal health disparities.

As part of our commitment to reducing high maternal morbidity and mortality rates, the Hospital IQR Program adopted the Maternal Morbidity Structural measure in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361 through 45365). This measure is designed to determine hospital participation in a state or national Perinatal Quality Improvement (QI) Collaborative and implementation of patient safety practices or bundles through that QI initiative. As noted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361 through 45365), hospital participation in QI collaboratives has been shown to be effective in improving the infrastructure surrounding management of obstetric conditions that may lead to severe maternal morbidity or mortality.[1300] Additionally, hospital implementation of related QI efforts has been associated with both enhanced quality and safety of maternity care as well as a reduction in the maternal health disparity gap.[1301] [1302] [1303] [1304]

The Maternal Morbidity Structural measure is specified to capture whether hospitals are: (1) Currently participating in a structured state or national Perinatal QI Collaborative; and (2) implementing patient safety practices or bundles as part of these QI initiatives. In reporting on this measure, hospitals respond ''Yes,'' ''No,'' or ''N/A (our hospital does not provide inpatient labor/delivery care)'' to a two-part question assessing these two topic areas.[1305] Data collection began with fourth quarter 2021 data, which hospitals must report by May 2022. We

[1289] US Government Accountability Office. MATERNAL MORTALITY Trends in Pregnancy-Related Deaths and Federal Efforts to Reduce Them. March 2020. Available at: *https://www.gao.gov/assets/gao-20-248.pdf.*

[1290] Raman S. COVID–19 Amplifies Racial Disparities in Maternal Health. Roll Call. May 14, 2020. Available at: *https://www.rollcall.com/2020/05/14/covid-19-amplifies-racial-disparities-in-maternal-health/.*

[1291] National Partnership for Women & Families. Black Women's Maternal Health: A Multifaceted Approach to Addressing Persistent and Dire Health Disparities. April 2018. Available at: *https://www.nationalpartnership.org/our-work/health/reports/black-womens-maternal-health.html.*

[1292] Bion X–S. Efforts to Reduce Black Maternal Mortality Complicated by COVID–19. California Health Care Foundation. April 2020. Available at: *https://www.chcf.org/blog/efforts-reduce-black-maternal-mortality-complicated-covid-19/.*

[1293] Getachew Y et al. Beyond the Case Count: The Wide-Ranging Disparities of COVID–19 in the United States The Commonwealth Fund. September 2020. Available at: *https://www.commonwealthfund.org/publications/2020/sep/beyond-case-count-disparities-covid-19-united-states.*

[1294] White House Fact Sheet: Vice President Kamala Harris Announces Call to Action to Reduce Maternal Mortality and Morbidity. *https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/07/fact-sheet-vice-president-kamala-harris-announces-call-to-action-to-reduce-maternal-mortality-and-morbidity/.*

[1295] HHS Initiative to Improve Maternal Health. *https://aspe.hhs.gov/topics/public-health/hhs-initiative-improve-maternal-health.*

[1296] 86 FR 20023, April 16, 2021. A Proclamation on Black Maternal Health Week, 2021. Available at: *https://www.federalregister.gov/documents/2021/04/16/2021-08008/black-maternal-health-week-2021.*

[1297] The White House. (2021). Fact Sheet: Vice President Kamala Harris Announces Call to Action to Reduce Maternal Mortality and Morbidity. Accessed January 26, 2022. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/07/fact-sheet-vice-president-kamala-harris-announces-call-to-action-to-reduce-maternal-mortality-and-morbidity/.*

[1298] Ibid.

[1299] Centers for Medicare & Medicaid Services. Evidence-Based Best Practices for Hospitals in Managing Obstetric Emergencies and Other Key Contributors to Maternal Health Disparities. Accessed December 20, 2021. Available at: *https://www.cms.gov/files/document/qso-22-05-hospitals.pdf.*

[1300] Main, E.K., Cape, V., Abreo, A., Vasher, J., Woods, A., Carpenter, A., Gould, J.B. (2017). Reduction of Severe Maternal Morbidity from Hemorrhage Using a State Perinatal Quality Collaborative. American Journal of Obstetrics and Gynecology, 216(3): 298.e1. Available at: *https://www.ncbi.nlm.nih.gov/pubmed/28153661.*

[1301] Callaghan-Koru JA et al. Implementation of the Safe Reduction of Primary Cesarean Births safety bundle during the first year of a statewide collaborative in Maryland. Obstet Gynecol 2019;134:109–19.

[1302] Main EK et al. Reduction of severe maternal morbidity from hemorrhage using a state perinatal quality collaborative. Am J Obstet Gynecol 2017;216(3):298.e1–298.e11.

[1303] King PL et al. Reducing time to treatment for severe maternal hypertension through statewide quality improvement. Am J Obstet Gynecol 2018;218:S4.

[1304] Main EK et al. Reduction in racial disparities in severe maternal morbidity from hemorrhage in a large-scale quality improvement collaborative. Am J Obstet Gynecol 2020;223:123.e1–14.

[1305] To report on this measure, hospitals will respond to a two-part question: ''Does your hospital or health system participate in a Statewide and/or National Perinatal Quality Improvement Collaborative Program aimed at improving maternal outcomes during inpatient labor, delivery and post-partum care, and has it implemented patient safety practices or bundles related to maternal morbidity to address complications, including, but not limited to, hemorrhage, severe hypertension/preeclampsia or sepsis?.'' Further details on this measure can be found in the FY 2022 IPPS/LTCH PPS final rule at 86 FR 45361 through 45365.

refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361 through 45365) for more details on the measure.

c. Proposed Establishment of a Publicly-Reported Hospital Designation To Capture the Quality and Safety of Maternity Care

In alignment with the announcement made during the ''Maternal Health Day of Action,'' [1306] we are proposing to establish a hospital designation to be publicly reported on a CMS website beginning in Fall 2023. Under this proposal, we would give this designation to hospitals that report ''Yes'' to both questions in the Maternal Morbidity Structural measure. This designation would initially be based only on data from hospitals reporting an affirmative attestation to the Maternal Morbidity Structural measure. This would allow us to initially award the designation based on the data hospitals are currently reporting on the Maternal Morbidity Structural measure under the Hospital IQR Program. In future notice and comment rulemaking, we intend to propose a more robust set of criteria for awarding the designation that may include other maternal health-related measures that may be finalized for the Hospital IQR Program measure set in the future. We note that in this proposed rule, we are proposing to adopt two new eCQMs for the Hospital IQR Program—the Cesarean Birth (ePC–02) and Severe Obstetric Complications (ePC–07)—in sections IX.E.5.c. and IX.E.5.d. of the preamble of this proposed rule, respectively.

Section 1886(b)(3)(B)(viii)(VII) of the Act, as amended by section 3001(a)(2) of the Affordable Care Act, requires that the Secretary establish procedures for making information regarding Hospital IQR Program measures available to the public (74 FR 43864; 75 FR 50184 through 50815). We believe adding this designation to a consumer-facing CMS website would allow patients and families to choose hospitals that have demonstrated a commitment to improving maternal health through their participation in related perinatal QI collaboratives and their implementation of best practices that support the delivery of high-quality maternity care.

We invite public comment on this proposal.

d. Solicitation of Comments on Designation Name and Additional Data Sources To Consider for Purposes of Awarding This Publicly-Reported Hospital Designation

While our goal is to designate hospitals with demonstrated commitment to the provision of high-quality and safe maternity care, we wish to do so in a way that is meaningful and useful to patients and their families as well as clinicians and hospitals pursuing high-quality maternal health care delivery. Therefore, we are soliciting comments on a name for this designation for future years.

In addition as noted previously, we are proposing to designate hospital commitment to maternity care quality and safety based initially on data collected on the Maternal Morbidity Structural measure. Our intent is to expand the criteria we use to award this designation so that it more comprehensively captures the quality and safety of the maternity care delivered by hospitals. Other future sources of data potentially include data collected on the two eCQMs we are proposing to add to the Hospital IQR Program measure set, if those proposals are finalized, or data on other Hospital IQR Program maternal health measures, should such measures be adopted in the future. We are also considering the feasibility of including other quality measurement data sources. In particular, we welcome comments about patient experience measures that could be relevant for this designation, including patient experience measures that are currently in use in care settings, patient experience measures that have been developed but require additional testing in pilot settings, or other measures of patient experience that would be appropriate for inclusion in the designation.

We invite public comment on these and other potential quality measurement data sources that would be appropriate to include in a designation that captures the quality and safety of maternity care furnished by hospitals, including quality measures used in other quality reporting programs or care delivery settings.

e. Additional Activities To Advance Maternal Health Equity—Request for Information

We are committed to advancing equity for all, including those in underserved communities (American Indian or Alaska Native, Asian or Pacific Islander, Black, Hispanic, and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality).

We specifically seek to explore how we can address the U.S. maternal health crisis through policies and programs, including, but not limited to, the Conditions of Participation (CoPs) and through measures in our quality reporting programs. The CoPs are the health and safety standards that Medicare-certified providers and suppliers must meet to receive Medicare and Medicaid payment. CMS has broad statutory authority to establish health and safety regulations for various providers and suppliers; that statutory authority is usually found within the statutory definition of each provider and supplier type. In the case of hospitals, section 1861(e)(9) of the Act defines ''hospital'' as in institution that, among other things, ''meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.''

We invite public comment on the following:

- CMS outlines best practices in the memorandum to state survey agencies entitled ''Evidence-Based Best Practices for Hospitals in Managing Obstetric emergencies and Other Key Contributors to Maternal Health Disparities.'' [1307] What other additional effective best practices or quality improvement initiatives are currently being utilized by hospitals? How else can hospitals improve maternal health outcomes, enhance their quality of maternity care, and reduce maternal health disparities?
- For hospitals that offer inpatient maternity services, including labor and delivery care, how could the CoPs be modified to improve maternity care and address disparities in maternal health outcomes? How would hospitals focus their governance, provider and staff training, and care-delivery activities to effectively demonstrate compliance with CoPs related to improving maternal health outcomes? What types of measurable activities targeting maternal health outcomes might demonstrate a reduction in maternal health care disparities or improvement in maternal health care delivery?

[1306] The White House. (2021). Fact Sheet: Vice President Kamala Harris Announces Call to Action to Reduce Maternal Mortality and Morbidity. Accessed January 26, 2022. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/07/fact-sheet-vice-president-kamala-harris-announces-call-to-action-to-reduce-maternal-mortality-and-morbidity/.*

[1307] Evidence-based best practices for hospitals in managing obstetric emergencies and other key contributors to maternal health disparities. U.S. Department of Health and Human Services. *https://www.hhs.gov/guidance/document/evidence-based-best-practices-hospitals-managing-obstetric-emergencies-and-other-key.*

- Are there new requirements that could be established in the CoPs that would require hospitals to address and improve the quality of postpartum care and support provided to patients? How can the CoPs specifically address the need to improve behavioral health services and monitoring offered during prenatal and postpartum care?
- Might the potential additional maternal health-focused CoPs have unintended consequences on providers with certain characteristics (such as being located in a rural area or having low-volume)? Please provide details on how certain providers might be differentially affected by potential maternal health CoPs. Are there barriers or facilitators that would influence rural hospital achievement of a publicly-reported maternal health designation that may not relate directly to the quality of services provided? How might maternal health CoPs impact providers considering whether it is feasible or viable to offer labor and delivery services in their area?
- What services and staff training should hospitals without inpatient maternity services have in place in preparation for patients in labor?
- What are the best practices that hospitals are utilizing to educate and conduct outreach to patients in underserved communities to increase access to timely maternity care?
- What are best practices for hospitals to actively engage with patients and their families, community-based organizations, and others within their local community to obtain information on ways to improve maternity care? Are there barriers to such engagement (if so, what are the barriers)?
- Do hospitals provide prevention-related education and community outreach on the specific maternal health conditions that have the greatest impact on disadvantaged and underserved communities?
- How can hospitals review and monitor aggregate data on the maternal health risks of the patient population that they serve? What data should hospitals review related to the maternal health risks of the patient population they serve? What data sharing best practices are required for hospitals to share data with external entities, including local and state health departments, community-based organizations, or other health care providers? How can hospitals connect data collected for mothers and their babies after delivery to support research and evaluation of maternal health care after delivery?
- What challenges are there to collecting data on patients with specific maternal health risks? Can these data be stratified by demographics (for example, race and ethnicity)? In addition, how can these data be used in a hospital's quality improvement efforts, and specifically, in their quality assurance and performance improvement (QAPI) program, to improve maternal health outcomes and advance health equity and reduce disparities within their facility? How can maternity care can be incorporated into an ongoing QAPI program?
- How do hospitals conduct reviews of maternal deaths that have occurred within the facility?
- Are hospitals currently utilizing community health needs assessments to determine the specific maternity care needs and social determinants of health of the patient population that they serve? For those hospitals that are utilizing community health needs assessments, are there certain best practices or examples of ways that this assessment can be used to reduce disparities in maternal outcomes?
- Do hospitals have reporting relationships or mechanisms among primary care physicians, obstetrician-gynecologists, and other healthcare providers such as nurses and certified nurse midwives, and community-based perinatal workers, such as doulas, for optimal coordination of care?
- Do hospitals have readily available referral relationships and points of contact with community resources or community-based organizations to address additional services that a postpartum patient may need upon discharge? This could include the consideration of behavioral and mental health services or resources to address health-related social needs, such as food insecurity, housing instability, and transportation challenges. If hospitals do not have readily available referral relationships and points of contact within the community, what barriers and facilitators impact hospital relationships with community resources or community-based organizations?
- How do hospitals evaluate their perinatal customer experience? What are best practices that are currently being utilized for getting robust input from patients on their perinatal experience?
- What best practices exist for ensuring systemic racism and biases, including implicit bias are not perpetuated in maternity care?

9. Future Considerations

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality and cost improvements through the inpatient hospital setting. We have identified potential future measures for future development, which we believe address areas that are important to stakeholders, but which are not currently covered in the Hospital IQR Program. Therefore, we seek comment on these potential future considerations, as detailed later in the section.

We also refer readers to the following sections: (1) Section IX.A. where we are seeking comments from stakeholders on the health impacts due to climate change, especially on underserved populations, and how we could potentially support hospitals and health systems to more effectively determine and plan for climate impacts, reduce greenhouse gas emissions, and track progress; (2) section IX.B. where we are seeking input on overarching principles in measuring healthcare quality disparities in hospital quality programs and value-based purchasing programs; and (3) section IX.C. where we are seeking input on ongoing ways we can advance digital quality measurement and use of Fast Healthcare Interoperability Resources (FHIR) in quality reporting programs.

a. Potential Future Inclusion of Two Digital National Healthcare Safety Network (NHSN) Measures

The Hospital IQR Program previously included NHSN measures that were finalized for removal from the measure set in the FY 2019 IPPS/LTCH PPS final rule (83 FR 4157 through 41553), and retained in the Hospital-Acquired Condition (HAC) Reduction Program (83 FR 41474 through 41477; 83 FR 41449 through 41452) and the Hospital VBP Program (83 FR 41449 through 41452). We have recently identified two new potential measures that utilize EHR-derived data to help address hospital-based adverse events, specifically, hospital-onset infections.

We discuss these two measures in more detail later in the section and seek public comment on the future inclusion of these measures in the Hospital IQR Program. We also invite public comment on other aspects of these two measures related to future implementation. In addition, we seek public comment on the application of one or both of these measures in other quality reporting programs, including the HAC Reduction Program, the Hospital VBP Program, the PCHQR Program, and the LTCH QRP.

(1) National Healthcare Safety Network (NHSN) Healthcare-Associated Clostridioides Difficile Infection Outcome Measure

(a) Background

Clostridioides difficile [1308] is a bacterium that causes diarrhea, pseudomembranous colitis, and toxic megacolon which can lead to sepsis or death.[1309] [1310] [1311] *Clostridioides difficile* infections (CDI) can be reduced in healthcare settings using a multi-faceted approach, including development of an infrastructure for monitoring CDI, implementation of effective antibiotic stewardship to reduce the use of unnecessary antibiotics, isolation and contact precautions for patients with CDI, performance of environmental cleaning with sporicidal agents, and other measures.[1312] CDI is one of the most common healthcare-associated infections (HAIs) in the U.S.[1313] [1314] At any given time, 1 in 31 patients has an HAI in the U.S., and over a million cases of HAIs are reported every year, making HAIs one of the most common adverse events that occurs in a healthcare setting.[1315] [1316]

As one of the most common HAIs, CDIs are a significant contributor to inpatient morbidity and mortality, particularly among older adults.[1317] Incidence of CDI is higher among White patients, female patients, and patients over 65 years of age.[1318] CDIs result in an estimated 500,000 cases annually and between 15,000 and 20,000 deaths.[1319] Additionally, costs associated with CDIs average about $11,400 per case and can have a significant impact on the U.S. healthcare system.[1320] More broadly, HAIs cost over $9.8 billion dollars annually with CDIs contributing to 15.4 percent, or about $1.5 billion dollars of these total annual costs.[1321] Therefore, we currently require reporting of CDI outcomes, along with other HAIs, in value-based purchasing programs like the Hospital VBP Program and HAC Reduction Program, in order to connect performance on HAI measures with payment adjustments.[1322]

The CDC has developed the National Healthcare Safety Network (NHSN) Healthcare-Associated *Clostridioides difficile* Infection Outcome measure that utilizes EHR-derived data. The goal of this measure is to drive an increase in prevention practices, which would result in fewer CDI cases and reduced morbidity and mortality in patients. We believe this would be especially useful given that most cases of CDIs may be prevented or stopped from spreading to other patients when inpatient facilities utilize infection control steps recommended by the CDC. We believe utilizing the CDC's NHSN reporting and submission infrastructure will impose less administrative burden related to data collection and submission for this measure.

Previously, the Hospital IQR Program included a CDI measure which only required CDI facility-wide Lab-ID event reporting (we refer readers to the FY 2012 IPPS/LTCH PPS final rule, 76 FR 51630 through 51631).[1323] The newly developed version of the measure would improve on the original version of the measure by requiring both microbiologic evidence of CDI in stool and evidence of antimicrobial treatment, whereas the original measure only required CDI facility-wide Lab-ID event reporting. The addition of anti-microbial treatment evidence may provide further validity in the reporting of CDIs, as it serves as a surrogate for test results that were clinically interpreted as true infections.

The NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure addresses the quality priority of ''Make Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measures Area of ''Healthcare Associated Infections.'' [1324] Additionally, pursuant to Meaningful Measures 2.0, this measure addresses the ''Safety'' and ''Wellness and Prevention'' priority areas and aligns with our commitment to a patient-centered approach in quality measurement to ensure that patients are safe and receive the highest quality care.[1325]

In this proposed rule, we are requesting feedback on the potential future inclusion of the NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure into the Hospital IQR Program measure set to aid in disease monitoring, provide hospitals and patients with more

[1308] The *Clostridioides difficile* bacterium was previously called clostridium difficile. The naming was updated in 2016 due to taxonomic updates.

[1309] Centers for Disease Control and Prevention (CDC). What is C. diff? Available at: *https://www.cdc.gov/cdiff/what-is.html.*

[1310] Centers for Disease Control and Prevention (CDC). *Clostridioides difficile* Infection (CDI) Tracking. Available at: *https://www.cdc.gov/hai/eip/cdiff-tracking.html.*

[1311] Centers for Medicare & Medicaid Services National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=606&sectionNumber=1.*

[1312] Centers for Disease Control and Prevention (CDC) CDI Prevention Strategies. Available at: *https://www.cdc.gov/cdiff/clinicians/cdi-prevention-strategies.html.*

[1313] Kwon, J.H., Olsen, M.A., Dubberke, E.R. (2015). The Morbidity, Mortality, and Costs Associated with Clostridium difficile Infection. Infect Dis Clin North Am. 29(1):123–34. Available at: *https://www.sciencedirect.com/science/article/abs/pii/S0891552014000804?via%3Dihub.*

[1314] Magil, S.S., O'Leary, E., Janelle, S.J., Thompson, D.L., Ghinwa, D., Nadle, J., et al. (2018). Changes in Prevalence of Health Care-Associated Infections in U.S. Hospitals. N Engl J Med. 379:1732–1744. DOI: 10.1056/NEJMoa1801550.

[1315] Magil, S.S., O'Leary, E., Janelle, S.J., Thompson, D.L., Ghinwa, D., Nadle, J., et al. (2018). Changes in Prevalence of Health Care-Associated Infections in U.S. Hospitals. N Engl J Med. 379:1732–1744. DOI: 10.1056/NEJMoa1801550.

[1316] Haque M, Sartelli M, McKimm J, Abu Bakar M. (2018). Health care-associated infections—an overview. Infect Drug Resist. 11:2321–2333. doi:10.2147/IDR.S177247.

[1317] Centers for Disease Control and Prevention. (2018). Analysis and Recommendations on the NHSN *Clostridioides difficile* Outcome. Available at: *https://www.cdc.gov/hicpac/pdf/NHSN-C-diff-H.pdf#:~:text=NHSN%20is%20the%20most%20widely%20used%20secure%2C%20internet-based,decreasing%20in%20contrast%20to%20other%20healthcare-associated%20infections.%202.*

[1318] Lessa FC, Mu Y, Bamberg WM, et al. (2015). Burden of Clostridium difficile infection in the United States. N Engl J Med. 372(9):825–34. doi: 10.1056/NEJMoa1408913.

[1319] Zaver, H.B., Moktan, V.P, Harper, E.P., et al. (2021). Reduction in Health Care Facility—Onset *Clostridioides difficile* Infection: A Quality Improvement Initiative. Mayo Clin Proc Innov Qual Outcomes. 5(6):1066–1074. doi: 10.1016/j.mayocpiqo.2021.09.004.

[1320] Zimlichman E, Henderson D, Tamir O, et al. (2013). Health care-associated infections: A meta-analysis of costs and financial impact on the US health care system. JAMA Intern Med. 173(22):2039–46. doi: 10.1001/jamainternmed.2013.9763.

[1321] Zimlichman E, Henderson D, Tamir O, et al. (2013). Health care-associated infections: A meta-analysis of costs and financial impact on the US health care system. JAMA Intern Med. 173(22):2039–46. doi: 10.1001/jamainternmed.2013.9763.

[1322] Centers for Disease Control and Prevention. (2018). Analysis and Recommendations on the NHSN *Clostridioides difficile* Outcome. Available at: *https://www.cdc.gov/hicpac/pdf/NHSN-C-diff-H.pdf#:~:text=NHSN%20is%20the%20most%20widely%20used%20secure%2C%20internet-based,decreasing%20in%20contrast%20to%20other%20healthcare-associated%20infections.%202.*

[1323] In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41547 through 41553) we removed the NHSN Facility-Wide Inpatient Hospital-Onset Clostridium difficile Infection (CDI) Outcome measure (NQF #1717) from the Hospital IQR Program measure set but retained it in the HAC Reduction Program and Hospital VBP Program where it is reported via the CDC NHSN portal (83 FR 41474 through 41477; 83 FR 41449 through 41452). We removed this measure under removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program (83 FR 41547).

[1324] Centers for Medicare & Medicaid Services. (2021). Meaningful Measures Hub. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[1325] Centers for Medicare & Medicaid Services. (2021). Quality Measurement Action Plan. Available at: *https://www.cms.gov/files/document/2021-cms-quality-conference-cms-quality-measurement-action-plan-march-2021.pdf.* We note that Meaningful Measures 2.0 is still under development.

information to inform care delivery, and improve patient outcomes.

(b) Overview of Measure

The NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure would track the development of new CDIs among patients already admitted to healthcare facilities, using algorithmic determinations from data sources widely available in EHRs. Both the original and new measure employ the Standardized Infection Ratio (SIR), a statistic used to track HAIs over time. Along with the SIR, this new measure would also use the Adjusted Ranking Metric (ARM) of hospital-onset CDIs among hospitalized patients. The SIR is a primary summary statistic used by the NHSN to track HAIs, and ARM is a new statistic available for acute care hospitals that accounts for differences in the volume of exposure (specifically, denominator) between facilities. ARM provides complementary information to the SIR as ARM provides the reliability-adjusted number of events and allows for ranking facilities.[1326]

The measure was previously endorsed by MAP on June 11, 2019. The CDC submitted the measure for re-endorsement and it was included in the publicly available ''List of Measures Under Consideration for December 1, 2021'' (MUC List),[1327] a list of measures under consideration for use in various Medicare programs. The NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure (MUC2021–098) was reviewed by the NQF MAP Hospital Workgroup on December 15, 2021, and received conditional support pending NQF review and re-endorsement once the revised measure is fully tested.[1328] The MAP Coordinating Committee, which provides direction to the MAP workgroups, concurred with the recommendations of the MAP Hospital Workgroup.[1329] We understand that the CDC intends to submit the measure in the future for NQF review and endorsement.

(c) Data Sources

Hospitals would provide data for this measure from their EHRs. The primary sources of data for determining numerator events include microbiology data (CDI test), medication administration data (CDI antimicrobial treatment), and patient encounter, demographic, and location information.

To facilitate rapid, automated, and secure data exchange, the CDC's NHSN is planning to enable and promote reporting of this measure using FHIR. However, as FHIR capabilities are evolving and not yet uniform across healthcare systems, the CDC is also planning on enabling reporting using the existing Health Level 7 (HL7) Clinical Document Architecture (CDA), and potentially other formats as well to provide all facilities with an option for reporting. We are also working with the CDC and ONC to consider how certified health IT can support reporting of data for this measure. We invite public comment on potential reporting formats for this measure.

(d) Outcome

The outcome of interest is the number of new CDIs among patients already admitted to healthcare facilities.

(e) Cohort

The measure cohort consists of all patients in the denominator: The expected number of hospital-acquired CDIs based on predictive models using facility- and patient-care location data as predictors.

(f) Exclusion Criteria

The measure excludes patients in the denominator who are not assigned to an inpatient bed in an applicable location, including outpatient clinics and ED visits. Patients <365 days old will also be excluded. As an aside, inpatient rehabilitation locations and inpatient psychiatric locations that have their own CMS Certification Number (CCN) are also excluded from the denominator.

(g) Risk Adjustment

The risk adjustment was developed with a statistical risk model. The SIR is risk-adjusted for each facility, and the ARM adjusts for volume of exposure between facilities as well as risk adjustment.

(h) Measure Calculation

The measure assesses the development of new CDI among patients already admitted to healthcare facilities.

(i) Numerator and Denominator

The measure's denominator consists of the expected number of hospital-associated CDIs based on predictive models using facility and patient care location data as predictors.

The numerator consists of the total observed number of observed CDIs among all inpatients in the facility based on the combination of laboratory test for CDIs plus a therapeutic administered within a window period around the specimen date.

(2) National Healthcare Safety Network (NHSN) Hospital-Onset Bacteremia & Fungemia Outcome Measure

(a) Background

HAIs are the most frequent adverse event in the delivery of healthcare globally.[1330] Incidence rates for most types of HAIs had been declining for several years in the U.S., but the COVID–19 pandemic reversed these trends.[1331] Central line-associated bloodstream infections (CLABSI) declined 31 percent between 2015 and 2019.[1332] Despite this initial trend, the SIR for CLABSI increased in 2020 compared to 2019 in the later quarters due to the pandemic. The NHSN found a 47 percent increase in CLABSI in Quarter 4 of 2020 compared to Quarter 4 of 2019. Overall, CLABSI increased by 24 percent from 2019 to 2020, with the largest increase (50 percent) being found in the ICU. Other types of infections also rose during this period, including hospital-onset MRSA by 15 percent, and Ventilator-Associated Events (VAE) by 35 percent.[1333]

One likely reason for this reversal was the staffing and institutional challenges

[1326] More information on how ARM and SIR compare can be found at: *https://www.cdc.gov/nhsn/ps-analysis-resources/arm/index.html.*

[1327] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. Available at: *https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf.*

[1328] National Quality Forum. (2022). Measure Applications Partnership (MAP) 2021–2022 Final Recommendations. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.*

[1329] National Quality Forum. (2022). Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care: Final Report. Available at: *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

[1330] Hongsuwan M, Srisamang P, Kanoksil M, et al. (2014). Increasing incidence of hospital-acquired and healthcare-associated bacteremia in northeast Thailand: a multicenter surveillance study. PLoS One. 2014;9(10):e109324. doi:10.1371/journal.pone.0109324.

[1331] Weiner-Lastinger, L., Pattabiraman, V., Konnor, R., Patel, P., Wong, E., Xu, S., Dudeck, M. (2022). The impact of coronavirus disease 2019 (COVID–19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. Infection Control & Hospital Epidemiology, 43(1), 12–25. doi:10.1017/ice.2021.362.

[1332] Centers for Disease Control and Prevention. Central Line-Associated Bloodstream Infections. Accessed on Available at: *https://arpsp.cdc.gov/profile/infections/clabsi?year-select-report=year2019&year-select-hai-state-list=year2019.*

[1333] Centers for Disease Control and Prevention. 2020 National and State Healthcare-Associated Infections Progress Report. Available at: *https://www.cdc.gov/hai/pdfs/progress-report/2020-Progress-Report-Executive-Summary-H.pdf.*

of caring for COVID–19 patients, which led to a breakdown in previous standards of care. In qualitative studies, infection prevention teams have reported that the pandemic made it difficult to maintain routine CLABSI prevention practices in the ICU.[1334] Another possible reason is that many hospitals underwent large staffing changes, leading to more workers who were not accustomed to the hospital's standard HAI prevention practices.[1335]

The NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure was developed to help further our goal of addressing patient safety outcomes in the hospital care setting. The frequency of hospital fungemia and bacteremia infection rates in the U.S. present unique opportunities for large-scale quality measurement and improvement activities. Statistics on preventability vary but suggest that a considerable proportion of fungemia and bacteremia could be prevented.[1336] The NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure is intended to facilitate safer patient care by increasing awareness of the dangers of fungemia and bacteremia, promoting adherence to recommended clinical guidelines, and encouraging hospitals to track and improve their practices of appropriate monitoring and care delivery for patients. For these reasons, we are requesting feedback on the potential future inclusion of this measure into the Hospital IQR Program measure set to aid in disease monitoring, provide hospitals and patients with more information to inform care delivery, and improve patient outcomes.

Under CMS' Meaningful Measures Framework, the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure addresses the quality priority of ''Make Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measures Area of ''Healthcare Associated Infection.'' [1337] Additionally, pursuant to Meaningful Measures 2.0, this measure addresses the ''Safety'' priority area and aligns with our commitment to a patient-centered approach in quality measurement to ensure that patients are safe and receive the highest quality care.[1338]

While the HAC Reduction Program and Hospital VBP Program use several HAI measures, we believe that the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure may be necessary to build upon previous efforts to reduce HAIs because it encompasses all types of bacteremia and fungemia that occur among already hospitalized patients. Meanwhile, the NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome measure and NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome measure only capture specific types of HAIs.

We invite public comment on the potential use of this measure in the Hospital IQR Program. We are also considering its use in the PCHQR Program and the possibility of replacing the current CLABSI and MRSA measures in the HAC Reduction Program and Hospital VBP Program with the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure.

(b) Overview of Measure

This measure captures the development of new bacteremia and fungemia among patients already admitted to acute care hospitals, using algorithmic determinations from data sources widely available in EHRs.

The NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure was previously endorsed by MAP on June 11, 2019. The CDC submitted the measure for re-endorsement and it was included in the publicly available ''List of Measures Under Consideration for July 15, 2021'' (MUC List),[1339] a list of measures under consideration for use in various Medicare programs. The NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure (MUC2021–100) was reviewed by the NQF MAP Hospital Workgroup on December 15, 2021 and received conditional support pending NQF review and re-endorsement once the revised measure is fully tested.[1340] The MAP Coordinating Committee, which provides direction to the MAP workgroups, concurred with the recommendations of the MAP Hospital Workgroup. We understand that the CDC intends to submit the measure in the future for NQF review and endorsement.

(c) Data Sources

The data submission and reporting standard procedures for the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure have been set forth by the CDC for NHSN participation in general and for submission of measure data. Although the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure is not specified as an eCQM, manual data entry is not available. The primary sources of data for determining numerator events include microbiology data (blood culture) and patient encounter, demographic, and location information often located in Admission-Discharge-Transfer data (Fast Healthcare Interoperability Resources (FHIR): Encounter, Patient, Observation, Location).

To facilitate rapid, automated, and secure data exchange, the CDC's NHSN is planning to enable and promote reporting of this measure using FHIR. However, as FHIR capabilities are evolving and not uniform across healthcare systems, the CDC is also planning on enabling reporting using the existing Health Level 7 (HL7) Clinical Document Architecture (CDA), and potentially other formats as well to provide all facilities with an option for reporting. We are also working with the CDC and ONC to consider how certified health IT can support reporting of data for this measure. We invite public comment on potential reporting formats for this measure.

(d) Outcome

The measures outcome (numerator) is defined as the observed number of HOB events. This is defined as growth of a recognized bacterial or fungal pathogen

[1334] Fakih, M., Bufalino, A., Sturm, L., Huang, R., Ottenbacher, A., Saake, K. Cacchione, J. (2021). Coronavirus disease 2019 (COVID–19) pandemic, central-line–associated bloodstream infection (CLABSI), and catheter-associated urinary tract infection (CAUTI): The urgent need to refocus on hardwiring prevention efforts. Infection Control & Hospital Epidemiology, 1–6. doi:10.1017/ice.2021.70.

[1335] Fakih, M., Bufalino, A., Sturm, L., Huang, R., Ottenbacher, A., Saake, K. Cacchione, J. (2021). Coronavirus disease 2019 (COVID–19) pandemic, central-line–associated bloodstream infection (CLABSI), and catheter-associated urinary tract infection (CAUTI): The urgent need to refocus on hardwiring prevention efforts. Infection Control & Hospital Epidemiology, 1–6. doi:10.1017/ice.2021.70.

[1336] Dantes RB, Rock C, Milstone AM, Jacob JT, Chernetsky-Tejedor S, Harris AD, Leekha S. (2019). Preventability of hospital onset bacteremia and fungemia: A pilot study of a potential healthcare-associated infection outcome measure. Infect Control Hosp Epidemiol, 40(3):358–361. doi: 10.1017/ice.2018.339.

[1337] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.* We note that Meaningful Measures 2.0 is still under development.

[1338] Centers for Medicare & Medicaid Services. (2021). CMS Quality Measurement Action Plan. Available at: *https://www.cms.gov/files/document/2021-cms-quality-conference-cms-quality-measurement-action-plan-march-2021.pdf.*

[1339] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. Available at: *https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf.*

[1340] National Quality Forum. (2022). Measure Applications Partnership (MAP) 2021–2022 Final Recommendations. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.*

from a blood culture specimen collected on the fourth calendar day of admission or later (where the date of admission to an inpatient location is calendar day 1).

(e) Cohort

The measures outcome (numerator) is defined as the observed number of hospital-onset bacteremia and fungemia (HOB) events based on predictive models using facility-level factors (community-onset incidence of bacteremia and fungemia, blood culture utilization rates), patient care location, and potentially other data as predictors.

(f) Exclusion Criteria

The measure has two numerator exclusions for patients with previous matching POA bacteremia or fungemia. The first numerator exclusion is HOB infections in which the pathogen is the same species or genus level as the one identified from a blood specimen by culture that the hospital collected in the POA window (defined as hospital calendar day three or earlier). Additionally, if multiple pathogens are identified from the same blood culture, then a match of any of those pathogens to a POA blood pathogen is sufficient to exclude the event from the HOB measure. The measure also excludes patients with a previous HOB event who experience additional HOB events during the same hospital admission. We understand that the CDC may consider additional exclusion criteria for patients with significant risk factors for bacteremia or fungemia infections that are judged not likely to be preventable in rigorous studies.

The measure has one denominator exclusion for data from patients who are not assigned to an inpatient bed in an applicable location. As an aside, denominator counts exclude data from inpatient rehabilitation units and inpatient psychiatric units with a unique CCN from the acute care facility.

(g) Measure Calculation

The measure is an outcome measure that assesses the observed number of HOB events. The measure calculates the ratio of the observed number of HOB events out of the expected number of HOB events based on predictive models using facility and patient care location data as predictors.

10. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. To successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program, hospitals must meet specific procedural, data collection, submission, and validation requirements. Previously, the applicable percentage increase for FY 2007 and each subsequent fiscal year until FY 2015 was reduced by 2.0 percentage points for subsection (d) hospitals failing to submit data in accordance with the previous description. In accordance with the statute, the FY 2023 payment determination will begin the ninth year that the Hospital IQR Program will reduce the applicable percentage increase by one-quarter of such applicable percentage increase.

b. Maintenance of Technical Specifications for Quality Measures

For each Hospital IQR Program payment determination, we require that hospitals submit data on each specified measure in accordance with the measure's specifications for a particular period of time. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538), in which we summarized how the Hospital IQR Program maintains the technical measure specifications for quality measures and the subregulatory process for incorporation of nonsubstantive updates to the measure specifications to ensure that measures remain up-to-date. We are not proposing any changes to these policies in this proposed rule.

The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet website at *https://qualitynet.cms.gov* (or other successor CMS designated websites). The CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update) contains the technical specifications for electronic clinical quality measures (eCQMs). The Annual Update contains updated measure specifications for the year prior to the reporting period. For example, for the CY 2022 reporting period/FY 2024 payment determination, hospitals are collecting and will submit eCQM data using the May 2021 Annual Update and any applicable addenda. The Annual Update and implementation guidance documents are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at *https://ecqi.healthit.gov/*.

Hospitals must register and submit quality data through the Hospital Quality Reporting (HQR) System (previously referred to as the QualityNet Secure Portal) (86 FR 45520). The HQR System is safeguarded in accordance with the HIPAA Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E.

We also refer readers to section IX.C. of the preamble of this proposed rule where we are requesting information on potential actions that would continue to transform the Hospital IQR Program's quality measurement enterprise toward the use of the FHIR standard for data submission.

c. Procedural Requirements

The Hospital IQR Program's procedural requirements are codified in regulation at 42 CFR 412.140. We refer readers to these codified regulations for participation requirements, as further explained by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810 through 50811) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57168). The previously finalized requirements, including setting up a QualityNet account and the associated timelines, are described at 42 CFR 412.140(a)(2) and (e)(2)(iii) and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51639 through 51640). In the FY 2022 IPPS/LTCH PPS final rule, we finalized the following changes to the Hospital IQR Program regulation text: (1) Update references to the QualityNet website at 42 CFR 412.140(a)(1) and (c)(2)(i); and (2) use the term ''QualityNet security official'' instead of ''QualityNet Administrator'' at 42 CFR 412.140(a)(2). We are not proposing any changes to these policies in this proposed rule.

d. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures. We are not proposing any changes to these policies in this proposed rule.

e. Reporting and Submission Requirements for eCQMs

(1) Background

For a discussion of our previously finalized eCQMs and policies, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810; 50811 through 50819), the FY 2015

IPPS/LTCH PPS final rule (79 FR 50241 through 50253; 50256 through 50259; and 50273 through 50276), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49692 through 49698; and 49704 through 49709), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57161; and 57169 through 57172), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38355 through 38361; 38386 through 38394; 38474 through 38485; and 38487 through 38493), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41567 through 41575; 83 FR 41602 through 41607), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42501 through 42506), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58932 through 58940), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45417 through 45421).

In the FY 2018 IPPS/LTCH PPS final rule, we finalized eCQM reporting and submission requirements such that hospitals were required to report only one, self-selected calendar quarter of data for four self-selected eCQMs for the CY 2018 reporting period/FY 2020 payment determination (82 FR 38358 through 38361). Those reporting requirements were extended to the CY 2019 reporting period/FY 2021 payment determination through the CY 2021 reporting period/FY 2023 payment determination (83 FR 41603 through 41604; 84 FR 42501 through 42503). In the FY 2020 IPPS/LTCH PPS final rule, we finalized that for the CY 2022 reporting period/FY 2024 payment determination, hospitals would be required to report one, self-selected calendar quarter of data for: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM, for a total of four eCQMs (84 FR 42503 through 42505).

In the FY 2021 IPPS/LTCH PPS final rule, we finalized a progressive increase in the number of required reported quarters of eCQM data, from one self-selected quarter of data to four quarters of data over a three-year period (85 FR 58932 through 58939). Specifically, for the CY 2021 reporting period/FY 2023 payment determination, hospitals were required to report two self-selected calendar quarters of data for each of the four self-selected eCQMs (85 FR 58939). For the CY 2022 reporting period/FY 2024 payment determination, hospitals are required to report three self-selected calendar quarters of data for each eCQM: (a) Three self-selected eCQMs, and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM (85 FR 58939). We clarified in the FY 2021 IPPS/LTCH PPS final rule that until hospitals are required to report all four quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination, they may submit consecutive or non-consecutive self-selected quarters of data (85 FR 58939). In the FY 2022 IPPS/LTCH PPS final rule, we did not propose any changes to these policies, and we clarified that the self-selected eCQMs must be the same eCQMs across quarters in a given reporting year (86 FR 45418). We are not proposing any changes to these policies in this proposed rule. The following Table IX.E–14. summarizes our finalized policy:

TABLE IX.E-14. eCQM DATA PUBLIC REPORTING REQUIREMENTS

Reporting Period / Payment Determination	eCQM Data Publicly Reported
CY 2021 / FY 2023	Two Quarters of Data
CY 2022 / FY 2024	Three Quarters of Data
CY 2023 / FY 2025 (and for subsequent years)	Four Quarters of Data

For the CY 2023 reporting period/FY 2025 payment determination and subsequent years, hospitals are required to report four calendar quarters of data for each eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids-Concurrent Prescribing eCQM (85 FR 58939). We are not proposing any changes to the eCQM reporting or submission requirements for the CY 2023 reporting period/FY 2025 payment determination.

In this proposed rule, we are proposing to modify eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

(2) Proposed Reporting and Submission Requirements for eCQMs for the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

In this proposed rule, we are proposing to modify the eCQM reporting and submission requirements, such that beginning with the CY 2024 reporting period/FY 2026 payment determination hospitals would be required to report four calendar quarters of data for each required eCQM: (1) Three self-selected eCQMs; (2) the Safe Use of Opioids—Concurrent Prescribing eCQM; (3) the proposed Cesarean Birth eCQM; and (4) the proposed Severe Obstetric Complications eCQM; for a total of six eCQMs. We refer readers to Table IX.E–15. which represents the progressive increase in eCQM reporting requirements, including our proposed changes.

TABLE IX.E-15. CURRENT AND PROPOSED eCQM REPORTING AND SUBMISSION REQUIREMENTS FOR THE CY 2022 REPORTING PERIOD/FY 2024 PAYMENT DETERMINATION AND FOR SUBSEQUENT YEARS

Reporting Period / Payment Determination	eCQM Data Publicly Reported	Total Number of eCQMs Reported	eCQMs Required to be Reported
CY 2022 / FY 2024	Three Quarters of Data	Four	• Four self-selected eCQMs
CY 2023 / FY 2025	Four Quarters of Data	Four	• Three self-selected eCQMs; and • Safe Use of Opioids—Concurrent Prescribing eCQM
Proposed: CY 2024 / FY 2026 (and for subsequent years)	Four Quarters of Data	Six	• Three self-selected eCQMs; and • Safe Use of Opioids—Concurrent Prescribing eCQM; and • Proposed Cesarean Birth eCQM; and • Proposed Severe Obstetric Complications eCQM

This proposal is made in conjunction with our proposals discussed in sections IX.E.5.c. and IX.E.5.d. of the preamble of this proposed rule, in which we are proposing to adopt the Cesarean Birth eCQM and Severe Obstetric Complications eCQM, respectively. Addressing the maternal health crisis, improving maternal health, and closing any gaps that exist as a result of health disparities are among our top goals for quality improvement. The high maternal mortality and morbidity rates in the U.S. necessitate large-scale quality measurement and improvement activities. As part of the effort to reduce maternal mortality and morbidity, we believe it to be important to receive data from all hospitals that provide perinatal care and not to limit data to just hospitals that may self-select those eCQMs. Requiring these eCQMs would also aid in the surveillance of maternal morbidity, mortality, and associated comorbidities and complications as we collect data from all of the hospitals participating in the Hospital IQR Program. Additionally, no maternal morbidity or obstetric complications outcome-based measures exist in national reporting programs, and we believe these measures have the potential to reduce preventable harm and costs associated with adverse events related to perinatal care.

Accordingly, if our proposals to adopt the Cesarean Birth eCQM and the Severe Obstetric Complications eCQM are finalized, all hospitals participating in the Hospital IQR Program would also be required to report these two eCQMs, increasing the total number of eCQMs reported from four to six beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

At the start of required eCQM reporting, we stated that increasing the reporting requirements over time is consistent with our goal of reporting on all eCQMs in the Hospital IQR Program in a stepwise manner while being responsive to hospitals' concerns about timing, readiness, and burden associated with the increased number of measures required to be reported (81 FR 57151 through 57152). With the addition of new measures to the eCQM measure set and increasing the quarters of eCQM data to be reported, our approach to eCQM reporting requirements has supported the goal to incrementally increase eCQM reporting requirements as hospitals continue to gain experience with eCQMs (84 FR 42502). After several years of a steady eCQM reporting requirement, we believe a proposed change to the reporting requirement is timely. We believe that allowing hospitals to continue self-selection of three eCQMs from the measure set for the CY 2024 reporting period/FY 2026 payment determination while requiring reporting of three additional eCQMs provides sufficient flexibility to report on eCQMs applicable to a hospital's quality improvement priorities while also reporting on measures that address the opioid and maternal health crises and that advance health equity. Additionally, we believe that our proposal for hospitals to submit data from three self-selected eCQMs and three required eCQMs continues our approach to collect data derived from EHRs and make progress toward a transition to fully digital quality measurement (86 FR 45345).

We invite public comment on our proposal to increase the number of mandatory measures to be reported from one to three, as described previously, and thereby increase the total number of required eCQMs from four to six.

We refer readers to section IX.H.10.b. of the preamble of this proposed rule for a discussion of a similar proposal by the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs).

(3) Continuation of Certification Requirements for eCQM Reporting

(a) Requiring Use of the 2015 Edition and 2015 Edition Cures Update Certification Criteria

In the CY 2021 Physician Fee Schedule (PFS) final rule (85 FR 84825 through 84828), we expanded flexibility under the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and for subsequent years to allow hospitals to use either: (1) Technology certified to the 2015 Edition criteria as was previously finalized for reporting eCQMs in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41537 through 41608), or (2) certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961). We adopted this flexible approach to encourage hospitals to be early implementers of the 2015 Edition Cures Update while remaining in compliance with Hospital IQR Program data submission requirements and maintaining alignment with requirements in the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs.

In the FY 2022 IPPS/LTCH PPS final rule, beginning with the CY 2023 reporting period/FY 2025 payment determination and subsequent years, we finalized the requirement for hospitals to use only certified technology updated consistent with the 2015 Edition Cures Update to submit data for the Hospital IQR Program data (86 FR 45418). We refer readers to the ONC 21st Century Cures Act final rule for additional information about the updates included in the 2015 Edition Cures Update (85 FR 25665). We are not proposing any changes to this policy.

(b) Requiring EHR Technology To Be Certified to All Available eCQMs

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42505 through 42506), we finalized the requirement that EHRs be certified to all available eCQMs used in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45418), we finalized the requirement for hospitals to use the 2015 Edition Cures Update beginning with the CY 2023 reporting period/FY 2025 payment determination, then all available eCQMs used in the Hospital IQR Program for the CY 2023 reporting period/FY 2025 payment determination and subsequent years would need to be reported using certified technology updated to the 2015 Edition Cures Update. We are not proposing any changes to this policy.

(4) File Format for EHR Data, Zero Denominator Declarations, and Case Threshold Exemptions

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57170) for our previously adopted eCQM file format requirements. Under these requirements, hospitals: (1) Must submit eCQM data via the Quality Reporting Document Architecture Category I (QRDA I) file format, (2) may use third parties to submit QRDA I files on their behalf, and (3) may either use abstraction or pull the data from non-certified sources to then input these data into Certified EHR Technology (CEHRT) for capture and reporting QRDA I. Hospitals can continue to meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemption (82 FR 38387).

More specifically regarding the use of QRDA I files, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57170) and the FY 2020 IPPS/LTCH PPS final rule (85 FR 58940), in which we stated that we expect QRDA I files to reflect data for one patient per file per quarter, and identified the five key elements that are utilized to identify the file:

- CMS Certification Number (CCN);
- CMS Program Name;
- EHR Patient ID;
- Reporting period specified in the Reporting Parameters section per the CMS Implementation Guide for the applicable reporting year, which is published on the eCQI Resource Center website at *https://ecqi.healthit.gov/QRDA*; and
- EHR Submitter ID (beginning with the CY 2021 reporting period/FY 2023 payment determination).

We are not proposing any changes to this policy.

(5) Submission Deadlines for eCQM Data

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49709), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57172) for our previously adopted policies to align eCQM data reporting periods and submission deadlines for both the Hospital IQR Program and the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), we finalized the alignment of the Hospital IQR Program eCQM submission deadline with that of the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs—the end of two months following the close of the calendar year—for the CY 2017 reporting period/FY 2019 payment determination and subsequent years. We note the submission deadline will be moved to the next business day if it falls on a weekend or Federal holiday. We are not proposing any changes to this policy.

f. Data Submission and Reporting Requirements for Hybrid Measures

(1) Background

The Hospital IQR Program recently adopted hybrid measures into the program's measure set. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38350 through 38355), we finalized voluntary reporting of the Hybrid Hospital-Wide Readmission (Hybrid HWR) measure for the CY 2018 reporting period. In the FY 2020 IPPS/LTCH PPS final rule, we finalized the adoption of the Hybrid HWR measure for the Hospital IQR Program (84 FR 42465 through 42481) such that, beginning with the FY 2026 payment determination, hospitals are required to report on the Hybrid HWR measure (84 FR 42479). In the FY 2022 IPPS/LTCH PPS final rule, we also finalized the adoption of the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (Hybrid HWM) measure in a stepwise fashion, beginning with a voluntary reporting period from July 1, 2022 through June 30, 2023, and followed by mandatory reporting from July 1, 2023 through June 30, 2024, affecting the FY 2026 payment determination and for subsequent years (86 FR 45365). We also finalized several requirements related to data submission and reporting requirements for hybrid measures under the Hospital IQR Program (84 FR 42506 through 42508). In this proposed rule, we are proposing changes specific to the zero denominator declarations and case threshold exemptions policies for hybrid measures, as discussed further in the subsequent section.

(2) Certification and File Format Requirements

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 19498 through 19499), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58941), and the CY 2021 PFS final rule (85 FR 84472) for our previously adopted policies regarding certification and file format requirements for hybrid measures in the Hospital IQR Program.

In the CY 2021 PFS final rule (85 FR 84825 through 84828), we finalized flexibility to allow hospitals to use either: (1) Technology certified to the 2015 Edition criteria as was previously finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41537 through 41608) or (2) certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961, 85 FR 50271), beginning with the CY 2020 reporting period/FY 2022 payment determination and subsequent years. The Hospital IQR Program offers flexibility to meet hybrid measure submission requirements to facilitate successful reporting during the period of transition as providers are updating certified technology to be consistent with the 2015 Edition Update. This flexibility applies to all Hospital IQR Program measures which use EHR data elements to calculate measure rates, including eCQMs and hybrid measures.

In the FY 2022 IPPS/LTCH PPS final rule, to align with the health IT certification requirements for eCQM reporting, we finalized to require hospitals to use only certified technology that has been updated

consistent with the 2015 Edition Cures Update to submit hybrid measure data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years (86 FR 45421). We are not proposing any changes to these policies in this proposed rule.

(3) Additional Submission Requirements

In the FY 2020 IPPS/LTCH PPS final rule, we finalized allowing hospitals to meet the hybrid measure reporting and submission requirements by submitting any combination of data via QRDA I files, zero denominator declarations, and case threshold exemptions (84 FR 42507). We also finalized applying similar zero denominator declaration and case threshold exemption policies to hybrid measure reporting as we allow for eCQM reporting (84 FR 42507 through 42508).

We note that the ONC 21st Century Cures Act final rule revises the clinical quality measurement criterion at 45 CFR 170.315(c)(3) to refer to CMS QRDA IGs and remove the HL7® QRDA standard requirements (85 FR 25645). We encourage all hospitals and their health IT vendors to submit QRDA I files early, and to use one of the pre-submission testing tools for electronic reporting, such as submitting test files to the HQR System, to allow additional time for testing and make sure all required data files are successfully submitted by the deadline.

(4) Proposed Modification of the Zero Denominator Declarations Policy and Case Threshold Exemptions Policy for Hybrid Measures

As stated in the previous section (section IX.E.10.f.(3).), in the FY 2020 IPPS/LTCH PPS final rule, we finalized applying the zero denominator declarations policy and case threshold exemptions policy to hybrid measure reporting (84 FR 42507 through 42508). Additionally, in the FY 2020 IPPS/LTCH PPS final rule, we indicated that zero denominator declarations and case threshold exemptions would not be necessary during the voluntary reporting periods for hybrid measures but would be an option for hospitals to utilize when hybrid measure reporting became mandatory (84 FR 42508).

In this proposed rule, we are proposing to remove zero denominator declarations and case threshold exemptions as an option for the reporting of hybrid measures beginning with the FY 2026 payment determination for reasons discussed in the subsequent section. We note that the FY 2026 payment determination is the first year for which hybrid measures, finalized as part of the Hospital IQR Program measure set, will become mandatory for reporting.

Zero denominator declarations allow a hospital whose EHR is capable of reporting hybrid measure data to submit a zero in the denominator for the reporting of a measure if the hospital does not have patients that meet the denominator criteria of that hybrid measure (84 FR 42507). Similarly, the case threshold exemptions policy allows for a hospital with five or fewer inpatient discharges per quarter or 20 or fewer inpatient discharges per year in a given denominator declaration be exempted from reporting on that individual hybrid measure (84 FR 42507). These policies were originally developed for eCQMs and were extended to hybrid measures to ensure hospitals were not penalized for the absence of patients that meet the denominator criteria in the reporting of those measures.

Upon further analysis, however, we do not believe that these policies are applicable for hybrid measures due to the process of reporting the measure data. Hybrid measures do not require that hospitals report a traditional denominator as is required for the submission of eCQMs. Instead, hybrid measures utilize the Initial Patient Population (IPP), as per their measure specifications, that identifies the patients for which hospitals need to extract the EHR data and annual claims data. Additionally, we calculate hybrid measures by merging both the claims and EHR data received. Therefore, since we would confirm the measure cohort to determine whether a hospital has met the denominator criteria, both the zero denominator declaration and the case threshold exemption for hybrid measures would not be applicable to hospitals.

We invite public comment on our proposal.

(5) Submission Deadlines for Hybrid Measures

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42508), where we finalized submission deadlines for hybrid measures. We are not proposing any changes to these policies in this proposed rule.

g. Sampling and Case Thresholds for Chart-Abstracted Measures

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49709) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. We are not proposing any changes to these policies in this proposed rule.

h. HCAHPS Administration and Submission Requirements

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820) for details on previously-adopted HCAHPS submission requirements. We also refer hospitals and HCAHPS Survey vendors to the official HCAHPS website at *https://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight, and data adjustments. We are not proposing any changes to these policies in this proposed rule.

i. Data Submission Requirements for Structural Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 through 53539) for details on the data submission requirements for structural measures. Hospitals are required to submit information for structural measures once annually using a CMS-approved web-based data collection tool available within the HQR System. The data submission period for structural measures begins in April and has the same submission deadline as the fourth calendar quarter chart-abstracted measure deadline. For example, for the FY 2025 payment determination, hospitals would be required to submit the required information between April 1, 2024 and May 15, 2024, with respect to the time period of January 1, 2023 through December 31, 2023.

We note that, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361), for the Maternal Morbidity Structural Measure and the CY 2021 reporting period/FY 2023 payment determination only, we finalized a shortened reporting period from October 1, 2021, through December 31, 2021, while retaining the standard data submission period. Specifically, for the shortened reporting period hospitals will be required to submit the data between April 1, 2022, and May 16, 2022 (we note that May 15, 2022, falls on a weekend and therefore the close of this data submission period is moved to May 16, 2022). Thereafter,

we finalized that the reporting period for the Maternal Morbidity Structural Measure will run from: January 1 through December 31 on an annual basis, and that the data submission period will continue to be consistent with our current policy (beginning in April until the same submission deadline as for the fourth calendar quarter of the chart-abstracted measures with respect to the reporting period for the previous calendar year) (86 FR 45361).

We are not proposing any changes to these policies in this proposed rule.

j. Data Submission and Reporting Requirements for CDC NHSN Measures

For details on the data submission and reporting requirements for measures reported via the CDC's National Healthcare Safety Network (NHSN), we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51629 through 51633; 51644 through 51645), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50259 through 50262). The data submission deadlines are posted on the QualityNet website.

We note that in the FY 2022 IPPS/LTCH PPS final rule, we finalized the adoption of the COVID–19 Vaccination Among Health Care Personnel measure, beginning in October 2021 for the October 1, 2021 through December 31, 2021 reporting period affecting the FY 2023 payment determination and continuing for each quarter in subsequent years (86 FR 45374). Specific details on data submission for this measure can be found in the CDC's Overview of the Healthcare Safety Component, available at *https://www.cdc.gov/nhsn/PDFs/slides/NHSN-Overview-HPS_Aug2012.pdf.* We are not proposing any changes to these policies in this proposed rule.

k. Proposed Data Submission and Reporting Requirements for Patient-Reported Outcome-Based Performance Measures (PRO–PMs)

In this proposed rule, in section IX.E.5.g., we are proposing the adoption of the hospital-level THA/TKA PRO–PM into the Hospital IQR Program measure set. In this section of the proposed rule, we are proposing the reporting and submission requirements for PRO–PM measures as a new type of measure to the Hospital IQR Program.

(1) Submission of PRO–PM Data

(a) Data Submission Generally

In section IX.E.5.g. of the preamble of this proposed rule, we are proposing adoption of the THA/TKA PRO–PM in the Hospital IQR Program. We are proposing that hospitals would have the choice of selecting from multiple submission approaches.

First we are proposing that hospitals may choose to: (1) Send their data to CMS for measure calculation directly; or (2) utilize an external entity, such as through a vendor or registry, to submit their data on behalf of the hospital to CMS for measure calculation. This data submission approach is consistent with stakeholder input received by the measure developer during measure development and comments as summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45411 through 45414) which recommended CMS provide multiple options for data submission mechanisms to ensure flexibility.

Whether a hospital chooses to submit the data itself or via a vendor, we are also proposing to allow a range of file formats. We are proposing that both hospitals and vendors use the HQR System for data submission for the THA/TKA PRO–PM. Use of the HQR System leverages existing CMS infrastructure already utilized for other quality measures (such as, HCAHPS or the Sepsis measure). The HQR System allows for data submission using the following file formats: CSV, XML, and a manual data entry option; allowing hospitals and vendors flexibility in data submission. We would provide hospitals with additional detailed information and instructions for submitting data using the HQR System through CMS' existing websites, such as on QualityNet, and through listservs or both.

(b) Data Submission Reporting Requirements

(1) Voluntary Reporting Requirements for the Proposed THA/TKA PRO–PM

As discussed earlier in this proposed rule, we are proposing a phased implementation approach for adoption of the THA/TKA PRO–PM, with two voluntary reporting periods for the CY 2025 and 2026 reporting periods prior to mandatory reporting beginning with the FY 2028 payment determination. Voluntary reporting prior to mandatory reporting would allow time for hospitals to incorporate the THA/TKA PRO–PM data collection into their clinical workflows and is responsive to stakeholder comments summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45411 through 45414). For each voluntary and subsequent mandatory reporting periods, we would collect data on the THA/TKA PRO–PM in accordance with, and to the extent permitted by, the HIPAA Privacy and Security Rules (45 CFR parts 160 and 164, subparts A, C, and E), and other applicable Federal law.

For hospitals participating in voluntary reporting, we are proposing that hospitals submit pre-operative PRO data, as well as matching post-operative PRO data for at least 50 percent of their eligible elective primary THA/TKA procedures. We are proposing that the first voluntary reporting period for CY 2025 would include pre-operative PRO data collection from October 3, 2022, through June 30, 2023 (for eligible elective THA/TKA procedures performed from January 1, 2023, through June 30, 2023) and post-operative PRO data collection from October 28, 2023, to August 28, 2024. Hospitals would submit pre-operative data in 2023 and post-operative data in 2024, and we intend to provide hospitals with their results in confidential feedback reports in 2025. We are proposing that hospitals submit pre-operative data for the first voluntary reporting three months following the end of the performance period. For post-operative data, we are proposing that hospitals would be required to submit data one month following the end of the performance period. If that day falls on a weekend, submissions would be due the following Monday. For example, for procedures performed between January 1, 2023, and June 30, 2023, pre-operative data would need to be submitted by October 2, 2023. After the initial submission of pre-operative data in the first voluntary period, hospitals would submit both pre-operative and post-operative data by the same day, but for different time periods. For example, hospitals would need to submit: (1) Post-operative data for the first voluntary reporting (for procedures performed between January 1, 2023, and June 30, 2023); and (2) pre-operative data for the second voluntary reporting (for procedures performed between July 1, 2023, and June 30, 2024) of the THA/TKA PRO–PM by September 30, 2024.

We are proposing that the second voluntary reporting period would include pre-operative PRO data collection from April 2, 2023, through June 30, 2024 (for eligible elective THA/TKA procedures performed from July 1, 2023, through June 30, 2024) and post-operative PRO data collection from April 26, 2024, to August 29, 2025. Hospitals would submit pre-operative data in 2024 and post-operative data in 2025, and we intend to provide hospitals with their results in confidential feedback reports in 2026.

We refer readers to Table IX.E–16. for an overview of the proposed performance period, pre- and post-operative data collection timeframes, and data submission deadlines during voluntary reporting.

TABLE IX.E-16. PROPOSED VOLUNTARY REPORTING OF PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO-PM

Reporting Period	*Performance Period*	*Pre-Operative Data Collection*	*Pre-Operative Data Submission Deadline*	*Post-Operative Data Collection*	*Post-Operative Data Submission deadline*
Voluntary Reporting 1 (2025)	January 1, 2023 through June 30, 2023	October 3, 2022 through June 30, 2023	October 2, 2023	October 28, 2023 to August 28, 2024	September 30, 2024
Voluntary Reporting 2 (2026)	July 1, 2023 through June 30, 2024	April 2, 2023 through June 30, 2024	September 30, 2024	April 26, 2024 to August 29, 2025	September 30, 2025

(2) Mandatory Reporting

Following the two voluntary reporting periods, we are proposing that mandatory reporting of the THA/TKA PRO–PM would begin with reporting PRO data for eligible elective THA/TKA procedures from July 1, 2024, through June 30, 2025 (performance period), impacting the FY 2028 payment determination. This initial mandatory reporting would include pre-operative PRO data collection from three months preceding the applicable performance period and from 10 to 14 months after the performance period. For example, pre-operative data from April 2, 2024, through June 30, 2025 (for eligible elective primary THA/TKA procedures from July 1, 2024, through June 30, 2025) and post-operative PRO data collection from April 27, 2025, to August 29, 2026. Pre-operative data submission would occur in 2025 and post-operative data submission in 2026 and we intend to provide hospitals with their results in 2027 before publicly reporting results on the Compare tool hosted by HHS, currently available at *https://www.medicare.gov/care-compare,* or its successor website. We are proposing that hospitals would be required to submit 50 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data as a minimum amount of data for mandatory reporting in the Hospital IQR Program.

We refer readers to Table IX.E–17. for an overview of the proposed performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the mandatory reporting period.

TABLE IX.E-17. PROPOSED MANDATORY REPORTING OF PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO-PM

Reporting Period	*Performance Period*	*Pre-operative Data Collection*	*Pre-operative Data Submission Deadline*	*Post-Operative Data Collection*	*Post-Operative Data Submission Deadline*
Mandatory Reporting (2027)	July 1, 2024 through June 30, 2025	April 2, 2024 through June 30, 2025	September 30, 2025	April 27, 2025 to August 29, 2026	September 30, 2026

We invite comment on all of these proposals.

11. Validation of Hospital IQR Program Data

In this proposed rule, we are proposing to update our eCQM validation process. Specifically, we are proposing to update our validation requirements for eCQMs from our current requirement that hospitals submit timely and complete data for 75 percent of requested records to submission of timely and complete data for 100 percent of requested records beginning with CY 2022 eCQM data affecting the FY 2025 payment determination and for subsequent years. We note that this proposal will not affect finalized policies with respect to validation of chart-abstracted measures.

a. Background

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49710 through 49712), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57181), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38403), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41607 through 41608), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42509), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58942 through 58953), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45423 through 45426) for detailed information on and previous changes to chart-abstracted and eCQM validation requirements for the Hospital IQR Program.

In the FY 2017 IPPS/LTCH PPS final rule, we finalized our policy to require submission of at least 75 percent of sampled eCQM medical records in a timely and complete manner for validation (81 FR 57181). To ensure we have adequate data to assess and validate eCQMs, we finalized a requirement that hospitals submit at least 75 percent of sampled eCQM medical records (81 FR 57173 through 57175). In the FY 2021 IPPS/LTCH PPS final rule, we combined the validation processes for eCQMs and chart-abstracted measures, but did not update the threshold submission percent for eCQM medical records (85 FR 58952 through 58944). In that rule, we adopted a policy to remove the separate process for eCQM validation, beginning with the

validation affecting the FY 2024 payment determination (for validation commencing in CY 2022 using data from the CY 2021 reporting period) (85 FR 58942 through 58953). Beginning with validation affecting the FY 2024 payment determination and subsequent years, we finalized a policy to incorporate eCQMs into the existing validation process for chart-abstracted measures such that there would be one pool of hospitals selected through random selection and one pool of hospitals selected using targeting criteria, for both chart-abstracted measures and eCQMs (85 FR 58942 through 58953). Under the aligned validation process, a single hospital could be selected for validation of both eCQMs and chart-abstracted measures and is expected to submit data for both chart-abstracted measures and eCQMs (85 FR 58942 through 58953). We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57179 through 57180) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures. We are not proposing any changes to finalized policies for validation of chart-abstracted measures.

b. Proposed Modifications to the Existing Processes for Validation of Hospital IQR Program eCQM Data

In this proposed rule, we are proposing to update our eCQM validation requirement to require that hospitals selected for validation submit timely and complete data for 100 percent of requested records for eCQM validation beginning with CY 2022 eCQM data, affecting the FY 2025 payment determination and for subsequent years. Hospitals selected for eCQM validation are required to submit timely and sufficient medical records. As finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 5718 through 57179), hospitals must submit timely medical records—within 30 days of the records request—to meet eCQM validation requirements. To meet the eCQM validation requirement for sufficient medical records, we are proposing to increase the submission threshold from 75 percent to 100 percent beginning with validation of CY 2022 eCQM data affecting the FY 2025 payment determination and for subsequent years.

Ever since validation of eCQMs commenced with CY 2017 data (81 FR 57173 through 57181), all hospitals selected for eCQM validation have successfully submitted at least 75 percent of eCQM medical records requested by the Clinical Data Abstraction Center (CDAC). Additionally, 95 percent of hospitals selected for participation in eCQM validation for the FY 2020 and FY 2021 payment determinations, which are the most recently available periods, voluntarily and successfully submitted 100 percent of requested records. We believe that increasing the submission threshold from 75 percent to 100 percent of the requested records would support our ongoing goal of continuing to assess the accuracy of eCQM measure data (81 FR 57155). Also, given the high rate of hospitals voluntarily submitting 100 percent of records, we believe updating the submission threshold to 100 percent will be feasible for hospitals.

We note that under our current policy, the accuracy of eCQM data (the extent to which data abstracted for validation matches the data submitted in the QRDA I file) submitted for validation does not affect a hospital's validation score as described in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57180 through 57181) and would not be impacted by this proposed update to the submission threshold. We also note that hospitals that fail to submit timely and complete medical records would not meet the eCQM validation requirement and be subject to payment reduction as described in our previously finalized policy (81 FR 57180). Chart-abstracted data continue to be weighted at 100 percent for payment determination as finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58942 through 58953) and would not be impacted by our proposed modification to the eCQM validation.

The previously finalized eCQM validation requirements, including data submission requirements, are described at 42 CFR 412.140(d)(2)(ii). We are also proposing to update the references to ''at least 75 percent'' in this Hospital IQR Program regulation text. Specifically, we propose to remove the phrase ''at least 75 percent'' and add in its place the phrase ''100 percent.'' We continue to evaluate data submitted for validation for potential future policy changes.

Our previously finalized and newly proposed validation scoring changes are summarized in Table IX.E–18.

TABLE IX.E-18. SUMMARY OF PREVIOUSLY FINALIZED AND PROPOSED eCQM VALIDATION SCORING

	Quarters of Data Required for Validation	Scoring
Previously Finalized Validation Scoring for the FY 2023 Payment Determination (81 FR 57179 through 57181)		
Chart-Abstracted Measures Validation: 400 Random Hospitals + up to 200 Targeted Hospitals	3Q 2020	At least 75% validation score
	4Q 2020	
eCQM Validation: Up to 200 Random Hospitals	1Q 2020 – 4Q 2020	Successful submission of at least 75% of requested medical records
Previously Finalized Validation Scoring for the FY 2024 Payment Determination (85 FR 58942 through 58953)		
COMBINED Process (Chart-Abstracted Measures and eCQM Validation): up to 200 Random Hospitals + up to 200 Targeted Hospitals	1Q 2021 – 4Q 2021	Chart-Abstracted Measures: at least 75% validation score (weighted at 100%) And eCQMs: Successful submission of 75% of requested medical records
Proposed Update to eCQM Validation Scoring for the FY 2025 Payment Determination and Subsequent Years		
COMBINED Process (Chart-Abstracted Measures and eCQM Validation): up to 200 Random Hospitals + up to 200 Targeted Hospitals	1Q 2022 – 4Q 2022	Chart-Abstracted Measures: at least 75% validation score (weighted at 100%) And eCQMs: Successful submission of 100% of requested medical records

We invite public comment on our proposals.

12. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for previously adopted details on DACA requirements. We are not proposing any changes to this policy in this proposed rule.

13. Public Display Requirements

a. Background

Section 1886(b)(3)(B)(viii)(VII) of the Act requires the Secretary to report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in inpatient settings in hospitals on the internet website of CMS. Section 1886(b)(3)(B)(viii)(VII) of the Act also requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. Our current policy is to report data from the Hospital IQR Program as soon as it is feasible on CMS websites such as the Compare tool hosted by HHS, currently available at *https://www.medicare.gov/care-compare,* or its successor website, after a 30-day preview period (78 FR 50776 through 50778). We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47364), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49712 through 49713), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41539), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58953) for details on public display requirements. The Hospital IQR Program quality measures are typically reported on the Compare tool hosted by HHS, currently available at *https://www.medicare.gov/care-compare.*

In this proposed rule, we are also proposing a publicly-reported hospital designation on a public-facing website to capture the quality and safety of maternity care. We refer readers to section IX.E.8. of the preamble of this proposed rule for more details on our proposal.

b. Public Reporting of eCQM Data

We direct readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58954 through 58959) where we finalized public reporting requirements of eCQM data reported by hospitals for the CY 2021 reporting period/FY 2023 payment determination and for subsequent years. We note that this policy incrementally increases the eCQM data publicly reported to four quarters of data for the CY 2023 reporting period/FY 2025 payment determination and subsequent years. We are not proposing any changes to these policies in this proposed rule.

c. Overall Hospital Star Ratings

In the CY 2021 OPPS/ASC final rule with comment period and interim final rule with comment period (85 FR 86193 through 86236), we finalized a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Ratings). The Overall Star Ratings utilizes data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the Hospital IQR Program. We refer readers to section XVI. of the CY 2021 OPPS/ASC final rule with comment period for details (85 FR 86193 through 86236). We are not proposing any changes to these policies in this proposed rule.

14. Reconsideration and Appeal Procedures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), and 42 CFR 412.140(e) for details on reconsideration and appeal procedures for the FY 2017 payment determination and subsequent years. We are not proposing any changes to these policies in this proposed rule.

15. Hospital IQR Program Extraordinary Circumstances Exceptions (ECE) Policy

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 through 51652), the FY 2014 IPPS/LTCH

PPS final rule (78 FR 50836 through 50837), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181 through 57182), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38409 through 38411), and 42 CFR 412.140(c)(2) for details on the current Hospital IQR Program ECE policy. We also refer readers to the QualityNet website at *https://qualitynet.cms.gov* for our current requirements for submission of a request for an exception. As finalized in the FY 2017 IPPS/LTCH PPS final rule, if a hospital is granted an Extraordinary Circumstances Exception with respect to eCQM reporting for the applicable eCQM reporting period, the hospital would be excluded from the eCQM validation sample due to its inability to supply data for validation (81 FR 57181). We are not proposing any changes to these policies in this proposed rule.

F. Proposed Updates to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Background

The PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program is authorized by section 1866(k) of the Act and applies to hospitals described in section 1886(d)(1)(B)(v) (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs''). For additional background information, including previously finalized measures and other policies for the PCHQR Program, we refer readers to the following final rules:

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53555 through 53567);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50853);
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50286);
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49723);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57193);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38411 through 38425);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41624);
- The CY 2019 OPPS/ASC final rule with comment period (83 FR 59149 through 59154);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42509 through 42524);
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58959 through 58966); and
- The FY 2022 IPPS/LTCH PPS final rule (86 FR 45426 through 45437).

We also refer readers to 42 CFR 412.23(f) and 412.124 for the PCHQR Program regulations.

2. Measure Retention and Removal Factors for the PCHQR Program

a. Current Measure Retention and Removal Factors

For a detailed discussion regarding our retention and removal factors, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57183), where we adopted policies for measure retention and removal, and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41611), where we updated our measure removal factors. We are not proposing any changes to our measure retention policy in this proposed rule. We describe our proposal to update our measure removal policy in the following section.

b. Proposal To Adopt a Patient Safety Exception to the Measure Removal Policy

To further align with the measure removal policies adopted in other quality programs such as the Hospital IQR Program (74 FR 43864), Hospital VBP Program (83 FR 41446), and HAC Reduction Program (84 FR 42404 to 42406), we are proposing that if we believe continued use of a measure in the PCHQR Program raises specific patient safety concerns, we may promptly remove the measure from the program without rulemaking and notify hospitals and the public of the removal of the measure, along with the reasons for its removal through routine communication channels to hospitals, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet website. We would then provide notice of the removal in the **Federal Register**. In circumstances where we do not believe that continued use of a measure raises specific patient safety concerns, we would use the regular rulemaking process to remove a measure. This proposed policy mirrors that of the Hospital IQR Program, Hospital VBP Program, and HACRP Program, and we continue to believe that a mechanism to immediately remove a quality measure that is causing specific and unintended patient harm aligns with our patient-centered focus.

We further propose to add this patient safety exception to our regulations by revising 42 CFR 412.24(d)(3) to add a new paragraph (d)(3)(iii). We invite public comment on these proposals.

3. Potential Adoption of Two National Healthcare Safety Network (NHSN) Measures—Request for Information

We are seeking comment on a potential future proposal to adopt the NHSN Healthcare-associated *Clostridioides difficile* Infection Outcome measure and NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure into the PCHQR Program. Details regarding these measures can be found in section IX.E.9.a. of the preamble of this proposed rule, where we request information on potentially adopting them for the Hospital IQR Program, and we note that we are also considering proposing them for the HAC Reduction Program. With respect to the PCHQR Program, we are considering adopting these measures because cancer patients are often immunosuppressed and therefore more vulnerable to healthcare-associated infections (HAIs). We believe these measures will drive an increase in prevention practices, which may lead to a reduction in the number of HAI cases, morbidity, and mortality.

4. Summary of PCHQR Program Measures for the FY 2024 Program Year and Subsequent Years

Table IX.F.–01 summarizes the PCHQR Program measure set for the FY 2024 program year and subsequent years. We are not proposing any changes to the PCHQR Program measure set in this proposed rule.

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TABLE IX.F.-01: FY 2024 PCHQR PROGRAM MEASURE SET AND SUBSEQUENT YEARS

Short Name	NQF Number	Measure Name
Safety and Healthcare-Associated Infection (HAI) Measures		
CAUTI	0138	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure
CLABSI	0139	National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure
HCP	0431	Influenza Vaccination Coverage Among Healthcare Personnel
Colon and Abdominal Hysterectomy SSI	0753	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery]
MRSA	1716	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure
CDI	1717	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure
COVID-19 HCP Vaccination	N/A	COVID-19 Vaccination Coverage Among HCP
Clinical Process/Oncology Care Measures		
EOL-Chemo	0210	Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life
EOL-Hospice	0215	Proportion of Patients Who Died from Cancer Not Admitted to Hospice
Intermediate Clinical Outcome Measures		
EOL-ICU	0213	Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life
EOL-3DH	0216	Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days
Patient Engagement/Experience of Care Measure		
HCAHPS	0166	HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) Survey
Claims Based Outcome Measures		
N/A	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
N/A	3188	30-Day Unplanned Readmissions for Cancer Patients
N/A	N/A	Surgical Treatment Complications for Localized Prostate Cancer

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5. Maintenance of Technical Specifications for Quality Measures

We maintain and periodically update technical specifications for the PCHQR Program measures. The specifications may be found on the QualityNet website at *https://qualitynet.cms.gov/pch*. We also refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281), where we adopted a policy to use a subregulatory process to make nonsubstantive updates to measures used for the PCHQR Program. We are not proposing any changes to our processes for maintaining technical specifications for PCHQR Program measures in this proposed rule.

6. Proposals Regarding Public Display Requirements

a. Background

Under section 1866(k)(4) of the Act, we are required to establish procedures for making the data submitted under the PCHQR Program available to the public. Such procedures must ensure that a PCH has the opportunity to review its data before they are made public. We are specifically required to report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished by PCHs on the CMS website.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57191 through 57192), we finalized that although we would continue to use rulemaking to establish what year we first publicly report data on each measure, we would publish the data as soon as feasible during that year. We also stated that our intent is to make the data available on at least a yearly basis, and that the time period for PCHs to review their data before the data are made public would be approximately 30 days in length. We announce the exact data review and public reporting timeframes on a CMS website and our applicable Listservs. Currently, the PCHQR measures' performance data are made publicly available on the Provider Data Catalog available at *https://data.cms.gov/provider-data/*.

We recognize the importance of being transparent and keeping the public abreast of any changes that arise with the PCHQR Program measure set. As such, in this proposed rule, we are making two proposals regarding the timetable for the public display of data for specific PCHQR Program measures.

b. Proposal To Begin Public Display of the End-of-Life (EOL) Measures Beginning With the FY 2024 Program Year Data

We are proposing to begin public display of the EOL-Chemo, EOL-Hospice, EOL–ICU, and EOL–3DH measures (collectively, the ''EOL measures'') beginning with FY 2024 program year data. We adopted these measures for the PCHQR measure set beginning with FY 2020 program year

data (82 FR 38414 through 38420). In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42523 through 42524), we finalized that we would confidentially report PCH performance on these measures to individual PCHs, and we indicated that we would propose to publicly display PCH performance on the measures after this initial confidential reporting period. We anticipate providing confidential reports on the data collected on the measures for the FY 2022 and FY 2023 program years, which correspond to data collected from July 1, 2019, to June 30, 2020 and July 1, 2020, to June 30, 2021, respectively, within calendar year 2022.Under our current policy, the measures are calculated on a yearly basis based on data collected from July 1 of the year 3 years prior to the program year to June 30 of the year 2 years prior to the program year. Therefore, we are proposing to begin public reporting of these measures beginning with the FY 2024 program year data, which corresponds to data collected from July 1, 2021, through June 30, 2022. We would make these data publicly available following a 30-day period in which PCHs would have an opportunity to review the data. Public display would occur during the July 2023 refresh cycle or as soon as feasible thereafter. We would announce the exact timeframe on a CMS website and our applicable listservs.

We invite public comment on the proposal to begin public display of the four EOL measures beginning with the FY 2024 program year data.

c. Proposal To Begin Public Display of the 30-Day Unplanned Readmissions for Cancer Patients Measure Beginning With the FY 2024 Program Year Data

We are proposing to begin public display of the 30-Day Unplanned Readmissions for Cancer Patients measure beginning with FY 2024 program year data. We adopted this measure for the PCHQR measure set beginning with FY 2021 program year data (83 FR 41613 through 41616). In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42523 through 42524), we finalized that we would confidentially report this measure to individual PCHs, and we indicated that we would propose public display after this initial confidential reporting period. We provided confidential reports on the data collected on this measure for the FY 2022 program year in July 2021. In addition, we anticipate confidentially reporting data collected on the measures for the FY 2023 program year, which corresponds to data collected from October 1, 2020, to September 30, 2021, this summer.

Under our current policy, the measure is calculated on a yearly basis based on data collected from October 1 of the year 3 years prior to the program year to September 30 of the year 2 years prior to the program year. We are proposing to begin public reporting of this measure beginning with the FY 2024 program year data, which corresponds to data collected from October 1, 2021, through September 30, 2022. We would make these data publicly available following a 30-day period in which PCHs would have an opportunity to review the data. Public display would occur during the October 2023 refresh cycle or as soon as feasible thereafter. We would announce the exact timeframe on a CMS website and our applicable listservs.

We invite public comment on the proposal to begin public display of the 30-Day Unplanned Readmissions for Cancer Patients measure beginning with the FY 2024 program year data.

d. Summary of Previously Finalized and Proposed Public Display Requirements for the PCHQR Program

Our previously finalized and proposed public display requirements for the PCHQR Program measures are shown in the following Table IX.F.–02:

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TABLE IX.F-02: PREVIOUSLY FINALIZED AND PROPOSED PUBLIC DISPLAY REQUIREMENTS FOR THE PCHQR PROGRAM

Summary of Previously Finalized and Proposed Public Display Requirements	
Measures	**Public Reporting**
• HCAHPS (NQF #0166) • Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (NQF #0383)*	2016 and subsequent years
• American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery] (NQF #0753) • National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure (NQF #1716) • National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) • National Healthcare Safety Network (NHSN) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)	2019 and subsequent years
• COVID-19 Vaccination Coverage Among Healthcare Personnel	October 2022 and subsequent years
• Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy	April 2020 and subsequent years
• CAUTI (NQF #0138) • CLABSI (NQF #0139)	Deferred until October 2022
• Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (NQF #0210)** • Proportion of Patients Who Died from Cancer Not Admitted to Hospice (NQF #0215)** • Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (NQF #0213)** • Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (NQF #0216)**	July 2023 or as soon as feasible thereafter
• 30-day Unplanned Readmissions for Cancer Patients (NQF #3188)**	October 2023 or as soon as feasible thereafter

**Measure finalized for removal, beginning with the FY 2024 program year.*
***Measure proposed for public display beginning with FY 2024 program year data.*

7. Form, Manner, and Timing of Data Submissions

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563 through 53567) for our previously finalized procedural requirements for the PCHQR Program. Data submission requirements and deadlines for the PCHQR Program are posted on the QualityNet website. We are not proposing any updates to our previously finalized data submission requirements and deadlines.

8. Extraordinary Circumstances Exceptions (ECE) Policy Under the PCHQR Program

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41623 through 41624), for a discussion of the Extraordinary Circumstances Exceptions (ECE) policy under the PCHQR Program. We are not proposing any changes to this policy.

G. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background and Statutory Authority

The Long-Term Care Hospital Quality Reporting Program (LTCH QRP) is authorized by section 1886(m)(5) of the Act, and it applies to all hospitals certified by Medicare as Long-Term Care Hospitals (LTCHs). Section 1886(m)(5)(C) of the Act requires LTCHs to submit to the Secretary quality measure data specified under section 1886(m)(5)(D) in a form and manner, and at a time, specified by the Secretary. In addition, section 1886(m)(5)(F) of the Act requires LTCHs to submit data on quality measures under section 1899B(c)(1) of the Act, resource use or other measures under section 1899B(d)(1) of the Act, and standardized patient assessment data required under section 1899B(b)(1) of the Act. LTCHs must submit the data required under section 1886(m)(5)(F) of the Act in the form and manner, and at the time, specified by the Secretary. Under the LTCH QRP, the Secretary must reduce by 2 percentage points the annual update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year if the LTCH has not complied with the LTCH QRP requirements specified for that fiscal year. For more information on the background for the LTCH QRP, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51744), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50853), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49725), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57193), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38425 through 38426), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41624 through 41634), the FY 2020 IPPS/LTCH PPS final rule

(84 FR 42524 through 42591), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45438 through 45446). For more information on the requirements under the LTCH QRP, we refer readers to 42 CFR 412.560.

2. General Considerations Used for the Selection of Quality Measures for the LTCH QRP

For a detailed discussion of the considerations we historically use for the selection of LTCH QRP quality, resource use, and other measures, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49728).

3. Quality Measures Currently Adopted for the FY 2023 LTCH QRP

The LTCH QRP currently has 18 measures for the FY 2023 LTCH QRP, which are set out in the following Table FF1. For a discussion of the factors used to evaluate whether a measure should be removed from the LTCH QRP, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41624 through 41634) and to the regulations at 42 CFR 412.560(b)(3).

TABLE IX.G.-01. QUALITY MEASURES CURRENTLY ADOPTED FOR THE FY 2022 LTCH QRP

Short Name	Measure Name & Data Source
LTCH CARE Data Set	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674)
Functional Assessment	Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)
Application of Functional Assessment/Care Plan	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)
Change in Mobility	Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital (LTCH) Patients Requiring Ventilator Support (NQF #2632)
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
Compliance with SBT	Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay
Ventilator Liberation	Ventilator Liberation Rate
TOH–Provider*	Transfer of Health Information to the Provider Post-Acute Care (PAC)
TOH–Patient*	Transfer of Health Information to the Patient Post-Acute Care (PAC)
NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
CLABSI	National Healthcare Safety Network (NHSN) Central Line-associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717)
HCP Influenza Vaccine	Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)
HCP COVID-19 Vaccine	COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)
Claims-Based	
MSPB LTCH	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP) (NQF #3562)
DTC	Discharge to Community (DTC)–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP) (NQF #3480)
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)

*In response to the COVID-19 public health emergency (PHE), we released an interim final rule (85 FR 27595 through 27597) which delayed the compliance date for the collection and reporting of the Transfer of Health Information measures. The compliance date for the collection and reporting of the Transfer of Health Information measures was revised to October 1, 2022 in the CY 2022 Home Health Prospective Payment System Rate Update final rule (86 FR 62386 through 62390).

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There are no proposals in this proposed rule for new measures for the LTCH QRP.

4. LTCH QRP Quality Measure Concepts Under Consideration for Future Years: Request for Information (RFI)

We are seeking input on the importance, relevance, and applicability of the concepts under consideration listed in Table IX.G.–02 for future years in the LTCH QRP. More specifically, we are seeking input on a cross-setting functional measure that would incorporate the domains of self-care and mobility. Our measure development contractor for the cross-setting functional outcome measure convened a Technical Expert Panel (TEP) on June 15 and June 16, 2021 to obtain expert input on the development of a functional outcome measure for PAC. During this meeting, the possibility of creating one measure to capture both self-care and mobility was discussed. We are also seeking input on measures of health equity, such as structural measures that assess an organization's leadership in advancing equity goals or assess progress towards achieving equity priorities. Finally, we seek input on the value of a COVID–19 Vaccination Coverage measure that would assess whether LTCH patients were up to date on their COVID–19 vaccine.

TABLE IX.G.-02: FUTURE MEASURE CONCEPTS UNDER CONSIDERATION FOR THE LTCH QRP

Quality Measure Concepts
Cross-Setting Function
Health Equity Measures
PAC - COVID-19 Vaccination Coverage among Patients

While we will not be responding to specific comments submitted in response to this RFI in the FY 2023 IPPS/LTCH PPS final rule, we intend to use this input to inform our future measure development efforts.

5. Inclusion of the National Healthcare Safety Network (NHSN) Healthcare-Associated Clostridioides difficile Infection Outcome Measure in the LTCH QRP—Request for Information (RFI)

a. Background

The LTCH QRP is authorized by section 1886(m)(5) of the Act and furthers our mission to improve the quality of health care for beneficiaries through measurement, transparency, and public reporting of data. The LTCH QRP and CMS's other quality programs are foundational for contributing to improvements in health care, enhancing patient outcomes, and informing consumer choice. In October 2017, we launched the Meaningful Measures Framework. This framework captures our vision to address healthcare quality priorities and gaps, including emphasizing digital quality measurement (dQM), reducing measurement burden, and promoting patient perspectives, while also focusing on modernization and innovation. The scope of the Meaningful Measures Framework has evolved to accommodate the changes in the healthcare environment, initially focusing on measure and burden reduction to include the promotion of innovation and modernization of all aspects of quality.[1341] As a result, CMS has identified a need to streamline our approach to data collection, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, improvement, and learning.

b. Potential Future Inclusion of a Digital National Healthcare Safety Network (NHSN) Measure

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50865 through 50868), we finalized the NHSN Facility-Wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717) for inclusion in the LTCH QRP.

Clostridioides difficile (*C. difficile*) is responsible for a spectrum of CDIs, including uncomplicated diarrhea, pseudomembranous colitis, and toxic megacolon, which can, in some instances, lead to sepsis and even death. CDIs are one of the most common healthcare-associated infections (HAIs), as healthcare-associated CDIs affected 0.54 percent of all hospitalizations in a 2015 survey.[1342] In 2017, the CDC estimated there were 223,900 CDIs requiring hospitalizations in the United States with 12,800 resulting in deaths.[1343] We have recently identified the NHSN Healthcare-Associated *Clostridioides Difficile* Infection (HA–CDI) Outcome measure as a potential measure which utilizes Electronic Health Record (EHR)-derived data to help address hospital-based adverse events, specifically hospital-onset infections.

CDIs are currently reported to the CDC's NHSN by various mechanisms, one of which is based on laboratory-identified events collected in the NHSN. The LTCH QRP measure, the NHSN Facility-Wide Inpatient Hospital CDI Outcome Measure, does not utilize EHR-derived data. Rather LTCHs collect data and submit them on a monthly basis to the CDC's NHSN using the CDC's NHSN Multidrug-Resistant Organism & *Clostridioides difficile* Infection (MDRO/CDI) Module. The CDC has now developed the NHSN HA–CDI measure that utilizes EHR-derived data.

The newly-developed version of the measure, the NHSN HA–CDI, would improve on the original version of the measure in two ways. First, the new measure would require both microbiologic evidence of *C. difficile* in stool and evidence of antimicrobial treatment, whereas the original measure only requires *C. difficile* facility-wide Laboratory-Identified (Lab-ID) event reporting. Second, consistent with the Meaningful Measures Framework, we specifically believe it would reduce reporting and regulatory burden on providers and accelerate the move to

[1341] Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

[1342] Magil SM, O'Leary E, Janelle SJ, et al. Changes in Prevalence of Health Care-Associated Infections in U.S. Hospitals. N Engl J Med 2018;379:1732–1744. Available at: *https://www.nejm.org/doi/full/10.1056/NEJMoa1801550.* Accessed February 3, 2022.

[1343] U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. Antibiotic Resistance Threats in the United States, 2019. Available at: *https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf.* Accessed February 3, 2022.

fully digital measures.[1344] We discuss each of these improvements below.

CDI testing practices have continued to evolve, with recent guidelines from the Infectious Disease Society of America recommending a multi-step testing algorithm to better distinguish between *C. difficile* colonization and active infection.[1345] However, the growing number of testing algorithms in use, each with different performance characteristics, poses a challenge for CDI surveillance. This new CDI measure defines CDI using both a positive microbiological test for *C. difficile* and evidence of treatment, increasing the specificity and sensitivity of the measure. Adding a requirement of CDI treatment to a CDI surveillance measure would increase the clinical validity of the measure, since a record of CDI treatment serves as a proxy for *C. difficile* test results that were interpreted as true infections by the clinician.

We believe there are important reasons for LTCHs to adopt and utilize EHRs, although we understand that for LTCHs who do not yet use EHRs there will be initial implementation and training costs. EHRs facilitate moving to fully digital measures, which we believe reduces reporting and regulatory burden on providers. Additionally, both surveys [1346] [1347] and studies [1348] [1349] have demonstrated that when healthcare providers have access to complete and accurate information, patients receive better medical care. We believe the utilization of EHRs can improve the ability to diagnose diseases and reduce (even prevent) medical errors, both of which improve patient outcomes.

[1344] Centers for Medicare & Medicaid Services. (2021) Quality Measurement Action Plan. Available at: *https://www.cms.gov/files/document/2021-cms-quality-conference-cms-quality-measurement-action-plan-march-2021.pdf.*

[1345] Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) (idsociety.org).

[1346] King J, Patel V, Jamoom E, Furukawa M. Clinical Benefits of Electronic Health Record Use: National Findings. Health Serv Res. 2014 Feb; 49(1 pt 2):392–404. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3925409/.*

[1347] Hoover R. Benefits of using an electronic health record. Nurs Crit Care. 2017;12(1):9–10. Available at: *https://journals.lww.com/nursingcriticalcare/fulltext/2017/01000/benefits_of_using_an_electronic_health_record.3.aspx.*

[1348] Escobar G, Turk B, Ragins A, Ha J, et al. Piloting electronic medical record-based early detection of inpatient deterioration in community hospitals. J Hosp Med. 2016 Nov;11(Suppl 1):S18–S24. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5510649/.*

[1349] Uslu A, Stausberg J. Value of the Electronic Medical Record for Hospital Care: Update from the literature. J Med internet Res. 2021;23(12):e26323. Available at: *https://www.jmir.org/2021/12/e26323.*

Additionally, the use of a fully digital measure using a Measure Calculation Tool (MCT) that pulls data directly from the EHR via a standardized Fast Healthcare Interoperability Resources (FHIR) interface would eliminate multiple steps for the provider, including creating or updating monthly reporting plans, and completing the data fields required for both numerator and denominator every month, even when no events were identified. Finally, the locally installed MCT would be responsible for extracting data, calculating the measure, and submitting the data and would eliminate the need for the LTCH to manually enter the data into the NHSN web-based application or via file imports. For example, if each LTCH executed approximately 6 *C. difficile* events per month (72 events per LTCH annually), then using 2020 Bureau of Labor Statistics (BLS) data,[1350] we estimate a potential time savings of approximately 2.5 hours per LTCH per month and a total cost savings of $1,598.25 per LTCH per year if a digital version of the measure replaced the NHSN-based measure.[1351]

c. Overview of the NHSN Healthcare-Associated Clostridioides difficile Infection Outcome Measure

The EHR-driven digital version of the NHSN HA–CDI measure would track the development of new CDI among patients already admitted to LTCHs, using algorithmic determinations from data sources widely available in EHRs.

The numerator would include those patient records with a qualifying *C. difficile*-positive assay on an inpatient encounter on day 4 or later of an LTCH admission and with no previously positive event in ≤14 days before the LTCH encounter, and new qualifying antimicrobial therapy for *C. difficile* started within the appropriate window period of stool specimen collection. The denominator would be the number of patients admitted to LTCHs.

The NHSN HA–CDI measure would use the Standardized Infection Ratio (SIR) of hospital-onset CDIs among patients to compare within facility types. SIR is a primary summary statistic used by the NHSN to track HAIs. The Adjusted Ranking Metric (ARM) is a new statistic currently available for acute-care hospitals that accounts for differences in the volume of exposure (specifically, in the denominator) between facilities. ARM provides complementary information to SIR and was developed for use in acute-care hospitals, but is also intended for use in post-acute care facilities.[1352]

[1350] U.S. Bureau of Labor Statistics. Occupational Employment and Wage Statistics. May 2020 National Occupational Employment and Wage Estimates. United States. Available at: *https://www.bls.gov/oes/current/oes_nat.htm#43-0000.* Accessed February 3, 2022.

[1351] Estimated using 10 minutes of clinical nursing time (Occupation Code 29–1141) and 15 minutes of clerical time (Occupation Code 43–6013) necessary to enter the data into the NHSN.

d. Measure Application Partnership (MAP) Review

The NHSN HA–CDI measure (MUC2021–098) was included in the publicly available ''List of Measures Under Consideration for December 1, 2021'' (MUC List),[1353] a list of measures under consideration for use in various Medicare programs, including the LTCH QRP. This allows multi-stakeholder groups to provide recommendations to the Secretary on the measures included on the list.

The NHSN HA–CDI measure (MUC2021–098) was included under the LTCH QRP Program on the MUC List. The National Quality Forum (NQF)-convened MAP Post-Acute Care—Long-Term Care (PAC–LTC) Workgroup met on January 19, 2022 and provided input on the proposed measure. The MAP offered conditional support of the NHSN HA–CDI measure for rulemaking contingent upon NQF endorsement, noting that the measure has the potential to mitigate unintended consequences from the current measure's design, which counts a case based on a positive test only, which may have led to a historical under-counting of observed HA–CDIs. The MAP recognized that the measure is consistent with the program's priority to measure HAIs and the Patient Safety Meaningful Measures 2.0 area.[1354] The final MAP report is available at *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

e. Data Sources

The data source for the NHSN HA–CDI would be the LTCHs' EHRs. The primary sources of data for determining numerator events would include microbiology data (*C. difficile* infection test), medication administration data (*C. difficile* infection antimicrobial

[1352] More information on how ARM and SIR compare can be found at: *https://www.cdc.gov/nhsn/ps-analysis-resources/arm/index.html.*

[1353] Centers for Medicare & Medicaid Services. List of Measures Under Consideration for December 1, 2021. Available at *https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf.* Accessed February 7, 2022.

[1354] 2021–2022 MAP Final Recommendations. Available at *https://www.qualityforum.org/map/.* Accessed February 3, 2021.

treatment), and patient encounter, demographic, and location information.

To facilitate rapid, automated, and secure data exchange, the CDC's NHSN is planning to enable and promote reporting of this measure using Health Level 7 (HL7) FHIR. However, as HL7 FHIR capabilities are evolving and not uniform across healthcare systems, CDC is also planning to enable reporting using the existing HL7 Clinical Document Architecture (CDA), and potentially other formats as well in order to provide all facilities with an option for reporting. Furthermore, this measure would not immediately replace the current NHSN CDI measure. NHSN would continue to host and support the current CDI measure until sufficient experience is achieved with the new measure to phase out the current CDI measure in each applicable setting.

f. Solicitation of Public Comment

In this proposed rule, we are requesting stakeholder input on the potential electronic submission of quality data from LTCHs via their EHRs under the LTCH QRP. We specifically seek public comment on the future inclusion of the NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure (HA–CDI) (MUC2021–098) as a digital quality measure in the LTCH QRP.

Specifically, we seek public comment on the following:

- Would you support utilizing LTCH EHRs as the mechanism of data collection and submission for LTCH QRP measures?
- Would your EHR support exposing data via HL7 FHIR to a locally installed MCT? For LTCHs using certified health IT systems, how can existing certification criteria under the Office of the National Coordinator (ONC) Health Information Technology (IT) Certification Program support reporting of these data? What updates, if any, to the Certification Program would be needed to better support capture and submission of these data?
- Is a transition period between the current method of data submission and an electronic submission method necessary? If so, how long of a transition would be necessary, and what specific factors are relevant in determining the length of any transition?
- Would vendors, including those that service LTCHs, be interested in or willing to participate in pilots or voluntary electronic submission of quality data?
- Do LTCHs anticipate challenges, other than the adoption of EHR, to adopting the NHSN HA–CDI measure, and if so, what are potential solutions for those challenges?

While we will not be responding to specific comments submitted in response to this RFI in the FY 2023 IPPS/LTCH PPS final rule, we will actively consider all input as we develop future regulatory proposals. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

6. Overarching Principles for Measuring Equity and Healthcare Quality Disparities Across CMS Quality Programs—Request for Information (RFI)

Significant and persistent inequities in healthcare outcomes exist in the United States. Belonging to an underserved community [1355] [1356] [1357] is often associated with worse health outcomes.[1358] [1359] [1360] [1361] [1362] [1363] With this in mind, CMS aims to advance health equity, by which we mean the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes. CMS is working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our enrollees need to thrive.[1364]

We are committed to achieving equity in healthcare outcomes for our beneficiaries by supporting healthcare providers' quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting healthcare provider accountability for healthcare disparities.[1365] Measuring healthcare disparities in quality measures is a cornerstone of our approach to advancing healthcare equity. Hospital performance results that illustrate differences in outcomes between patient populations have been reported to hospitals confidentially since 2015. We provide additional information about this program in section IX.E.6.a.1. of this proposed rule.

This RFI consists of three sections. The first section discusses a general framework that could be utilized across CMS quality programs to assess disparities in healthcare quality. The next section outlines approaches that could be used in the LTCH QRP to assess drivers of healthcare quality disparities in the LTCH QRP. Additionally, this section discusses measures of health equity that could be adapted for use in the LTCH QRP. Finally, the third section solicits public comment on the principles and approaches listed in the first two sections as well as seeking other thoughts about disparity measurement guidelines for the LTCH QRP.

[1355] Joynt KE, Orav E, Jha AK. Thirty-day readmission rates for Medicare beneficiaries by race and site of care. JAMA. 2011;305(7):675–681.

[1356] Lindenauer PK, Lagu T, Rothberg MB, et al. Income inequality and 30 day outcomes after acute myocardial infarction, heart failure, and pneumonia: Retrospective cohort study. BMJ. 2013 Feb 14;346:f521. doi: 10.1136/bmj.f521.

[1357] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and equity of care in U.S. hospitals. N Engl J Med. 2014;371(24):2298–2308.

[1358] Polyakova M, Udalova V, Kocks G, et al. Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. Health Affairs. 2021;40(2):307–316.

[1359] Rural Health Research Gateway. (2018). Rural communities: Age, Income, and Health status. Rural Health Research Recap. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.* Accessed February 3, 2022.

[1360] U.S. Department of Health and Human Services. Office of the Secretary. Progress Report to Congress. HHS Office of Minority Health. 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. FY 2020. Available at: *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.* Accessed February 3, 2022.

[1361] Heslin, KC, Hall JE. Sexual Orientation Disparities in Risk Factors for Adverse COVID–19-Related Outcomes, by Race/Ethnicity—Behavioral Risk Factor Surveillance System, United States, 2017–2019. Morbidity and Mortality Weekly Report (MMWR). 2021;70(5):149–154. Centers for Disease Control and Prevention. February 5, 2021. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm?s_cid=mm7005a1_w.* Accessed February 3, 2022.

[1362] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. [Preprint] medRxiv. 2020;2020.07.21.20159327. doi:10.1101/2020.07.21.20159327. PMID: 32743608; PMCID: PMC7386532.

[1363] Vu M, Azmat A, Radejko T, Padela AI. Predictors of Delayed Healthcare Seeking Among American Muslim Women. Journal of Women's Health. 2016 Jun;25(6):586–593; Nadimpalli SB, Cleland CM, Hutchinson MK, et al. The Association between Discrimination and the Health of Sikh Asian Indians. Health Psychol. 2016 Apr;35(4):351–355.

[1364] Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/pillar/health-equity.* Accessed February 9, 2022.

[1365] CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf.* Accessed February 3, 2022.

a. Cross-Setting Framework To Assess Healthcare Quality Disparities

CMS has identified five key considerations that we could apply consistently across CMS programs when advancing the use of measurement and stratification as tools to address healthcare disparities and advance health equity. The remainder of this section describes each of these considerations.

(1) Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Programs

By quantifying healthcare disparities through quality measure stratification (that is, measuring performance differences among subgroups of beneficiaries), we aim to provide useful tools for healthcare providers to drive improvement based on data. We hope that these results support healthcare provider efforts in examining the underlying drivers of disparities in their patients' care and to develop their own innovative and targeted quality improvement interventions. Quantification of health disparities can also support communities in prioritizing and engaging with healthcare providers to execute such interventions, as well as providing additional tools for accountability and decision-making.

There are several different conceptual approaches to reporting health disparities. In the acute care setting, two complementary approaches are already used to confidentially provide disparity information to hospitals for a subset of existing measures. The first approach, referred to as the ''within-hospital disparity method,'' compares measure performance results for a single measure between subgroups of patients with and without a given factor. This type of comparison directly estimates disparities in outcomes between subgroups and can be helpful to identify potential disparities in care. This type of approach can be used with most measures that include patient-level data. The second approach, referred to as the ''between-hospital disparity methodology,'' provides performance on measures for only the subgroup of patients with a particular social risk factor (SRF). These approaches can be used by a healthcare provider to compare their own measure performance on a particular subgroup of patients against subgroup-specific state and national benchmarks. Alone, each approach may provide an incomplete picture of disparities in care for a particular measure, but when reported together with overall quality performance, these approaches may provide detailed information about where differences in care may exist or where additional scrutiny may be appropriate. For example, the ''between-hospital'' disparity method may indicate that an LTCH underperformed (when compared to other facilities on average) for patients with a given SRF, which would signal the need to improve care for this population. However, if the LTCH also underperformed for patients without that SRF (the ''within-hospital'' disparity, as described above), the measured difference, or disparity in care could be negligible even though performance for the group that has been historically marginalized remains poor. We refer readers to the technical report describing the CMS Disparity Methods in detail as well as the FY 2018 IPPS/LTCH PPS final rule (82 FR 38405 through 38407) and the posted Disparity Methods Updates and Specifications Report posted on the QualityNet website.[1366]

CMS is interested in whether similar approaches to the two discussed in the previous paragraph could be used to provide confidential stratified measure results for selected LTCH QRP measures, as appropriate and feasible. However, final decisions regarding disparity reporting will be made at the program level, as CMS intends to tailor the approach used in each setting to achieve the greatest benefit and avoid unintentional consequences or biases in measurement that may exacerbate disparities in care.

(2) Guiding Principles for Selecting and Prioritizing Measure for Disparity Reporting

We intend to expand our efforts to provide stratified reporting for additional clinical quality measures, provided they offer meaningful, actionable, and valid feedback to healthcare providers on their care for populations that may face social disadvantage or other forms of discrimination or bias. We are mindful, however, that it may not be possible to calculate stratified results for all quality measures, and that there may be situations where stratified reporting is not desired. To help inform prioritization of candidate measures for stratified reporting, we aim to receive feedback on several systematic principles under consideration that we believe will help us prioritize measures for disparity reporting across programs:

- Programs may consider stratification, among existing *clinical quality measures for further disparity reporting,* prioritizing recognized measures which have met industry standards for measure reliability and validity.
- Programs may consider measures for prioritization that show *evidence that a treatment or outcome being measured is affected by underlying healthcare disparities* for a specific social or demographic factor. Literature related to the measure or outcome should be reviewed to identify disparities related to the treatment or outcome, and should carefully consider both SRFs and patient demographics. In addition, analysis of Medicare-specific data should be done in order to demonstrate evidence of disparity in care for some or most healthcare providers that treat Medicare patients.
- Programs may consider establishing *statistical reliability and representation standards* (for example, the percent of patients with a SRF included in reporting facilities) prior to reporting results. They may also consider prioritizing measures that reflect performance on greater numbers of patients to ensure that the reported results of the disparity calculation are reliable and representative.
- After completing stratification, programs may consider prioritizing the *reporting of measures that show differences in measure performance* between subgroups across healthcare providers.

(3) Principles for SRF and Demographic Data Selection and Use

SRFs are the wide array of non-clinical drivers of health known to negatively impact patient outcomes. These include factors such as socioeconomic status, housing availability, and nutrition (among many others), often inequitably affecting historically marginalized communities on the basis of race and ethnicity, rurality, sexual orientation and gender identity, religion, and disability.[1367] [1368] [1369] [1370] [1371] [1372] [1373] [1374]

[1366] Centers for Medicare & Medicaid Services (CMS), HHS. Disparity Methods Confidential Reporting. Available at: *https://qualitynet.cms.gov/inpatient/measures/disparity-methods.* Accessed February 3, 2022.

[1367] Joynt KE, Orav E, Jha AK. Thirty-day readmission rates for Medicare beneficiaries by race and site of care. JAMA. 2011;305(7):675–681.

[1368] Lindenauer PK, Lagu T, Rothberg MB, et al. Income inequality and 30 day outcomes after acute myocardial infarction, heart failure, and pneumonia: Retrospective cohort study. BMJ. 2013 Feb 14;346:f521.

[1369] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and equity of care in U.S. hospitals. N Engl J Med. 2014;371(24):2298–2308.

Continued

Identifying and prioritizing social risk or demographic variables to consider for disparity reporting can be challenging. This is due to the high number of variables that have been identified in the literature as risk factors for poorer health outcomes and the limited availability of many self-reported SRFs and demographic factors across the healthcare sector. Several proxy data sources, such as area-based indicators of social risk and imputation methods, may be used if individual patient-level data are not available. Each source of data has advantages and disadvantages for disparity reporting.

- *Patient-reported data* are considered to be the gold standard for evaluating quality of care for patients with SRFs.[1375] While data sources for many SRFs and demographic variables are still developing among several CMS settings, demographic data elements collected through assessments already exist in LTCHs. Beginning October 1, 2022, LTCHs (86 FR 62390) will begin collecting additional standardized patient data elements about race, ethnicity, preferred language, transportation, health literacy, and social isolation.
- *CMS Administrative Claims data* have long been used for quality measurement due to their availability and will continue to be evaluated for usability in measure development and or stratification. Using these existing data allows for high impact analyses with negligible healthcare provider burden. For example, dual eligibility for Medicare and Medicaid has been found to be an effective indicator of social risk in beneficiary populations.[1376] There are, however, limitations in these data's usability for stratification analysis.
- *Area-based indicators of social risk* create approximations of patient risk based on neighborhood context. Several indexes, such as the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) Index,[1377] the Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Social Vulnerability Index (SVI),[1378] and the Health Resources and Services Administration (HRSA) Area Deprivation Index (ADI),[1379] provide multifaceted contextual information about an area and may be considered as an efficient way to stratify measures that include many SRFs.
- *Imputed data sources* use statistical techniques to estimate patient-reported factors, including race and ethnicity. One such tool is the Medicare Bayesian Improved Surname Geocoding (MBISG) method (currently in version 2.1), which combines information from administrative data, surname, and residential location to estimate race and ethnicity of patients at a population level.[1380]

(4) Identifying Meaningful Performance Differences

While we aim to use standardized approaches where possible, differences in performance on stratified results will be identified at the program level due to contextual variations across programs and settings. We look forward to feedback on the benefits and limitations of the possible reporting approaches described below:

- *Statistical approaches* could be used to reliably group results, such as using confidence intervals, creating cut points based on standard deviations, or using a clustering algorithm.
- Programs could use a *ranked ordering and percentile approach,* ordering providers in a ranked system based on their performance on disparity measures to quickly allow them to compare their performance to other similar providers.
- LTCHs could be categorized into groups based on their performance using *defined thresholds,* such as fixed intervals of results of disparity measures, indicating different levels of performance.
- *Benchmarking,* or comparing individual results to a state or national average, is another potential reporting strategy.
- Finally, a ranking system is not appropriate for all programs and healthcare settings, and some programs may *only report disparity results.*

(5) Guiding Principles for Reporting Disparity Measures

Reporting of the results discussed above can be employed in several ways to drive improvements in quality. Confidential reporting, or reporting results privately to healthcare providers, is generally used for new programs or new measures recently adopted for programs through notice-and-comment rulemaking to give healthcare providers an opportunity to become more familiar with the calculation methods and to improve before other forms of reporting are used. In addition, many results are reported publicly, in accordance with the statute. This method provides all stakeholders with important information on healthcare provider quality, and in turn, relies on market forces to incentivize healthcare providers to improve and become more competitive in their markets without directly influencing payment from CMS.

[1370] Polyakova M, Udalova V, Kocks G, et al. Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. Health Affairs. 2021;40(2):307–316.

[1371] Rural Health Research Gateway. (2018). Rural communities: Age, Income, and Health status. Rural Health Research Recap. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.* Accessed February 3, 2022.

[1372] HHS Office of Minority Health (2020). 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Available at: *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.* Accessed February 3, 2022.

[1373] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. medRxiv [Preprint]. 2020.07.21.20159327. doi: 10.1101/2020.07.21.20159327. PMID: 32743608; PMCID: PMC7386532.

[1374] Vu M, Azmat A, Radejko T, Padela AI. Predictors of Delayed Healthcare Seeking Among American Muslim Women. Journal of Women's Health. 2016 Jun;25(6):586–593; Nadimpalli SB, Cleland CM, Hutchinson MK, et al. The Association between Discrimination and the Health of Sikh Asian Indians. Health Psychol. 2016 Apr;35(4):351–355.

[1375] Jarrín OF, Nyandege AN, Grafova IB, Dong X, Lin H. Validity of race and ethnicity codes in Medicare administrative data compared with gold-standard self-reported race collected during routine home health care visits. Med Care. 2020;58(1):e1–e8. doi: 10.1097/MLR.0000000000001216. PMID: 31688554; PMCID: PMC6904433.

[1376] Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program. December 20, 2016. Available at: *https://www.aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs.* Accessed February 3, 2022.

[1377] Bonito A, Bann C, Eicheldinger C, Carpenter L. *Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries.* Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare & Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008. Available at: *https://archive.ahrq.gov/research/findings/final-reports/medicareindicators/medicareindicators1.html.* Accessed February 7, 2022.

[1378] Flanagan BE, Gregory EW, Hallisey EJ, Heitgerd JL, Lewis B. A social vulnerability index for disaster management. Journal of Homeland Security and Emergency Management. 2011;8(1):1–22. Available at: *https://www.atsdr.cdc.gov/placeandhealth/svi/img/pdf/Flanagan_2011_SVIforDisasterManagement-508.pdf.* Accessed February 3, 2022.

[1379] Center for Health Disparities Research. University of Wisconsin School of Medicine and Public Health. Neighborhood Atlas. Available at: *https://www.neighborhoodatlas.medicine.wisc.edu/*. Accessed February 3, 2022.

[1380] Haas A, Elliott MN, Dembosky JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Serv Res. 2019;54(1):13–23. doi: 10.1111/1475–6773.13099. Epub 2018 Dec 3. PMID: 30506674; PMCID: PMC6338295. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6338295/pdf/HESR-54-13.pdf.* Accessed February 3, 2022.

One important consideration is to assess differential impact on LTCHs, such as those located in rural or critical access areas, to ensure that reporting does not disadvantage already resource-limited settings. The type of reporting chosen by programs will depend on the program context.

Regardless of the methods used to report results, it is important to report stratified measure data alongside overall measure results. Review of both measures results along with stratified results can illuminate greater levels of detail about quality of care for subgroups of patients, providing important information to drive quality improvement. Unstratified quality measure results address general differences in quality of care between healthcare providers and promote improvement for all patients, but unless stratified results are available, it is unclear if there are subgroups of patients that benefit most from initiatives. Notably, even if overall quality measure scores improve, without identifying and measuring differences in outcomes between groups of patients, it is impossible to track progress in reducing disparity for patients with heightened risk of poor outcomes.

b. Approaches To Assessing Drivers of Healthcare Quality Disparities and Developing Measures of Healthcare Equity in the LTCH QRP

This section presents information on two approaches for the LTCH QRP. The first section presents information about a method that could be used to assist LTCHs in identifying potential drivers of healthcare quality disparities. The second section describes measures of healthcare equity that might be appropriate for inclusion in the LTCH QRP.

(1) Performance Disparity Decomposition

In response to the FY 2022 IPPS/LTCH PPS proposed rule's RFI (86 FR 25616 through 25618), ''Closing the Health Equity Gap in Post-Acute Care Quality Reporting Programs,'' some stakeholders noted that, while stratified results provide more information about disparities compared to overall measure scores, they provide limited information toward understanding the drivers of these disparities. As a result, it is up to the LTCHs to determine which factors are leading to performance gaps so that they can be addressed. Unfortunately, identifying which factors are contributing to the performance gaps may not always be straightforward, especially if the LTCH has limited information or resources to determine the extent to which a patient's social determinants of health (SDOH) or other mediating factors (for example, health histories) explain a given disparity. An additional complicating factor is the reality that there are likely multiple SDOH and other mediating factors responsible for a given disparity, and it may not be obvious to the LTCH which of these factors are the primary drivers.

Consequently, CMS may consider methods to use the data already available in enrollment, claims, and assessment data to estimate the extent to which various SDOH (for example, transportation, health literacy) and other mediating factors drive disparities in an effort to provide more actionable information. Researchers have utilized decomposition techniques to examine inequality in health care and, specifically, as a way to understand and explain the underlying causes of inequality.[1381] At a high level, regression decomposition is a method that allows one to estimate the extent to which disparities (that is, differences) in measure performance between subgroups of patient populations are due to specific factors. These factors can be either non-clinical (for example, SDOH) or clinical. Similarly, CMS may utilize regression decomposition to identify and calculate the specific contribution of SDOHs and other mediating factors to observed disparities. This approach may better inform our understanding of the extent to which providers and policy-makers may be able to narrow the gap in healthcare outcomes. Additionally, provider-specific decomposition results could be shared through confidential feedback so that LTCHs can see the disparities within their facility with more granularity, allowing them to set priority targets in some performance areas while knowing which areas of their care are already relatively equitable. Importantly, these results could help providers identify reasons for disparities that might not be obvious without having access to additional data sources (for example, the ability to link data across providers).

To more explicitly demonstrate the types of information that could be provided through decomposition of a measure disparity, consider the following example for a given LTCH. Figures 1 through 3 depict an example (using hypothetical data) of how a disparity in a measure of Medicare Spending Per Beneficiary (MSPB) between dually eligible beneficiaries (that is, those enrolled in Medicare and Medicaid) and non-dually eligible beneficiaries (that is, those with Medicare only) could be decomposed among two mediating factors, one SDOH and one clinical factor: (1) Low health literacy; and (2) high volume of emergency department (ED) use. These examples were selected because if they were shown to be drivers of disparity in their LTCH, the healthcare provider could mitigate their effects. Additionally, high-volume ED use is used as a potential mediating factor that could be difficult for LTCHs to determine on their own, as it would require having longitudinal data for patients across multiple facilities.

In the example in Figure 1, the overall Medicare spending disparity is $1,000: Spending, on average, is $5,000 per non-dual beneficiary and $6,000 per dual beneficiary. We can also see from Figure 2 that in this LTCH, the dual population has twice the prevalence of beneficiaries with low health literacy and high ED use compared to the non-dual population. Using regression techniques, the difference in overall spending between non-dual and dual beneficiaries can be divided into three causes: (1) A difference in the prevalence of mediating factors (for example, low health literacy and high ED use) between the two groups, (2) a difference in how much spending is observed for beneficiaries with these mediating factors between the two groups, and (3) differences in baseline spending that are not due to either (1) or (2). In Figure 3, the Non-Dual beneficiaries column breaks down the overall spending per non-dual beneficiary, $5,000, into a baseline spending of $4,600 plus the effects of the higher spending for the 10 percent of non-dual beneficiaries with low health literacy ($300) and the 5 percent with high ED use ($100). The Dual beneficiaries column similarly decomposes the overall spending per dual beneficiary ($6,000) into a baseline spending of $5,000, plus the amounts due to dual beneficiaries' 20 percent prevalence of low health literacy ($600, twice as large as the figure for non-dual beneficiaries because the prevalence is twice as high), and dual beneficiaries' 10 percent prevalence of high-volume ED use ($200, similarly twice as high as for non-dual beneficiaries due to higher prevalence). This column also includes an additional $100 per risk factor because dual beneficiaries experience a higher cost than non-dual beneficiaries

[1381] Rahimi E, Hashemi Nazari S. A detailed explanation and graphical representation of the Blinder-Oaxaca decomposition method with its application in health inequalities. Emerg Themes Epidemiol. 2021;18:12. *https://doi.org/10.1186/s12982-021-00100-9*. Accessed February 24, 2022.

within the low health literacy risk factor, and similarly within the high ED use risk factor. Based on this information, an LTCH can determine that the overall $1,000 disparity can be divided into differences simply due to risk factor prevalence ($300 + $100 = $400 or 40 percent of the total disparity), disparities in costs for beneficiaries with risk factors ($100 + $100 = $200 or 20 percent) and disparities that remain unexplained (differences in baseline costs: $400 or 40 percent).

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Figure 1

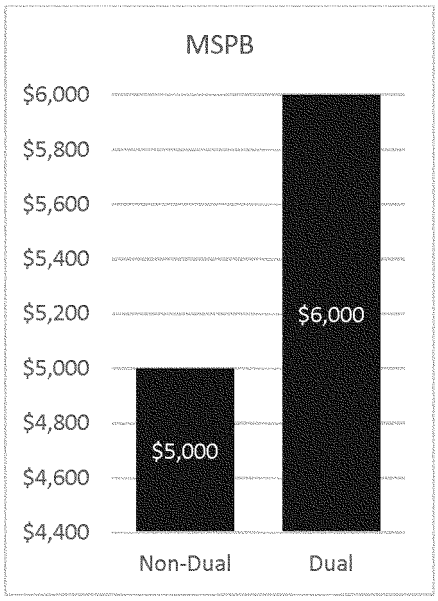


Figure 2

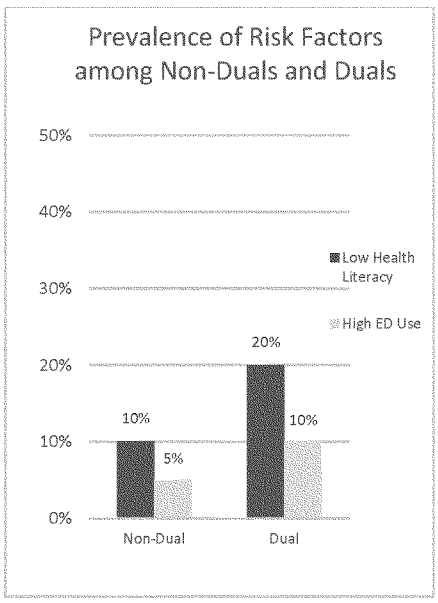
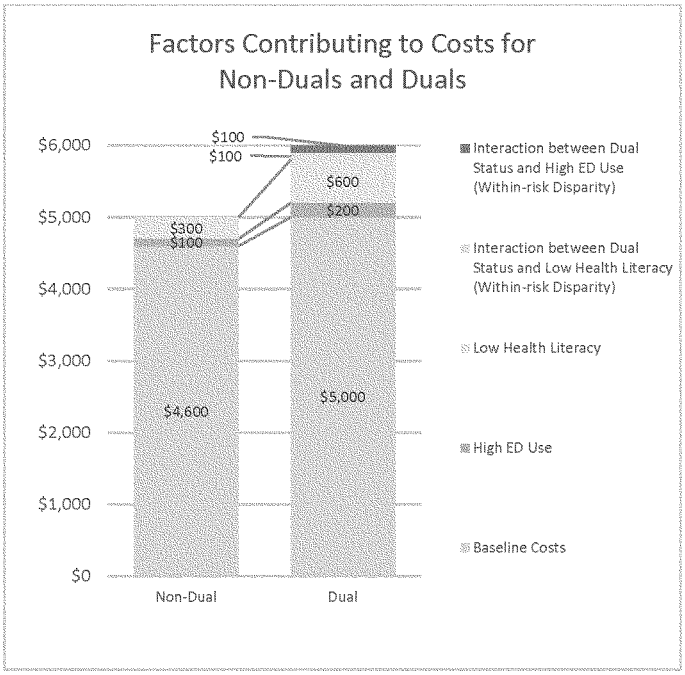


Figure 3



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In particular, the LTCH can see that simply having more patients with low health literacy and high ED use accounts for a disparity of $400. In addition, there is still a $200 disparity stemming from differences in costs between non-dual and dual patients for a given risk factor, and another $400 that is not explained by either low health literacy or high ED use. These differences may instead be explained by other SDOH that have not yet been included in this breakdown, or by the distinctive pattern of care decisions made by providers for dual and non-dual beneficiaries. These cost estimates would provide additional information that facilities could use when determining where to devote resources aimed at achieving equitable health outcomes (for example, facilities may choose to focus efforts on the largest drivers of a disparity).

(2) Measures Related to Health Equity

Beyond identifying disparities in individual health outcomes and by individual risk factors, there is interest in developing more comprehensive measures of health equity that reflect organizational performance. When determining which equity measures could be prioritized for development for the LTCH QRP, CMS will draw from its experience with the CMS Measures Management System (MMS)

Blueprint [1382] and may consider the following:

- Measures should be actionable in terms of quality improvement.
- Measures should help beneficiaries and their caregivers make informed healthcare decisions.
- Measures should not create incentives to lower the quality of care.
- Measures should adhere to high scientific acceptability standards.

CMS has developed measures assessing health equity, or designed to promote health equity, in other settings outside of the LTCH. As a result, there may be measures that could be adapted for use in the LTCH QRP. The remainder of this section discusses two such measures, beginning with the Health Equity Summary Score (HESS), and then a structural measure assessing the degree of hospital leadership engagement in health equity performance data.

(a) Health Equity Summary Score

The HESS measure was developed by the CMS Office of Minority Health (OMH) [1383] to identify and to reward healthcare providers (that is, Medicare Advantage [MA] plans) that perform relatively well on measures of care provided to beneficiaries with SRFs, as well as to discourage the non-treatment of patients who are potentially high-risk, in the context of value-based purchasing. Additionally, a version of the HESS is in development for the Hospital Inpatient Quality Reporting (HIQR) program.[1384] This composite measure provides a summary of equity of care delivery by combining performance and improvement across multiple measures and multiple at-risk groups. The HESS was developed with the following goals: Allow for ''multiple grouping variables, not all of which will be measurable for all plans,'' allow for ''disaggregation by grouping variable for nuanced insights,'' and allow for the future usage of additional and different SRFs for grouping.[1385]

The HESS computes across-provider disparity in performance, as well as within-provider and across-provider disparity improvement in performance. Calculation starts with a cross-sectional score and an overall improvement score for each SRF of race/ethnicity and dual eligibility, for each plan. The overall improvement score is based on two separate improvement metrics: Within-plan improvement and nationally benchmarked improvement. Within-plan improvement is defined as how that plan improves the care of patients with SRFs relative to higher-performing patients between the baseline period and performance period, and is targeted at eliminating within-plan disparities. Nationally benchmarked improvement is improvement of care for beneficiaries with SRFs served by that MA plan, relative to the improvement of care for similar beneficiaries across all MA plans, and is targeted at improving the overall care of populations with SRFs. Within-plan improvement and nationally benchmarked improvement are then combined into an overall improvement score. Meanwhile, the cross-sectional score measures overall measure performance among beneficiaries with SRFs during the performance period, regardless of improvement.

To calculate a provider's overall score, the HESS uses a composite of five clinical quality measures based on Healthcare Effectiveness Data and Information Set (HEDIS) data and seven MA Consumer Assessment of Healthcare Providers and Systems (CAHPS) patient experience measures. A provider's overall HESS score is calculated once using only CAHPS-based measures and once using only HEDIS-based measures, due to incompatibility between the two data sources. The HESS uses a composite of these measures to form a cross-sectional score, a nationally benchmarked improvement score, and a within-plan improvement score, one for each SRF. These scores are combined to produce an SRF-specific blended score, which is then combined with the blended score for another SRF to produce the overall HESS.

(b) Degree of Hospital Leadership Engagement in Health Equity Performance Data

CMS has developed a structural measure for use in acute care hospitals assessing the degree to which hospital leadership is engaged in the collection of health equity performance data, with the motivation that that organizational leadership and culture can play an essential role in advancing equity goals. This structural measure, entitled the Hospital Commitment to Health Equity measure (MUC2021–106), was included on the CMS List of Measures under Consideration (MUC List) [1386] and assesses hospital commitment to health equity using a suite of equity-focused organizational competencies aimed at achieving health equity for racial and ethnic minorities, people with disabilities, sexual and gender minorities, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. We are proposing the Hospital Commitment to Health Equity measure for the Hospital Inpatient Quality Reporting (IQR) program beginning with the CY 2023 Reporting Period/FY 2025 Payment Determination (see section IX.D.5.a. of this proposed rule). The measure will include five attestation-based questions, each representing a separate domain of commitment. A hospital will receive a point for each domain where it attests to the corresponding statement (for a total of 5 points). At a high level, the five domains cover the following: (1) Strategic plan to reduce health disparities; (2) approach to collecting valid and reliable demographic and SDOH data; (3) analyses performed to assess disparities; (4) engagement in quality improvement activities; [1387] (5) leadership involvement in activities designed to reduce disparities. The specific questions asked within each domain, as well as the detailed measure specification are found in the CMS MUC List for December 2021 here: *https://www.cms.gov/files/document/measures-under-consideration-list-2021-*

[1382] Centers for Medicare & Medicaid Services. CMS Measures Management System Blueprint. Version 17.0. September 2021. Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

[1383] Agniel D, Martino SC, Burkhart Q, et al. Incentivizing excellent care to at-risk groups with a health equity summary score. J Gen Intern Med. 2021;36(7):1847–1857. doi: 10.1007/s11606–019–05473–x. Epub 2019 Nov 11. PMID: 31713030; PMCID: PMC8298664. Available at: *https://link.springer.com/content/pdf/10.1007/s11606-019-05473-x.pdf.* Accessed February 3, 2022.

[1384] Centers for Medicare & Medicaid Services, FY 2022 IPPS/LTCH PPS proposed rule. 88 FR 25560. May 10, 2021.

[1385] Centers for Medicare & Medicaid Services Office of Minority Health (CMS OMH). 2021. ''Health Equity as a 'New Normal': CMS Efforts to Address the Causes of Health Disparities.'' Presented at CMS Quality Conference, March 2–3, 2021.

[1386] Centers for Medicare & Medicaid Services. List of Measures Under Consideration for December 1, 2021. Available at: *https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf.* Accessed March 1, 2022.

[1387] Quality is defined by the National Academy of Medicine as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. Quality improvement is the framework used to systematically improve care. Quality improvement seeks to standardize processes and structure to reduce variation, achieve predictable results, and improve outcomes for patients, healthcare systems, and organizations. Structure includes things like technology, culture, leadership, and physical capital; process includes knowledge capital (for example, standard operating procedures) or human capital (for example, education and training). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Quality-Measure-and-Quality-Improvement-.* Accessed March 1, 2022.

report.pdf. An LTCH could receive a point for each domain where data are submitted through a CMS portal to reflect actions taken by the LTCH for each corresponding domain (for a point total).

CMS believes this type of organizational commitment structural measure may complement the health disparities approach described in previous sections, and support LTCHs in quality improvement, efficient, effective use of resources, and leveraging available data. As defined by AHRQ, structural measures aim to ''give consumers a sense of a healthcare provider's capacity, systems, and processes to provide high-quality care.'' [1388] We acknowledge that collection of this structural measure may impose administrative and reporting requirements or both for LTCHs.

We are interested in obtaining feedback from stakeholders on conceptual and measurement priorities for the LTCH QRP to better illuminate organizational commitment to health equity.

7. Solicitation of Public Comment

The goal of this request for information is to describe some key principles and approaches that we will consider when advancing the use of quality measure development and stratification to address healthcare disparities and advance health equity across our programs.

We invite general comments on the principles and approaches described previously in this section of the rule, as well as additional thoughts about disparity measurement guidelines suitable for overarching consideration across CMS's QRP programs. Specifically, we invite comment on the following:

- *Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Reporting Programs*

++ The use of the within- and between-hospital disparity methods in LTCHs to present stratified measure results

++ The use of decomposition approaches to explain possible causes of measure performance disparities

++ Alternative methods to identify disparities and the drivers of disparities

- *Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting*

++ Principles to consider for prioritization of health equity measures and measures for disparity reporting, including prioritizing stratification for validated clinical quality measures, those measures with established disparities in care, measures that have adequate sample size and representation among healthcare providers and outcomes, and measures of appropriate access and care.

- *Principles for Social Risk Factor (SRF) and Demographic Data Selection and Use*

++ Principles to be considered for the selection of SRFs and demographic data for use in collecting disparity data including the importance of expanding variables used in measure stratification to consider a wide range of SRFs, demographic variables, and other markers of historic disadvantage. In the absence of patient-reported data we will consider use of administrative data, area-based indicators, and imputed variables as appropriate.

- *Identification of Meaningful Performance Differences*

++ Ways that meaningful difference in disparity results should be considered.

- *Guiding Principles for Reporting Disparity Measures*

++ Guiding principles for the use and application of the results of disparity measurement.

- *Measures Related to Health Equity*

++ The usefulness of a HESS score for LTCHs, both in terms of provider actionability to improve health equity, and in terms of whether this information would support Care Compare website users in making informed healthcare decisions.

++ The potential for a structural measure assessing an LTCH's commitment to health equity, the specific domains that should be captured, and options for reporting these data in a manner that would minimize burden.

++ Options to collect facility-level information that could be used to support the calculation of a structural measure of health equity.

++ Other options for measures that address health equity.

While we will not be responding to specific comments submitted in response to this RFI in the FY 2023 IPPS/LTCH PPS final rule, we will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

8. Form, Manner, and Timing of Data Submission Under the LTCH QRP

We refer readers to the regulatory text at 42 CFR 412.560(b) for information regarding the current policies for reporting LTCH QRP data.

For more details about the required reporting periods of measures or standardized patient assessment data during the first and subsequent years upon adoption, please refer to the FY 2020 IPPS/LTCH PPS final rule (84 FR 24588 through 24590).

9. Policies Regarding Public Display of Measure Data for the LTCH QRP

We are not proposing any new policies regarding the public display of measure data at this time.

H. Proposed Changes to the Medicare Promoting Interoperability Program

1. Statutory Authority for the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs

The Health Information Technology for Economic and Clinical Health Act (HITECH Act) (Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), together with Title XIII of Division A of the ARRA) authorized incentive payments under Medicare and Medicaid, as well as downward payment adjustments under Medicare, for the adoption and meaningful use of certified electronic health record technology (CEHRT). Incentive payments under Medicare were available to eligible hospitals and critical access hospitals (CAHs) for certain payment years (as authorized under sections 1886(n) and 1814(l) of the Act, respectively) if they successfully demonstrated meaningful use of CEHRT, which included reporting on clinical quality measures using CEHRT. In accordance with the timeframe set forth in the statute, these incentive payments under Medicare are no longer available. Sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act authorize downward payment adjustments under Medicare, beginning with Federal fiscal year (FY) 2015 (and beginning with FY 2022 for subsection (d) Puerto Rico hospitals), for eligible hospitals and CAHs that do not successfully demonstrate meaningful use of CEHRT for certain associated electronic health record (EHR) reporting periods.

2. EHR Reporting Period

Under the definition of ''EHR reporting period for a payment

[1388] Agency for Healthcare Research and Quality. Types of Health Care Quality Measures. 2015. Available at: *https://www.ahrq.gov/talkingquality/measures/types.html.* Accessed February 3, 2022.

adjustment year'' at 42 CFR 495.4, for eligible hospitals and CAHs that are new or returning participants in the Medicare Promoting Interoperability Program, the EHR reporting period in calendar year (CY) 2023 is a minimum of any continuous 90-day period within CY 2023, and the EHR reporting period in CY 2024 is a minimum of any continuous 180-day period within CY 2024. For more information, we refer readers to the discussion in the FY 2022 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital (IPPS/LTCH) Prospective Payment System (PPS) final rule (86 FR 45460 through 45462).

a. CEHRT Requirements

The Promoting Interoperability Program and the Quality Payment Program (QPP) require the use of CEHRT as defined at 42 CFR 495.4 and 414.1305, respectively. Since 2019, in general, this has consisted of EHR technology (which could include multiple technologies) certified under the Office of the National Coordinator for Health Information Technology (ONC) Health Information Technology (IT) Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to certain other 2015 Edition health IT certification criteria as specified in the definition.

The ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' final rule (also referred to as the ''ONC 21st Century Cures Act final rule''), published in the May 1, 2020, **Federal Register** (85 FR 25642 through 25961), finalized a number of updates to the 2015 Edition of health IT certification criteria (also referred to as the 2015 Edition Cures Update) and introduced new 2015 Edition certification criteria. In connection with these updates, ONC also finalized that health IT developers have 24 months from the publication date of the final rule (until May 2, 2022) to make technology available that is certified to the updated, or new criteria. In response to additional calls for flexibility in response to the Public Health Emergency (PHE) for COVID–19, ONC published an interim final rule with comment period on November 4, 2020 entitled, ''Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency'' (hereinafter the ''ONC interim final rule'') (85 FR 70064). In this interim final rule, ONC finalized extended compliance dates for certain 2015 Edition certification criteria. Specifically, where the ONC 21st Century Cures Act final rule provided that developers of certified health IT have 24 months from the publication date of the final rule to make technology certified to new or updated criteria available, ONC extended the timeline until December 31, 2022 (and until December 31, 2023, for 45 CFR 170.315(b)(10), ''electronic health information (EHI) export'').

In the CY 2021 Physician Fee Schedule (PFS) final rule (85 FR 84815 through 84825), we finalized that the technology used by health care providers to satisfy the definitions of CEHRT at 42 CFR 495.4 and 414.1305 must be certified under the ONC Health IT Certification Program, in accordance with the updated 2015 Edition certification criteria as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642). We further finalized aligning the transition period during which health care providers participating in the Promoting Interoperability Program or QPP may use technology certified to either the existing or updated 2015 Edition certification criteria, with the December 31, 2022, date established in the ONC interim final rule for health IT developers to make updated certified health IT available. After this date, health care providers will be required to use only certified technology updated to the 2015 Edition Cures Update for an EHR reporting period or performance period in CY 2023. We are not proposing any changes to this final policy within this proposed rule.

We remind readers that health care providers would not be required to demonstrate that they are using updated technology to meet the CEHRT definitions immediately upon the transition date of December 31, 2022. In accordance with the EHR reporting period and performance period established for the Promoting Interoperability Program and the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category, participants are only required to use technology meeting the CEHRT definitions during a self-selected EHR reporting period or performance period of a minimum of any consecutive 90 days in CY 2023, including the final 90 days of 2023 (86 FR 45460 through 45462 and 86 FR 65466, respectively). The eligible hospital, CAH, or MIPS eligible clinician is not required to demonstrate meaningful use of technology meeting the 2015 Edition Cures Update until the EHR reporting period or performance period they have selected.

3. Electronic Prescribing Objective: Proposed Changes to the Query of Prescription Drug Monitoring Program Measure and Technical Update to the E-Prescribing Measure

a. Query of Prescription Drug Monitoring Program Measure Background

We have adopted the Query of Prescription Drug Monitoring Program (PDMP) measure under the Electronic Prescribing Objective. For background on this measure, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41648 through 41653), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42593 through 42595), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58967 through 58969), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45462 through 45464). In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58967 through 58969), we finalized that the Query of PDMP measure will remain optional and eligible for 5 bonus points in CY 2021. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45464), we finalized that the Query of PDMP measure will remain optional and increased the eligible bonus points to 10 points for CY 2022.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42593 through 42596), FY 2021 IPPS/LTCH PPS final rule (85 FR 58967 through 58969), and FY 2022 IPPS/LTCH PPS final rule (86 FR 45462 through 45464), we described the concern expressed by stakeholders who believed it was premature for the Medicare Promoting Interoperability Program to require the Query of PDMP measure and to score it based on performance. We heard extensive feedback from EHR developers that effectively incorporating the ability to count the number of PDMP queries in the EHR would require more robust measurement specifications. These stakeholders stated that EHR developers may face significant cost burdens if they fully develop numerator and denominator calculations and are then required to change the specification at a later date. Stakeholders stated that the costs of additional development would likely be passed on to health care providers without additional benefit, as this development would be solely for the purpose of calculating the measure, rather than furthering the clinical goal of the measure. While we recognize that a numerator/denominator-based measure remains challenging, we also note (as discussed in more detail later in this section) that the widespread availability of PDMPs across the

country, and recent progress toward solutions for connecting PDMPs with provider EHR systems, has made use of PDMPs feasible through a wide variety of approaches.

b. Current Status of PDMP Adoption

Today, all 50 states and several localities host PDMPs.[1389] The final state to establish a PDMP, the state of Missouri, passed legislation to address this issue in 2021, and is currently working to make its PDMP operational. A 2021 American Medical Association report found that physicians and others used state PDMPs more than 910 million times in 2020.[1390] An assessment of PDMPs conducted by the PDMP Training and Technical Assistance Center (TTAC) at the Institute for Intergovernmental Research (IIR) found an increase in the number of PDMPs that are integrated with Health Information Exchanges (HIEs), EHRs, and/or Pharmacy Dispensing Systems (PDSs), with 44 PDMPs integrated in 2021 reflecting an increase from 28 PDMPs with at least one type of integration in 2017. We refer readers to Table IX.H.–01. for the report's findings on the type of integration and the number of PDMPs that have implemented that type of integration in 2021.

TABLE IX.H.-01.: PDMP INTEGRATION – TYPE AND NUMBER OF PDMPS[1391]

Type of Integration	# of PDMPs
EHR and PDS	35
HIE and EHR	20
HIE, EHR, and PDS	18
EHR only	5
HIE only	1
PDS only	1

Moreover, a number of enhancements to PDMPs are occurring across the country, including enhancements to RxCheck, which is a free, federally supported interstate exchange hub for PDMP data. To date, the prototype has been successfully tested in several states. The goal of the project is to allow any health care provider who is live on the eHealth Exchange to use that existing connection to query a patient's record on the RxCheck Hub, which routes the query to individual State PDMPs that are also live on RxCheck. This solution enables health care providers to query PDMPs via existing connections to health information exchange networks. Most states use either RxCheck or Prescription Monitoring Program (PMP) InterConnect or both to facilitate the sharing of PDMP information between states, allowing providers to query other states' PDMP information from within their own state PDMP.[1392]

We also note that the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115–271), enacted in 2018, has focused on ways to address the nation's opioid epidemic. The SUPPORT for Patients and Communities Act included new requirements for PDMP enhancement and integration, to help reduce opioid misuse and overprescribing and promote the effective prevention and treatment of opioid use disorder beginning in October of 2021. Enhanced Federal matching funds were available to states to support related PDMP design, development, and implementation activities during fiscal years 2019 and 2020.

c. Proposed Changes to the Query of PDMP Measure and Related Policies

(1) Proposal To Change the Query of PDMP Measure Description

The description of the Query of PDMP measure provides that for at least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law (42 CFR 495.24(e)(5)(iii)(B)). Beginning with the EHR reporting period in CY 2023, we are proposing in section IX.H.3.c.(2) of this proposed rule to require the Query of PDMP measure for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program. In section IX.H.3.c.(4). of this proposed rule, we note that should we finalize our proposal to require the Query of PDMP measure beginning with the EHR reporting period in CY 2023, we are proposing two exclusions beginning with the EHR reporting period in CY 2023: (1) Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances that include drugs from Schedules II, III, and IV, and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period; and (2) any eligible hospital or CAH that cannot report on this measure in accordance with applicable law. Should we finalize the proposals to require the Query of PDMP measure and the associated exclusions, we believe the inclusion of the phrase ''except where prohibited and in accordance with applicable law'' in the description of the Query of PDMP measure and the inclusion of the phrase ''in accordance with applicable law'' in the second proposed exclusion for the Query of PDMP measure would be duplicative and potentially cause confusion. Therefore, we are proposing to remove the phrase ''except where prohibited and in accordance with applicable law'' from the description of the Query of

[1389] Prescription Drug Monitoring Program Training and Technical Assistance Center, PDMP Policies and Capabilities: Results From 2021 State Assessment, September 2021, *https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202021%20Assessment%20Results_20210921.pdf.*

[1390] American Medical Association, 2021 Overdose Epidemic Report, *https://www.ama-assn.org/system/files/ama-overdose-epidemic-report.pdf.*

[1391] PDMP Policies and Capabilities: Results From 2021 State Assessment, September 2021, *https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202021%20Assessment%20Results_20210921.pdf.*

[1392] Government Accountability Office. GAO–21–22, PRESCRIPTION DRUG MONITORING PROGRAMS: Views on Usefulness and Challenges of Programs.

PDMP measure should our proposals to require the Query of PDMP measure and the associated exclusions be finalized. We refer readers to section IX.H.3.c.(1) of this proposed rule for our proposed measure description that would reflect this proposed change and additional proposed policy changes for the Query of PDMP measure.

Should our proposal at section IX.H.8. of this proposed rule to remove associated regulatory text related to measures and objectives for the Medicare Promoting Interoperability Program not be finalized, we are proposing to update the regulatory text to reflect these proposed changes at 42 CFR 495.24(e)(5). We are inviting public comment on these proposals.

(2) Proposal To Require the Query of PDMP Measure

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45462), we noted that the decision to maintain the Query of PDMP as an optional measure for CY 2022 considered the current efforts to improve the technical foundation for EHR–PDMP integration, the continued implementation of the SUPPORT for Patients and Communities Act, our ongoing review of alternative measure approaches, and stakeholder concerns about the current readiness across states for implementation of the existing measure. We also noted that this measure can play an important role in helping health care providers to improve clinical decision making by utilizing this information to identify potential opioid use disorders, inform the development of care plans, and develop effective interventions (86 FR 45463); maintaining it as an optional measure with bonus points signals to the hospital and vendor community that this is an important measure which can help spur development and innovation to reduce barriers and challenges (86 FR 45463); and increasing bonus points to 10 points is consistent with the policy finalized for MIPS eligible clinicians in the CY 2021 Physician Fee Schedule final rule (85 FR 84887 through 84888) and aligns with the MIPS Promoting Interoperability performance category (86 FR 45464).

We continue to believe that PDMPs play an important role in patient safety by assisting in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. Querying the PDMP is important for tracking dispensed controlled substances and improving prescribing practices. Efforts to expand the use of PDMPs and integrate PMDPs with health information technology systems are supported by Federal stakeholders including ONC, the Centers for Disease Control and Prevention (CDC), the Department of Justice (DOJ), and the Substance Abuse and Mental Health Services Administration (SAMHSA). The Query of PDMP measure offers a way to reward health care providers who participate in current PDMP initiatives that are supported by Federal partners.

While work continues to improve standardized approaches to PDMP and EHR interoperability, we believe that it is feasible at this time to require providers to report the current Query of PDMP measure requiring a ''yes/no'' response. Given our policies for the Query of PDMP measure that included increasing the eligible bonus points to reward eligible hospitals and CAHs that could report the measure, as well as the recent progress in the availability of PDMPs in all fifty states, and solutions which support accessibility of PDMPs to providers, we believe eligible hospitals and CAHs have had time to grow familiar with what this measure requires of them, even as technical approaches to the use of PDMPs continue to advance. By requiring a ''yes/no'' response the current measure allows providers to use a variety of technical solutions to conduct a query of the PDMP and receive credit for the measure.

Therefore, beginning with the EHR reporting period in CY 2023, we are proposing to require the current Query of PDMP measure requiring a ''yes/no'' response for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program. We would maintain the associated points at 10 points and refer readers to section IX.H.6. of this proposed rule for a discussion of our scoring methodology and proposed concurrent changes. As a result of this proposal, the maximum total points available for the Electronic Prescribing Objective would remain at 20 points for CY 2023. Should our proposal at section IX.H.8. of this proposed rule to remove associated regulatory text related to measures and objectives for the Medicare Promoting Interoperability Program not be finalized, we are proposing to update the regulatory text to reflect these proposed changes at 42 CFR 495.24(e)(5)(iii)(B).

We are inviting public comment on these proposals.

(3) Proposal To Change the Query of PDMP Measure To Include Schedules II, III, and IV

Under 42 CFR 495.24(e)(5)(iii)(B), the Query of PDMP measure provides that for at least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law. The Query of PDMP measure was adopted in the FY 2019 IPPS/LTCH PPS final rule as one of two measures under the Electronic Prescribing Objective intended to support HHS initiatives related to the treatment of opioid and substance use disorders by helping health care providers avoid inappropriate prescriptions, improving coordination of prescribing amongst health care providers, and focusing on the advanced use of CEHRT (83 FR 41648 through 41653).

Under the Controlled Substances Act (CSA),[1393] the Drug Enforcement Administration classifies drugs, substances, and certain chemicals used to make drugs into five distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. A drug's abuse rate is a factor used to determine its classification; for example, Schedule I medications have the highest abuse potential while medications in Schedule V have a low abuse potential. We refer readers to Table IX.H.–02. for information on each Schedule, including abuse potential, medicinal use, if any, and drug examples. For additional information, we refer readers to the listing of drugs and their schedule located at CSA Scheduling at *https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.*[1394]

[1393] Public Law 91–513, tit. II, 84 Stat. 1236, 1242–84 (1970); codified, as amended, at 21 U.S.C. 801 *et seq.*

[1394] See also *https://www.dea.gov/sites/default/files/2020-04/Drugs%20of%20Abuse%202020-Web%20Version-508%20compliant-4-24-20_0.pdf.*

TABLE IX.H.-02.: CONTROLLED SUBSTANCE SCHEDULES, DESCRIPTIONS, AND EXAMPLES[1395]

Schedule	Description	Examples
Schedule I	No accepted medical use, are unsafe, and hold a high potential for abuse.	Heroin and LSD
Schedule II	Accepted medical use, high potential for abuse, abuse could lead to severe psychological or physical dependence.	Hydrocodone, methadone, Demerol, OxyContin, Percocet, morphine, codeine, and amphetamine
Schedule III	Accepted medical use, less potential for abuse than schedule I or II substances, abuse may lead to moderate or low physical dependence or high psychological dependence.	Tylenol with Codeine and anabolic steroids
Schedule IV	Accepted medical use, low potential for abuse relative to schedule III substances, abuse may lead to limited physical or psychological dependence relative to schedule III substances.	Xanax, Klonopin, Valium, and Ativan
Schedule V	Accepted medical use, low potential for abuse relative to schedule IV substances, abuse may lead to limited physical or psychological dependence relative to schedule IV substances.	Cough syrups containing codeine

PDMPs are operated at the state level and individual state requirements for reporting and use differ from state to state.[1396] Currently, every state collects data on schedules II, III, and IV.[1397] Some states collect information about certain non-controlled substances that are potentially subject to abuse or on all prescription drugs.[1398] While state laws vary, we note that most state PDMPs require physicians and dispensing pharmacists to review a patient's prescribing information for the past twelve months prior to prescribing or dispensing any Schedule II, III, and IV controlled substances.[1399]

PDMPs play an important role in patient safety by assisting in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. We believe that expanding the requirements of the Query of PDMP measure to include Schedule II, III, and IV drugs would further support HHS initiatives related to the treatment of opioid and substance use disorders by expanding the types of drugs included in the Query of PDMP measure while aligning with the PDMP requirements in a majority of states. We also believe this expansion to include additional Scheduled drugs would facilitate more informed prescribing practices and improve patient outcomes. Therefore, beginning with the EHR reporting period in CY 2023, we are proposing to expand the Query of PDMP measure to include Schedule II, III, and IV drugs.

Proposed Measure Description: For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history.

To align with policy for the Query of PDMP measure with regard to Schedule II opioids, we are proposing the query of the PDMP for prescription drug history must occur prior to the electronic transmission of an electronic prescription for a Schedule II opioid or Schedule III or Schedule IV drug. We also note that this measure would include all permissible prescriptions and dispensing of Schedule II, III, or IV drugs no matter how small the amount prescribed during an encounter in order for eligible hospitals and CAHs to identify multiple health care provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, and controlled substances prescribed in high quantities. We also note that multiple prescriptions for Schedule II opioids or Schedule III and IV drugs prescribed on the same date by the same eligible hospital or CAH would not require multiple queries of the PDMP and only one query would have to be performed for this measure. Eligible hospitals and CAHs would have flexibility to query the PDMP using data from CEHRT in any manner allowed under state law. Should our proposal at section IX.H.8. of this proposed rule to remove associated regulatory text related to measures and objectives for the Medicare Promoting Interoperability Program not be finalized, we are

[1395] GAO–21–22, Prescription Drug Monitoring Programs: Views on Usefulness and Challenges of Programs; 21 U.S.C. 812, and the U.S. Drug Enforcement Administration.

[1396] For additional information, we refer readers to *https://www.cdc.gov/drugoverdose/pdf/Leveraging-PDMPs-508.pdf*; *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4605194/*; and *https://www.pdmpassist.org/Policies/Legislative/StatutesAndRegulations.*

[1397] *https://www.pdmpassist.org/State.*

[1398] GAO report, GAO–21–22 Prescription Drug Monitoring Programs.

[1399] *https://www.pdmpassist.org/State.*

proposing to update the regulatory text to reflect these proposed changes at 42 CFR 495.24(e)(5)(iii)(B).

We are inviting public comment on these proposals. We are also inviting public comment on whether to expand this measure to include Schedule V or other drugs with potential for abuse.

(4) Exclusions

In FY 2019 IPPS/LTCH PPS final rule, we finalized exclusions for eligible hospitals and CAHs from reporting the Query of PDMP measure beginning with CY 2020 when the measure would have been required by the Medicare Promoting Interoperability Program (83 FR 41653). The finalized exclusions included: (1) Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period; and (2) any eligible hospital and CAH that could not report on this measure in accordance with applicable law. We also finalized the policy that beginning in CY 2020 an eligible hospital or CAH that qualifies for the e-Prescribing measure exclusion is also excluded from reporting on the Query of PDMP measure (83 FR 41649). We also noted our intention to propose an additional exclusion for health care providers in states where integration with a statewide PDMP is not yet feasible or not yet widely available (83 FR 41652).

In FY 2020 IPPS/LTCH PPS final rule (84 FR 42595), we finalized the removal of the exclusions associated with the Query of PDMP measure, noting that exclusions were not necessary because we finalized the Query of PDMP measure as optional for CY 2020. We also finalized the Query of the PDMP measure as an optional measure for CY 2021 and CY 2022 in FY 2021 IPPS/LTCH PPS final rule (85 FR 58969) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45464) and did not finalize any changes to our exclusions policy.

In section IX.H.3.c.(2) of this proposed rule, beginning with the EHR reporting period in CY 2023, we are proposing to require the Query of PDMP measure for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program. Should we finalize our proposal to require the Query of PDMP measure beginning with CY 2023, we believe that exclusions for the measure would be needed for eligible hospitals and CAHs. Therefore, we have revisited the exclusions we established in the FY 2019 IPPS/LTCH PPS final rule and subsequently removed in the FY 2020 IPPS/LTCH PPS final rule because the Query of PDMP measure would continue to be an optional measure. We believe these exclusions would address circumstances when an eligible hospital or CAH is unable to report on the measure. Specifically, if we finalize our proposal to require the Query of PDMP measure in section IX.H.3.c.(2) of this proposed rule, we are proposing the following exclusions that we modified from the exclusions established in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41649 through 41653) and subsequently removed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42593 through 42895) to reflect proposed policy changes in this proposed rule and that would begin with the EHR reporting period in CY 2023: (1) Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances that include drugs from Schedules II, III, and IV, and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period; and (2) any eligible hospital or CAH that cannot report on this measure in accordance with applicable law. We refer readers to section IX.H.6. of this proposed rule for our proposed policy to redistribute points to the e-Prescribing measure under the Electronic Prescribing Objective should an eligible hospital or CAH claim an exclusion for the Query of PDMP measure for an EHR reporting period. Should our proposal at section IX.H.8. of this proposed rule to remove associated regulatory text related to measures and objectives for the Medicare Promoting Interoperability Program not be finalized, we are proposing to update the regulatory text to reflect these proposed changes at 42 CFR 495.24(e)(5).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41652), we signaled our intention to propose an additional exclusion beginning in CY 2020 for providers in states where integration with a statewide PDMP is not yet feasible or not yet widely available. We no longer believe this exclusion is needed given the flexibility of the Query PDMP measure, which requires a ''yes/no'' response, as well as the implementation of PDMPs in all 50 states and several localities and the increasing number of PDMPs offering some degree of integration with EHRs (from 28 PDMPs with at least one type of integration in 2017 to 44 PDMPs that are integrated with HIEs, EHRs, and/or PDSs in 2021 [1400]). We also believe that broadly requiring this measure across providers who may access PDMPs in different ways would help to continue to drive development of improved solutions for PDMP access. While we believe the Query of PDMP measure is achievable for eligible hospitals and CAHs and that the proposed exclusions offer significant flexibilities such that most providers would be able to meet the measure or claim an exclusion we welcome public comment on other barriers, including barriers related to technology solutions, cost, and workflow, that should be considered. We also request comment on any additional exclusions that we should consider for this measure and may propose in the future.

We are inviting public comment on these proposals.

d. Future Direction

While we believe that proposing to require the Query of PDMP measure is feasible and appropriate at this time, we are continuing to work with industry and other Federal partners to advance common standards for exchange of information between PDMPs, EHRs, pharmacy information systems, and exchange networks. We believe this work will ultimately allow us to achieve our ideal state, under which we would modify the Query of PDMP measure to be numerator/denominator-based and require use of standardized functionality within certified health IT systems to support the actions associated with the measure and reporting of a numerator and denominator. We will continue to collaborate with ONC to monitor developments across the industry and efforts to advance relevant standards, and plan to revisit this measure in the future to explore further specifying health IT requirements if they become available and are incorporated into the ONC Health IT Certification Program.

Federally supported activities continue to focus on developing and refining standards-based approaches to enable effective integration into clinical workflows; exploring emerging technical solutions to enhance access to and use of PDMP data; and providing technical resources to a variety of stakeholders to advance and scale the interoperability of health IT systems and PDMPs. Moreover, updates to certified health IT systems incorporating application programming interfaces

[1400] PDMP Policies and Capabilities: Results From 2021 State Assessment, September 2021, *https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202021%20Assessment%20Results_20210921.pdf.*

(APIs) based on HL7® FHIR® standard version Release 4 (85 FR 25642) can help support future technical approaches that enable more seamless exchange of data between CEHRT and PDMP systems. For more information about current and emerging standards related to PDMP data capture and exchange, we refer readers to the ONC Interoperability Standards Advisory.[1401]

e. Proposed Technical Update to the E-Prescribing Measure

The ONC 21st Century Cures Act final rule (85 FR 25642; 85 FR 25660 through 25661) retired the ''drug-formulary and preferred drug list checks'' certification criterion at 45 CFR 170.315(a)(10) which was associated with measures under the Electronic Prescribing Objective for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category (80 FR 62882 and 83 FR 59817). ONC retired this criterion after January 1, 2022 (85 FR 26661).

In the CY 2021 PFS final rule, we finalized that the ''drug-formulary and preferred drug list checks'' criterion will no longer be associated with measures under the Electronic Prescribing Objective and will no longer be required to meet the CEHRT definition for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, beginning with CY 2021 EHR reporting and performance periods (85 FR 84815 through 84825).

In the FY 2022 IPPS/LTCH PPS final rule, we inadvertently omitted a revision to Table IX.F.–02.: Objectives and Measures for the Medicare Promoting Interoperability Program in 2022 to reflect this change and included the text ''queried for a drug formulary'' in the measure description and in the numerator of the e-Prescribing measure (86 FR 45484). In an effort to more clearly capture the previously established policy finalized in the CY 2021 PFS final rule with respect to the e-Prescribing measure, we are proposing to revise the measure description in Table 56 to read ''For at least one hospital discharge, medication orders for permissible prescriptions (for new and changed prescriptions) are transmitted electronically using CEHRT'' and the numerator will be updated to read to indicate ''[t]he number of prescriptions in the denominator generated and transmitted electronically'' to reflect the removal of the health IT certification criterion ''drug-formulary and preferred drug list checks'' (86 FR 65478).

We are inviting public comments on this proposal.

4. Health Information Exchange (HIE) Objective: Proposed Addition of an Alternative Measure for Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA)

a. Background on the Health Information Exchange Objective

The Health Information Exchange (HIE) Objective and its associated measures for eligible hospitals and CAHs hold particular importance because of the role they play within the care continuum. In addition, these measures encourage and leverage interoperability on a broader scale and promote health IT-based care coordination. The Health Information Exchange Objective currently includes three measures: Support Electronic Referral Loops by Sending Health Information, Support Electronic Referral Loops by Receiving and Reconciling Health Information, and Health Information Exchange Bi-Directional Exchange. For background on this objective and its associated measures, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41656 through 41661), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42596 through 42597), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58969), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45465 through 45470).

In the FY 2022 IPPS/LTCH PPS final rule, we finalized the HIE Bi-Directional Exchange measure, under the Health Information Exchange Objective (86 FR 45465 through 45470). The HIE Bi-Directional Exchange measure is worth 40 points, the maximum number of points of the Health Information Exchange Objective, and was finalized as an alternative to reporting on the two existing Health Information Exchange Objective measures: The Support Electronic Referral Loops by Sending Health Information measure (42 CFR 495.24(e)(6)(ii)(A)) and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure (42 CFR 495.24(e)(6)(ii)(B)). To meet the measure, eligible hospitals and CAHs must attest to the following statements:

- *Statement 1:* Participating in an HIE to enable secure, bi-directional exchange of information to occur for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy.
- *Statement 2:* Participating in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners.
- *Statement 3:* Using the functions of CEHRT to support bi-directional exchange with an HIE.

We stated that, by enabling bi-directional exchange of information between health care providers and aggregating data across health care providers with disparate systems, HIEs (including a wide range of organizations facilitating health information exchange) can bring together the information needed to create a true longitudinal care record and support improved care coordination by facilitating timely access to robust health information across care settings (86 FR 45465). We further described how participation in HIEs can amplify health care providers' capacity to share information beyond what a health care provider can achieve through the sending and receiving actions described in the existing measures under the Health Information Exchange Objective, for instance, by facilitating information exchange when a health care provider is unaware of another health care provider's need to receive information about a patient (86 FR 45466). By finalizing this measure for eligible hospitals and CAHs, we sought to ensure that health care providers participating in the Medicare Promoting Interoperability Program would be rewarded for connecting to exchange arrangements that can enable this type of robust information sharing.

b. Background on TEFCA

Section 4003(b) of the 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, amended section 3001(c) of the Public Health Service Act (42 U.S.C. 300jj–11(c)), and required HHS to take steps to advance interoperability for the purpose of ensuring full network-to-network exchange of health information. Specifically, Congress directed the National Coordinator to ''develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' Since the enactment of the 21st Century Cures Act, HHS has pursued development of a Trusted Exchange Framework and Common

[1401] *https://www.healthit.gov/isa/allows-a-provider-request-a-patients-medication-history-a-state-prescription-drug-monitoring.*

Agreement, or TEFCA. ONC's goals for TEFCA are: [1402]

Goal 1: Establish a universal policy and technical floor for nationwide interoperability.

Goal 2: Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value.

Goal 3: Enable individuals to gather their health care information.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20537), we requested comment on whether eligible hospital or CAH participation in TEFCA should be considered a health IT activity that could count for credit within the Health Information Exchange Objective in lieu of reporting on measures for this objective. We received comments in support of this concept, although some commenters disagreed indicating that they were concerned about adding additional burden (83 FR 41669).

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25631 through 25634), in which we proposed the HIE Bi-Directional Exchange measure for eligible hospitals and CAHs, we noted that the proposed attestation statements for the measure did not explicitly refer to participation in a health information network, or partnering with a health information network that participates in TEFCA. However, we stated TEFCA was likely to be an important way for eligible hospitals and CAHs to enable bi-directional health information exchange in the future and that we would continue to explore ways to provide further guidance or update this measure to align with the use of health information networks that participate in TEFCA in the future (86 FR 25634). In the final rule, we noted that several commenters were encouraged to see our acknowledgement that this measure could align with the efforts on TEFCA (86 FR 45468).

Since the publication of the FY 2022 IPPS/LTCH PPS final rule, important additional developments have occurred with respect to TEFCA.[1403] On January 18, 2022, ONC announced a significant TEFCA milestone by releasing the Trusted Exchange Framework [1404] and Common Agreement Version 1.[1405] The Trusted Exchange Framework is a set of non-binding principles for health information exchange, and the Common Agreement for Nationwide Health Information Interoperability Version 1 (also referred to as Common Agreement) is a contract that advances those principles. The Common Agreement and the incorporated by reference Qualified Health Information Network (QHIN) Technical Framework Version 1 (QTF) [1406] establish the technical infrastructure model and governing approach for different health information networks and their users to securely share clinical information with each other—all under commonly agreed-to terms. The Common Agreement is a legal contract that QHINs [1407] sign with the ONC Recognized Coordinating Entity (RCE),[1408] a private-sector entity that implements the Common Agreement and ensures QHINs comply with its terms.

The technical and policy architecture of how exchange occurs under TEFCA follows a network-of-networks structure, which allows for connections at different levels and is inclusive of many different types of entities at different levels, such as health information networks, care practices, hospitals, public health agencies, and Individual Access Services (IAS) [1409] Providers.[1410] QHINs connect directly to each other to facilitate nationwide interoperability, and each QHIN can connect Participants, which can connect Subparticipants.[1411] Compared to most nationwide exchange today, the Common Agreement includes an expanded set of Exchange Purposes beyond Treatment to include Individual Access Services, Payment, Health Care Operations, Public Health, and Government Benefits Determination [1412]—all built upon common technical and policy requirements to meet key needs of the U.S. health care system.[1413] This

[1402] See *https://www.healthit.gov/buzz-blog/interoperability/321tefca-is-go-for-launch.*

[1403] For more information on current developments related to TEFCA, we refer readers to *www.HealthIT.gov/TEFCA.*

[1404] Trusted Exchange Framework (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf.*

[1405] Common Agreement for Nationwide Health Information Interoperability Version 1 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[1406] Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf.*

[1407] The Common Agreement defines a QHIN as ''to the extent permitted by applicable SOP(s), a Health Information Network that is a U.S. Entity that has been Designated by the RCE and is a party to the Common Agreement countersigned by the RCE.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 10 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf*

[1408] In August 2019, ONC awarded a cooperative agreement to The Sequoia Project to serve as the initial RCE. The RCE will operationalize and enforce the Common Agreement, oversee QHIN-facilitated network operations, and ensure compliance by participating QHINs. The RCE will also engage stakeholders to create a roadmap for expanding interoperability over time. *https://sequoiaproject.org/onc-awards-the-sequoia-project-a-cooperative-agreement-for-the-trusted-exchange-framework-and-common-agreement-to-support-advancing-nationwide-interoperability-of-electronic-health-information/.*

[1409] The Common Agreement defines Individual Access Services (IAS) as ''with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, to the extent consistent with Applicable Law, to an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[1410] The Common Agreement defines ''IAS Provider'' as: ''Each QHIN, Participant, and Subparticipant that offers Individual Access Services.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[1411] For the Common Agreement definitions of QHIN, Participant, and Subparticipant, *see* Common Agreement for Nationwide Health Information Interoperability Version 1, at 8–12 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[1412] For the Common Agreement definitions of Payment, Health Care Operations, Public Health, and Government Benefits Determination, *see* Common Agreement for Nationwide Health Information Interoperability Version 1, at 6–10 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[1413] Exchange Purpose(s): means the reason, as authorized by [the] Common Agreement including the Exchange Purposes SOP, for a Request, Use, Disclosure, or Response transmitted via QHIN-to-QHIN exchange as one step in the transmission. Authorized Exchange Purposes are: Treatment, Payment, Health Care Operations, Public Health, Government Benefits Determination, Individual Access Services, and any other purpose authorized as an Exchange Purpose by the Exchange Purposes SOP, each to the extent permitted under Applicable Law, under all applicable provisions of [the] Common Agreement, and, if applicable, under the implementation SOP for the applicable Exchange Purpose. Definitions for each of these exchange purposes can be found in the Common Agreement for Nationwide Health Information Interoperability Version 1, at 6 *(Jan. 2022), https://www.healthit.gov/sites/default/files/page/2022-01/*

Continued

flexible structure allows stakeholders to participate in the way that makes the most sense for them, while supporting simplified, seamless exchange.

The QTF,[1414] which was developed and released by the RCE, describes the functional and technical requirements that a Health Information Network (HIN) [1415] must fulfill to serve as a QHIN under the Common Agreement. The QTF specifies the technical underpinnings for QHIN-to-QHIN exchange and certain other responsibilities described in the Common Agreement. The technical and functional requirements described in the QTF enable information exchange modalities, including querying and message delivery across participating entities.

In general, the information to be exchanged within the TEFCA ecosystem allows for the use of the Health Level Seven (HL7®) Implementation Guide for Clinical Document Architecture (CDA®) Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1 (C–CDA 2.1) document format, including data defined as part of U.S. Core Data for Interoperability (USCDI), with allowance for flexibility to further expand the content to support a multitude of use cases.[1416] The Common Agreement and the QTF do not require HL7® Fast Healthcare Interoperability Resource (FHIR®) based exchange. TEFCA allows for the optional exchange of FHIR content using more traditional, established standards to enable the transport of that content. However, TEFCA can nonetheless be a strong catalyst for network enablement of FHIR maturation. To that end, the RCE released a three-year FHIR Roadmap for TEFCA Exchange, which lays out a deliberate strategy to add FHIR-based exchange under TEFCA in the near future.[1417]

c. Proposed New Enabling Exchange Under TEFCA Measure

In 2022, prospective QHINs are anticipated to begin signing the Common Agreement and applying for designation. The RCE will then begin onboarding and designating QHINs to share information. In 2023, HHS expects stakeholders across the care continuum to have increasing opportunities to enable exchange under TEFCA. Specifically, this would mean such stakeholders would be: (1) Signatories to either the Common Agreement or an agreement that meets the flow-down requirements of the Common Agreement (called a Framework Agreement [1418] under the Common Agreement), (2) in good standing (that is not suspended) under that agreement, and (3) enabling secure, bi-directional exchange of information to occur, in production. TEFCA is expected to give individuals and entities easier, more efficient access to more health information. The Common Agreement will require strong privacy and security protections for all entities who elect to participate, including entities not covered by the Health Insurance Portability and Accountability Act (HIPAA).[1419]

By connecting to an entity that connects to a QHIN or connecting directly to a QHIN, an eligible hospital or CAH can share health information in the same manner as described in the attestation statements previously finalized for the HIE Bi-Directional Exchange measure (42 CFR 495.24(e)(6)(ii)(C)). By connecting to an entity that connects to a QHIN, or connecting directly to a QHIN, that supports sharing information on patients as part of a Framework Agreement,[1420] an eligible hospital or CAH would be thereby enabling bi-directional exchange with other providers as described in Statement 1 of the HIE Bi-Directional Exchange measure. Since participation in a Framework Agreement as a QHIN, Participant, or Sub-participant will be open to all qualifying entities and will not be restricted by use of a single vendor, a connection via a Framework Agreement would also satisfy the requirements of Statement 2 of the HIE Bi-Directional Exchange measure. Finally, as discussed above, the technical requirements for exchanging information by entities through the Common Agreement and Framework Agreements utilize standards included in certified technology referenced under the CEHRT definition (see 42 CFR 495.4), including the ability to exchange and receive data using the C–CDA standard (see certification criteria at 45 CFR 170.315(b)(1) and (2)), thus providers participating in a Framework Agreement can use the functions of CEHRT to support bi-directional exchange with an HIE.

To offer health care providers more opportunities to earn credit for the Health Information Exchange Objective, and given the alignment between enabling exchange under TEFCA and the existing HIE Bi-Directional Exchange measure, we are proposing to add an additional measure through which an eligible hospital or CAH could earn credit for the Health Information Exchange Objective by connecting to an entity that connects to a QHIN or connecting directly to a QHIN. Specifically, we are proposing to add the following new measure to the Health Information Exchange Objective beginning with the EHR reporting period in CY 2023: Enabling Exchange Under TEFCA measure. We propose eligible hospitals and CAHs would have three reporting options for the Health Information Exchange Objective: (1) Report on both the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure, (2) report on the HIE Bi-Directional Exchange measure, or (3) report on the proposed Enabling Exchange Under TEFCA measure.

We propose the Enabling Exchange Under TEFCA measure would be worth the total amount of points available for the Health Information Exchange Objective. Under the current scoring methodology finalized in the FY 2022 IPPS/LTCH PPS final rule, the Health

Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.

[1414] Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf.*

[1415] ''Health Information Network'' under TEFCA has the meaning assigned to the term ''Health Information Network or Health Information Exchange'' in the information blocking regulations at 45 CFR 171.102.

[1416] User's Guide to the Trusted Exchange Framework and Common Agreement—TEFCA (Jan 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/Common-Agreement-Users-Guide.pdf.*

[1417] FHIR® Roadmap for TEFCA Exchange Version 1 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/FHIR-Roadmap-v1.0_updated.pdf.*

[1418] The Common Agreement defines ''Framework Agreement(s)'' as: ''any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.'' See Common Agreement for Nationwide Health Information Interoperability Version 1, at 6 (Jan. 2022) *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[1419] Common Agreement for Nationwide Health Information Interoperability Version 1 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[1420] The Common Agreement defines ''Framework Agreement(s)'' as: ''any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 6 (Jan. 2022) *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

Information Exchange Objective is worth a total of 40 points (86 FR 45466). We note in section IX.H.6. of this proposed rule, we are proposing changes to the scoring methodology beginning with the EHR reporting period in CY 2023 such that the Health Information Exchange Objective would be worth no more than 30 points. Therefore, under our proposal, the proposed Enabling Exchange Under TEFCA measure would be worth 30 points. We are proposing this change to the scoring methodology as a result of our proposal in section IX.H.3.c.(2) of this proposed rule to make the Query of PDMP measure required and worth 10 points. However, should we not finalize the Query of PDMP measure proposal, we propose the Enabling Exchange Under TEFCA measure would be worth 40 points (the current total point value of the Health Information Exchange Objective). In no case could more than 40 points total be earned for the Health Information Exchange Objective. In section IX.H.8. of this proposed rule, we are proposing to remove text for the objectives and measures from paragraph (e) under 42 CFR 495.24 beginning in CY 2023. If we do not finalize that proposal, we would revise 42 CFR 495.24(e) to reflect the addition of the proposed Enabling Exchange Under TEFCA measure.

We believe the new measure for enabling exchange under TEFCA that we are proposing would incentivize eligible hospitals and CAHs to exchange information by connecting directly or indirectly to a QHIN and support health information exchange at a national level. We believe that fulfillment of this measure is an extremely high value action. The overall TEFCA goal of establishing a universal floor of interoperability across the country aligns with our commitment to promoting and prioritizing interoperability and exchange of healthcare data. Incentivizing providers to enable exchange under TEFCA is a critical component to advancing healthcare data exchange nationwide. We are proposing eligible hospitals and CAHs would report the Enabling Exchange Under TEFCA measure by attestation, and the measure would require a ''yes/no'' response. A ''yes'' response would enable eligible hospitals and CAHs to earn the proposed 30 points allotted to the Health Information Exchange Objective. Further, we propose this measure may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT. A patient's record is maintained using CEHRT if sufficient data were entered in the CEHRT to allow the record to be saved, and not rejected due to incomplete data.

We propose that eligible hospitals and CAHs would attest to the following:

- Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website) (in good standing that is not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy.
- Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.

Similar to the HIE Bi-Directional Exchange measure, to successfully attest to this measure, we propose the eligible hospital or CAH must use the capabilities of CEHRT to support bi-directional exchange under a Framework Agreement, which includes capabilities that support exchanging the clinical data within the Common Clinical Data Set (CCDS) or the United States Core Data for Interoperability (USCDI). This is consistent with the other measures under the Health Information Exchange Objective, which point to the use of CEHRT to support the exchange of the clinical data within the CCDS or the USCDI.

We believe there are numerous certified health IT capabilities that can support bi-directional exchange under a Framework Agreement. For instance, participants may exchange information under a Framework Agreement by using technology certified to the criterion at 45 CFR 170.315(b)(1), ''Care coordination—Transitions of care,'' to transmit C–CDAs across a network. Where supported, participants could also utilize API technology certified to either the criterion at 45 CFR 170.315(g)(8), ''Design and performance—Application access—data category request,'' or (g)(10), ''Design and performance—Standardized API for patient and population services,'' as finalized in the ONC 21st Century Cures Act final rule (85 FR 25742), to enable exchange of data in the CCDS or USCDI from a participant's EHR. Additional certified health IT modules may also support exchange of information under a Framework Agreement for transitions of care, including modules certified to certification criteria at 45 CFR 170.315(g)(7), ''Design and performance—Application access—patient selection,'' and (g)(9), ''Design and performance—Application access—all data request,'' which support information exchange via API; the certification criterion at 45 CFR 170.315(e)(1), ''Patient engagement—View, download, and transmit to 3rd party,'' which supports patient access to their information; and the certification criterion at 45 CFR 170.315(g)(6), ''Design and performance—Consolidated CDA creation performance,'' which supports creation of a summary of care record. We recognize that entities that will connect directly or indirectly to a QHIN are currently interacting with health care providers using certified health IT in a variety of ways, and, as with the Bi-directional HIE Exchange measure, believe that we should allow for substantial flexibility in how health care providers use certified health IT to exchange data under a Framework Agreement.

The Enabling Exchange Under TEFCA measure could offer health care providers an alternative to earn credit for the Health Information Exchange Objective. The Enabling Exchange Under TEFCA measure would not require an eligible hospital or CAH to assess whether they participate in a health information exchange that meets the attributes of attestation Statement 2 under the HIE Bi-Directional Exchange measure regarding exchange across a broad network of unaffiliated exchange partners including those using disparate EHRs. These attributes are key to the goals of TEFCA, which aims to offer providers a uniform set of expectations around information sharing regardless of which network for information exchange they participate in.

We are inviting public comment on these proposals.

5. Public Health and Clinical Data Exchange Objective

a. Background

The Medicare Promoting Interoperability Program for eligible hospitals and CAHs has been an important mechanism for encouraging healthcare data exchange for public health purposes through the Public Health and Clinical Data Exchange Objective. Effective responses to public health events, such as the COVID–19 PHE, require fast, accurate exchange of data between health care providers and Federal, state, and local public health agencies (PHAs). Health care providers collect these data for patient care, and

PHAs need them to protect the public, whether to track an outbreak, initiate contact tracing, find gaps in vaccine coverage, or pinpoint the source of a foodborne outbreak.

There are six measures under the Public Health and Clinical Data Exchange Objective: Immunization Registry Reporting, Syndromic Surveillance Reporting, Electronic Case Reporting, Electronic Reportable Laboratory (ELR) Result Reporting, Public Health Registry Reporting, and Clinical Data Registry Reporting. For background on this objective and its associated measures, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41665 through 41667), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45470 through 45479). In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45470 through 45479), we finalized the requirement for eligible hospitals and CAHs to report four of the six of the measures associated with the Public Health and Clinical Data Exchange Objective, beginning with the EHR reporting period in CY 2022: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting. These four measures will put PHAs on better footing for future health threats and a long-term COVID–19 pandemic recovery by strengthening three important public health functions: (1) Early warning surveillance, (2) case surveillance, and (3) vaccine uptake. Requiring these measures will enable nationwide syndromic surveillance for early warning of emerging outbreaks and threats; automated case and laboratory reporting for fast public health response; and local and national visibility on immunization uptake so PHAs can tailor vaccine distribution strategies.

b. Proposed Modifications to the Reporting Requirements for the Public Health and Clinical Data Exchange Objective: Antimicrobial Use and Resistance (AUR) Surveillance Measure

Antimicrobial-resistant (AR) infections are caused by pathogens that no longer respond to the drugs designed to kill them and directly threaten patient and population health. An effective national response to the threat presented by antimicrobial resistant bacteria requires robust systems for systematically collecting, analyzing, and using antimicrobial use and resistance data to direct action.

Each year in the United States, more than three million people are infected by an antimicrobial-resistant pathogen or *C. difficile* (an opportunistic pathogen associated with antimicrobial use), and nearly 50,000 people die.[1421] As more pathogens become resistant to available antimicrobials, options for reliably and rapidly treating infections—including pneumonias, foodborne illnesses, and healthcare-associated infections—become increasingly limited, more expensive and, in some cases, nonexistent. The CDC has found that one-third to one-half of all antimicrobials used in inpatient and outpatient settings are either unnecessary or prescribed incorrectly.[1422] The misuse and overuse of antimicrobials both facilitates the emergence of drug-resistant pathogens and exposes patients to needless risk for adverse effects. AR infections can also complicate the response to and recovery from other serious health risks, such as COVID–19. Rates of AR infections have increased in healthcare settings since the beginning of the COVID–19 pandemic, reversing previous prevention successes such as declines of AR infections by as much as 30 percent prior to the pandemic.[1423] Additionally, Methicillin-resistant *Staphylococcus aureus* (MRSA) infections increased five consecutive quarters from 2020 to 2021, including some quarter over quarter increases of 39 percent.[1424] Strengthening of infection prevention and control and antibiotic stewardship is needed to address these challenges and ensure a solid foundation for future public health emergencies.

As outlined in the National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), 2020–2025,[1425] an effective national response to the threat presented by AR bacteria and fungi depends in part on slowing the emergence of new resistant threats and preventing the spread of existing resistant infections. Successfully meeting this goal, in turn, requires robust systems for collecting, analyzing, and using AUR data to direct action. Systematically collecting AUR data also helps inform the availability and potential need for new antibiotics to address emerging forms of resistance.

Antimicrobial use (AU) data delivered to antimicrobial stewardship programs (ASPs) enable stewards to develop, select, and assess interventions aimed at optimizing antimicrobial prescribing. These interventions, in turn, serve to improve antimicrobial treatment effectiveness, protect patients from harms caused by unnecessary antimicrobial exposure, and curb antimicrobial resistance associated with prophylactic and therapeutic excess. Studies have shown that ASPs can help slow the emergence of antimicrobial resistance while optimizing treatment and minimizing costs—all in support of safe and appropriate care for patients.

Antimicrobial resistance data can aid in clinical decision making (hospital cumulative antibiograms) and direct transmission prevention and antimicrobial stewardship efforts. With timely and complete reporting, these data can also facilitate rapid identification and control of potential outbreaks, as well as longer term assessment of progression or improvement to guide public health response efforts. Currently, acute care hospitals and CAHs voluntarily report to CDC's National Healthcare Safety Network's (NHSN) AUR Module with approximately 2000 eligible hospitals and 1000 CAHS reporting on AUR NHSN. Compared to the hospitals that have not reported AUR data, those that reported were more likely to be larger and teaching hospitals.

The extensive voluntary participation in NHSN's AUR surveillance, which calls for hospitals to buy or build an AUR reporting solution, indicates that thousands of hospitals see value in NHSN's AUR surveillance. However, incomplete participation in NHSN's AUR surveillance limits the generalizability of the AUR data: The data is subject to selection bias and do not provide a comprehensive national picture. Other comparable NHSN reporting pathways—such as those used to report data on blood stream infections, urinary tract infections, and other healthcare-associated infections—are required under CMS quality reporting and value-based payment programs, including the Hospital Value-Based Purchasing (VBP) and Hospital-Acquired Condition (HAC) Reduction Programs. In the Hospital VBP and HAC Reduction Programs, the reporting coverage and compliance with NHSN measures is routinely approximately 97 percent. The benefits of monitoring

[1421] CDC. Antibiotic Resistance Threats in the United States, 2019. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019.

[1422] CDC. Antibiotic Use in the United States, 2018 Update: Progress and Opportunities. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019.

[1423] CDC. 2020 National and State Healthcare-Associated Infections Progress Report. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2021.

[1424] Weiner-Lastinger, Lindsey M., et al. ''The Impact of Coronavirus Disease 2019 (COVID–19) on Healthcare-Associated Infections in 2020: A Summary of Data Reported to the National Healthcare Safety Network.'' *Infection Control & Hospital Epidemiology,* vol. 43, no. 1, 2022, pp. 12–25., doi:10.1017/ice.2021.362.

[1425] Office of the Assistant Secretary for Planning and Evaluation (ASPE). (2020). National Action Plan for Combatting Antibiotic-Resistant Bacteria, 2020–2025. Available at: *https://aspe.hhs.gov/reports/national-action-plan-combating-antibiotic-resistant-bacteria-2020-2025*.

AUR data for patient care and public health are most likely to be achieved when data collection and analysis are systematic, standardized, and achieve complete coverage across eligible facilities. In fact, as more hospitals participate, the system becomes better at detecting emerging threats as the network for data collection grows.

We believe that requiring an AUR measure under the Medicare Promoting Interoperability Program would enable the development of a true national picture of the threat posed by antimicrobial overuse and resistance. Requiring AUR reporting through CDC's NHSN would produce inpatient AU and AR benchmarks that can be used to guide clinical and public health action and enable a true national picture of the threat posed by antimicrobial overuse and resistance. We are proposing the following new AUR Surveillance measure under the Public Health and Clinical Data Exchange Objective:

AUR Surveillance measure: The eligible hospital or CAH is in active engagement with CDC's National Healthcare Safety Network (NHSN) to submit antimicrobial use and resistance (AUR) data for the EHR reporting period and receives a report from NHSN indicating their successful submission of AUR data for the EHR reporting period.

We are proposing to require eligible hospitals and CAHs to report this measure beginning with the EHR reporting period in CY 2023. Eligible hospitals and CAHs that report a ''yes'' response or an exclusion for which they are eligible would receive credit for reporting the measure. Eligible hospitals and CAHs that report a ''no'' response or fail to report any response would not receive credit for reporting the measure and would fail to satisfy the Public Health and Clinical Data Exchange Objective. No additional points would be associated with the reporting of this measure, but it would be one of five required measures required to satisfy the Public Health and Clinical Data Exchange Objective. See section IX.H.6. for our proposal to modify the scoring of this objective.

For purposes of this proposed measure, we are proposing eligible hospitals and CAHs must use technology certified to the criterion at 45 CFR 170.315(f)(6), ''Transmission to public health agencies—antimicrobial use and resistance reporting.'' We are also aware of an updated version of this specification [1426] and will work with our partners at CDC and ONC to consider avenues for addressing use of this specification within the ONC Health IT Certification program.

We are proposing three exclusions for the AUR Surveillance measure as follows: the eligible hospital or CAH: (1) Does not have any patients in any patient care location for which data are collected by NHSN during the EHR reporting period; (2) Does not have electronic medication administration records (eMAR)/barcoded medication administration (BCMA) records or an electronic admission discharge transfer (ADT) system during the EHR reporting period; or (3) Does not have an electronic laboratory information system (LIS) or electronic ADT system during the EHR reporting period. We anticipate reevaluating exclusions #2 and #3 for future EHR reporting periods. The AUR Surveillance measure would leverage the standards and functionality included in certified technology referenced under the CEHRT definition, including the ability to transmit to public health agencies for antimicrobial use and resistance reporting.

Further, we propose this measure must be calculated by reviewing all patient records, not just those whose records are maintained using CEHRT.

We are inviting public comment on these proposals. We also invite comments on the feasibility of the timeline and any additional exclusions that we should consider for this measure for proposal in future rulemaking.

c. Proposed Revisions to Active Engagement

(1) Background

The Medicare Promoting Interoperability Program has been an important mechanism for encouraging data exchange between healthcare providers and public health agencies through the Public Health and Clinical Data Exchange Objective. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45471 through 45479), we finalized beginning with the EHR reporting period in CY 2022, eligible hospitals and CAHs must report on the four required measures to obtain points under the Public Health and Clinical Data Exchange Objective: (1) Syndromic Surveillance Reporting; (2) Immunization Registry Reporting; (3) Electronic Case Reporting; and, (4) Electronic Reportable Laboratory Result Reporting. We believe these required measures will motivate electronic health record vendors to implement the necessary capabilities in their products and encourage eligible hospitals and CAHs to engage in the reporting activities described in the measures.

Despite these gains, ensuring the nation's thousands of hospitals implement and initiate data production for these vital public health capabilities remains an ongoing and important effort. The Medicare Promoting Interoperability Program provides an opportunity to continue strengthening the incentives for eligible hospitals and CAHs to engage in these essential reporting activities. Without adequate incentives, it will be difficult to attain the comprehensive data exchange needed to ensure fast, complete, actionable data in response to future public health threats.

In the EHR Incentive Program Stage 3 final rule (80 FR 62862 through 62864), beginning with the EHR reporting period in 2016, we established a definition for active engagement under the Public Health and Clinical Data Registry Reporting Objective. Active engagement is defined as when an eligible hospital or CAH is in the process of moving towards sending ''production data'' to a public health agency or clinical data registry, or is sending production data to a public health agency or clinical data registry. We noted that the term ''production data'' refers to data generated through clinical processes involving patient care and it is used to distinguish between this data and ''test data'' which may be submitted for the purposes of enrolling in and testing electronic data transfers. We established the following three options for eligible hospitals and CAHs to demonstrate active engagement:

Option 1—Completed registration to submit data: The eligible hospital or CAH registered to submit data with the PHA or, where applicable, the clinical data registry (CDR) to which the information is being submitted; registration was completed within 60 days after the start of the EHR reporting period; and the eligible hospital or CAH is awaiting an invitation from the PHA or CDR to begin testing and validation. Eligible hospitals or CAHs that have registered in previous years do not need to submit an additional registration to meet this requirement for each EHR reporting period.

Option 2—Testing and validation: The eligible hospital or CAH is in the process of testing and validation of the electronic submission of data. Eligible hospitals or CAHs must respond to requests from the PHA or, where applicable, the CDR within 30 days; failure to respond twice within an EHR reporting period would result in that provider not meeting the measure.

Option 3—Production: The eligible hospital or CAH has completed testing and validation of the electronic

[1426] *https://www.hl7.org/implement/standards/product_brief.cfm?product_id=426.*

submission and is electronically submitting production data to the PHA or CDR.

For more information about the current options for active engagement, we refer readers to the EHR Incentive Program Stage 3 final rule (80 FR 62862 through 62864).

(2) Proposed Revision to Options for Active Engagement

The three active engagement options provided flexibility for eligible hospitals and CAHs to meet the measures under the Public Health and Clinical Data Exchange Objective in a variety of ways, but they did not provide an incentive to move through the options and get to option 3, production, where there is the ongoing electronic submission of data. Option 1, completed registration to submit data, was an important option in 2016 as many PHAs and CDRs were starting to come online, and thus the provision of this option recognized that many eligible hospitals and CAHs were just beginning to engage in electronic data exchange with PHAs and CDRs. Now many years have passed, and we believe that eligible hospitals and CAHs have had ample time to complete option 1.

Thus, we propose to consolidate current options 1 and 2 into one option beginning with the EHR reporting period in CY 2023. We are not proposing any substantive changes to the individual options or requirements for selecting the individual options; rather, we would combine current options 1 and 2 into a single option, as follows:

1. Proposed Option 1. Pre-production and Validation (a combination of current option 1, completed registration to submit data, and current option 2, testing and validation);

2. Proposed Option 2. Validated Data Production (current option 3, production).

Eligible hospitals and CAHs must demonstrate their level of active engagement as either proposed Option 1 (pre-production and validation) or proposed Option 2 (validated data production) to fulfill each measure. We are inviting public comment on these proposed changes to the options for active engagement.

(3) Proposed Reporting Requirement for Level of Engagement

Although we established the active engagement options, eligible hospitals and CAHs currently are not required to report their level of active engagement for any of the measures associated with the Public Health and Clinical Data Exchange Objective. During the recent COVID–19 PHE, we recognized the importance of public health reporting (as discussed further in section IX.H.5. of this proposed rule), and we believe that knowing the level of active engagement that an eligible hospital or CAH selects would provide information on the types of registries and geographic areas with health care providers in the Pre-production and Validation stage. Our goal is for all health care providers nationwide to be at the Validated Data Production stage so that data will be actively flowing and public health threats can be monitored. Therefore, for the Public Health and Clinical Data Exchange Objective, in addition to submitting responses for the required measures and any optional measures a hospital chooses to report, we propose to require eligible hospitals and CAHs to submit their level of active engagement, either Pre-production and Validation or Validated Data Production (as proposed in section IX.H.5.c.(2)), for each measure they report beginning with the EHR reporting period in CY 2023. If our proposal to reduce the three current options of active engagement to two options is not finalized, we propose to require eligible hospitals and CAHs to submit one of the three current options of active engagement for each measure they report. We believe that this information regarding the level of active engagement would be helpful as it would enable HHS to identify registries and PHAs which may be having difficulty onboarding eligible hospitals and CAHs and moving them to the Validated Data Production phase. If we can identify these hospitals we believe we will be able to identify the barriers that prevent them from moving to the Validated Data Production stage and work to develop solutions to overcome the barriers.

We are inviting public comment on the proposal to require submission of the level of active engagement.

(4) Proposed Changes to the Duration of Active Engagement Options

As discussed in section IX.H.5.c.(3), eligible hospitals and CAHs currently are not required to report their level of active engagement, or advance from one option to the next option within a certain period of time. As we are now proposing to require eligible hospitals and CAHs to submit their level of active engagement for each measure they report, we are also proposing, beginning with the EHR reporting period in CY 2023, that eligible hospitals and CAHs may spend only one EHR reporting period at the Pre-production and Validation level of active engagement per measure, and that they must progress to the Validated Data Production level for the next EHR reporting period for which they report a particular measure. For example, under this proposal, if an eligible hospital or CAH submits a level of active engagement at the proposed option 1 (Pre-production and Validation phase) for the Syndromic Surveillance Reporting measure for the EHR reporting period in CY 2023, the hospital must report a level of active engagement at the proposed option 2 (Validated Data Production phase) for the next EHR reporting period for which it reports the Syndromic Surveillance Reporting measure, or it would fail to satisfy the Public Health and Clinical Data Exchange Objective for its next EHR reporting period. The options for active engagement assume the same PHA or CDR is used by the hospital. In the event an eligible hospital or CAH chooses to switch between one or more CDRs or PHAs, we are proposing they would be permitted to spend an additional EHR reporting period at the Pre-production and Validation phase to assist with onboarding to the new CDR or PHA. As electronic transmission of high-quality data is achieved at the Validated Data Production phase, we want all eligible hospitals and CAHs to reach this level.

We are inviting public comments on these proposed changes to the duration of the active engagement options.

(5) Public Health Reporting and Information Blocking

The ONC 21st Century Cures Act final rule (85 FR 25642) implemented policies related to information blocking as authorized under section 4004 of the 21st Century Cures Act. The ONC 21st Century Cures Act final rule established a regulatory definition of information blocking, under which information blocking is, in general, a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider (actors [1427]) that, except as required by law or covered by an exception in 45 CFR part 171, subpart B or C, is likely to interfere with (as defined in 45 CFR 171.102) access, exchange, or use of EHI.[1428] [1429] For a

[1427] Actor is defined in 45 CFR 171.102 as ''health care provider, health IT developer of certified health IT, health information network or health information exchange.''

[1428] For purposes of the definition of information blocking, for the period before October 6, 2022, electronic health information is defined in 45 CFR 171.103(b). As of that date, electronic health information will be defined as it is in 45 CFR 171.102.

[1429] In order for a practice to be considered information blocking, additional requirements at 45

health care provider (as defined in 45 CFR 171.102), information blocking (see 45 CFR 171.103) means a practice—except as required by law or covered by an exception defined in 45 CFR part 171—that is likely to interfere with access, exchange, or use of EHI that the health care provider knows is unreasonable and is likely to interfere with access, exchange, or use of electronic health information.[1430] [1431]

ONC recently released an information blocking frequently asked question (FAQ) (IB.FAQ43.1.2022FEB) that highlights important points about public health reporting and information blocking.[1432] Specifically, if an actor is required to comply with another law that relates to the access, exchange, or use of EHI, failure to comply with that law may implicate the information blocking regulations. As an example, where a law requires actors to submit EHI to public health authorities, an actor's failure to submit EHI to public health authorities could be considered an interference under the information blocking regulations. For example, many states legally require reporting of certain diseases and conditions to detect outbreaks and reduce the spread of disease. Should an actor that is required to comply with such a law fail to report, the failure could be an interference with access, exchange, or use of EHI under the information blocking regulations. Practices would be evaluated to determine whether the unique facts and circumstances constitute information blocking, consistent with additional ONC frequently asked questions.[1433]

6. Proposed Changes to Scoring Methodology for the EHR Reporting Period in CY 2023

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636 through 41645), we adopted a new performance-based scoring methodology for eligible hospitals and CAHs attesting under the Medicare Promoting Interoperability Program beginning with the CY 2019 EHR reporting period, which included a minimum scoring threshold of a total score of 50 points or more which eligible hospitals and CAHs must meet to satisfy the requirement to report on the objectives and measures of meaningful use under 42 CFR 495.24. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45491 through 45492), we increased the minimum scoring threshold from 50 points to 60 points beginning with the EHR reporting period in CY 2022. As shown in Table IX.H.–03, the points associated with the required measures sum to 100 points, and the optional measures may add additional bonus points. The scores for each of the measures are added together to calculate a total score of up to 105 possible points for each eligible hospital or CAH (83 FR 41636 through 41645).

Table IX.H.–03 reflects the objectives and measures for the EHR reporting period in CY 2022 and was included in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45492).

TABLE IX.H.-03: PERFORMANCE-BASED SCORING METHODOLOGY EHR REPORTING PERIOD IN CY 2022

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing	10 Points
	Bonus: Query of PDMP	10 points (*bonus*)*
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	20 points
	-OR-	
	Health Information Exchange Bi-Directional Exchange*	40 points*
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report the following four measures:* • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Electronic Reportable Laboratory Result Reporting	10 points
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting	5 points (*bonus*)*

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of MACRA are required, but will not be scored. Electronic clinical quality measures (eCQM) measures are required, but will not be scored.
*Signifies a final policy adopted in the FY 2022 IPPS/LTCH PPS final rule.

CFR 171.103(a)(2) or (3) apply, depending on the type of actor engaging in the practice.

[1430] For other types of actors (health IT developers of certified health IT and health information networks or health information exchanges, as defined in 45 CFR 171.102), the definition of ''information blocking'' (see 45 CFR 171.103) specifies that the actor ''knows, or should know, that such practice is likely to interfere with access, exchange, or use of electronic health information.''

[1431] The exceptions to the definition of information blocking (practices that are required by law or covered by an exception in 45 CFR part 171, subpart B or C) described in the previous sentence apply to this definition as well.

[1432] See *https://www.healthit.gov/curesrule/faq/would-not-complying-another-law-implicate-information-blocking-regulations.*

[1433] See *https://www.healthit.gov/curesrule/faq/how-would-any-claim-or-report-information-blocking-be-evaluated.*

In this proposed rule, we are making various proposals that would affect the scoring of the objectives and measures for the EHR reporting period in CY 2023. In proposing to make the Query of PDMP measure required, we would retain the 10 points associated with it, which are allocated as bonus points for the EHR reporting period in CY 2022. To accommodate this change if our proposal is finalized, we are proposing to reduce the points associated with the Health Information Exchange Objective measures from the current 40 points to 30 points beginning with the CY 2023 EHR reporting period.

The Public Health and Clinical Data Exchange Objective, with its current four required measures, is currently worth only 10 points. Despite increasing the number of required measures from two to four to make the objective more effective in promoting public health data electronic exchange, the total number of points did not change between CY 2021 and CY 2022. We believe that increasing the point value of the Public Health and Clinical Data Exchange Objective would create a more meaningful incentive for eligible hospitals and CAHs to engage in the electronic reporting of public health information and recognize the importance of public health systems affirmed by the COVID–19 pandemic. Increasing the point value would make the Public Health and Clinical Data Exchange Objective a more central piece of the Promoting Interoperability Program and better incentivize eligible hospitals and CAHs to implement these essential public health data exchange capabilities. Without adequate incentives, there remains a risk that eligible hospitals and CAHs will simply not prioritize implementing these capabilities, which are essential to ongoing efforts to address COVID–19 and will be indispensable for responding to future public health threats and emergencies. Increasing the point value would more appropriately incentivize eligible hospitals and CAHs to engage in the electronic reporting of public health information and would align the value of the objective with the objective's importance and the effort necessary to meet the required measures.

Thus, we are proposing to increase the points allocated to the Public Health and Clinical Data Exchange Objective from 10 to 25 points to better align with the true value of this objective beginning with the CY 2023 EHR reporting period. This proposal is independent of our proposal to add the AUR Surveillance measure to this objective and we may finalize the point increase in this objective regardless of whether the proposal to add the AUR Surveillance measure to the objective is finalized. We believe assigning 25 points to the objective reflects the importance of comprehensive, nationwide health care data exchange between eligible hospitals and CAHs and public health agencies. Nationwide health care data exchange would provide immense value to the public by improving the speed and effectiveness of public health responses, as well as to eligible hospitals and CAHs, since better public health response reduces pressure on hospitals, which can be overwhelmed in a public health crisis. To balance the increase in the points associated with the Public Health and Clinical Data Exchange Objective, we are proposing to reduce the points associated with the Provide Patients Electronic Access to Their Health Information measure from the current 40 points to 25 points beginning with the CY 2023 EHR reporting period. We are inviting public comment on these proposed changes to our scoring methodology.

Table IX.H.–04. reflects the objectives, measures, and maximum points available for the EHR reporting period in CY 2023 if the proposals discussed in section IX.H.3.c.(2), section IX.H.4.c., and section IX.H.5.b. are finalized.

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TABLE IX.H.-04: PROPOSED PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIOD IN CY 2023

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP*	10 points*	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points*	Required (eligible hospital or CAH's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points*	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points*	
	-OR-		
	Enabling Exchange under TEFCA*	30 points*	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points*	Required
Public Health and Clinical Data Exchange	Report the following five measures:* • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Electronic Reportable Laboratory Result Reporting • AUR Surveillance Reporting*	25 points*	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting	5 points (*bonus*)*	Optional

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of MACRA are required, but will not be scored. eCQM measures are required, but will not be scored.

*Signifies a proposal made in this FY 2023 IPPS/LTCH PPS proposed rule.

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The maximum points available in Table IX.H.–04. do not include the points that would be redistributed in the event an exclusion is claimed. For ease of reference, Table IX.H.–05. shows how points would be redistributed among the objectives and measures for the EHR reporting period in CY 2023 in the event an eligible hospital or CAH claims an exclusion, if the proposals discussed in this section are finalized.

TABLE IX.H.-05.: PROPOSED EXCLUSION REDISTRIBITION FOR EHR REPORTING PERIOD IN CY 2023

Objective	Measure	Redistribution if exclusion is claimed
Electronic Prescribing	e-Prescribing	10 points to HIE Objective
	Query of PDMP*	10 points to e-Prescribing measure
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	No exclusion
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	No exclusion
	-OR-	
	Health Information Exchange Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange under TEFCA*	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following five measures:* • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Electronic Reportable Laboratory Result Reporting • AUR Surveillance Reporting*	If an exclusion is claimed for each of the five measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of MACRA are required, but will not be scored. eCQM measures are required, but will not be scored.
*Signifies a proposal made in this FY 2023 IPPS/LTCH PPS proposed rule.

7. Proposed Public Reporting of Medicare Promoting Interoperability Program Data

Section 1886(n)(4)(B) of the Act requires the Secretary to post in an easily understandable format a list of the names and other relevant data, as determined appropriate by the Secretary, of eligible hospitals and CAHs who are meaningful EHR users under the Medicare FFS program, on a CMS website. In addition, that section requires the Secretary to ensure that an eligible hospital or CAH has the opportunity to review the other relevant data that are to be made public with respect to the eligible hospital or CAH prior to such data being made public. As the Medicare Promoting Interoperability Program has evolved over the years, we have continued to expand the scope of relevant data points across the Medicare Promoting Interoperability Program to publicly report. For example, we post information on a CMS website available to the public regarding the attestations made by eligible hospitals and CAHs concerning actions to limit or restrict the compatibility or interoperability of CEHRT under 42 CFR 495.40(b)(2)(i)(I), as established in the 2020 Patient Access and Interoperability final rule (85 FR 25578 through 25580). Additionally, in alignment with the Hospital IQR Program and goals to encourage data accuracy and transparency, we finalized proposals to begin publicly reporting eCQM data required under the Medicare Promoting Interoperability Program beginning with the eCQM data reported by eligible hospitals and CAHs for the CY 2021 reporting period and for subsequent years (85 FR 58975 through 58976).

To date, we have not publicly reported eligible hospitals' and CAHs' total scores for the Medicare Promoting Interoperability Program. We have stated that we calculate a total score of up to 100 possible points by adding together the points earned for each required measure and any optional measures reported by an eligible hospital or CAH (83 FR 41636 through 41645). However, we are now proposing to post the eligible hospital's or CAH's actual score up to 105 possible points so that consumers can clearly see the high performing hospitals. We believe the addition of the bonus points will be informative for consumers. We believe an eligible hospital's or CAH's total score for the Medicare Promoting Interoperability Program measures could constitute other relevant data because it would help consumers make informed decisions regarding their health care team, such as knowing whether and to what extent their health care provider is involved in health information exchange or providing patients with electronic access to their health information. We believe that publicly reporting additional Medicare Promoting Interoperability Program data demonstrates our commitment to providing data to patients, consumers, and providers to assist them in their decision-making; promoting enhanced health information exchange processes across eligible hospitals and CAHs; and continually aligning processes and policies with the Hospital IQR Program and the MIPS Promoting Interoperability performance category. For example, for the MIPS Promoting Interoperability performance category, individual measure scores and the total performance score across all measures reported by eligible clinicians are posted on a CMS website available to the public.

Therefore, in alignment with our goals to encourage interoperability and transparency, we are proposing to publicly report certain Medicare Promoting Interoperability Program data submitted by eligible hospitals and

CAHs beginning with the EHR reporting period in CY 2023. Specifically, as a first step, we are proposing to publish on a CMS website available to the public the total score of up to 105 points for each eligible hospital and CAH, and the CMS EHR certification ID that represents the CEHRT used by the eligible hospital or CAH, beginning with the total scores and CMS EHR certification IDs for the EHR reporting period in CY 2023. We are not proposing to publish individual measure scores at this time, but we will continue to evaluate that possibility for future rulemaking. For example, under our proposal, if an eligible hospital scored a total of 75 points for the EHR reporting period in CY 2023, we would publish the total score of 75 points and not the number of points earned for each individual measure within the total score. If our proposal is finalized, the total score and CMS EHR certification ID data could be made available to the public as early as the Fall of CY 2024 or as soon as operationally feasible. In addition, as required by section 1886(n)(4)(B) of the Act, we are proposing that eligible hospitals and CAHs would have the opportunity to review their data that we would publish, during a 30-day preview period before the data are made public. We are proposing to follow our current policy and operational process that eligible hospitals are already familiar with for the Hospital IQR Program and use the Hospital Quality Reporting (HQR) system (formerly, the QualityNet Secure Portal) for eligible hospitals and CAHs to access and review their Medicare Promoting Interoperability Program data during a 30-day preview period before publication. We are proposing to post the Medicare Promoting Interoperability Program data using the Compare tool hosted by Health and Human Services currently available at *https://www.medicare.gov/care-compare.*

We are inviting public comments on these proposals. Specifically, we are interested in comments that provide information on how these proposals might affect existing incentives and burdens under the Medicare Promoting Interoperability Program, as well as the benefit and utility of such data being publicly available. We are also seeking comments on which Medicare Promoting Interoperability Program data points to publish in future years, including specific objectives or measure performance rates.

8. Proposed Modifications and Additions to the Regulatory Text

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636 through 41668), we finalized the objectives, measures, exclusion criteria, and scoring methodology for eligible hospitals and CAHs attesting under the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2019 and codified these policies in paragraph (e) under 42 CFR 495.24. We have updated the regulatory text to reflect policy changes in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42616), the FY 2021 IPPS/LTCH PPS final rule (85 FR 59026), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45522).

We note that historically, the objectives, measures, exclusion criteria, and associated scoring methodology for the Medicare Promoting Interoperability Program have been included in both the preamble and associated regulatory text under 42 CFR part 495 (see, for example, the Medicare and Medicaid EHR Incentive Programs Stage 1 final rule (75 FR 44314)). We also note that many CMS quality reporting and performance-based programs, including, but not limited to, the Hospital VBP Program, Hospital IQR Program, the End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Quality Payment Program/MIPS, do not include the text of the measures (also referred to as the measure specifications) adopted for those programs in the Code of Federal Regulations. Instead, the measure specifications generally are included in the rulemaking preamble or maintained by measure stewards outside of CMS and referenced in the preamble. For example, the specifications for the objectives and measures for the Promoting Interoperability performance category of MIPS are not included in the regulatory text for the program under 42 CFR part 414 and instead appear in the preamble only (for example, see CY 2022 PFS final rule (86 FR 65466 through 65485)).

We believe that aligning with the approach taken by other CMS programs to include measures only in the preamble would simplify the Medicare Promoting Interoperability Program and minimize confusion by ensuring consistency across similar CMS programs. We also believe taking this approach for the Medicare Promoting Interoperability Program would reduce burden on regulated parties, CMS, and the general public both during and outside of the rulemaking process. Ensuring the objectives and measures are described consistently in the preamble and regulation text can involve significant effort in terms of time and resources, and inconsistency has the potential to create confusion for regulated parties and the general public. For these reasons, we are proposing to remove the text of the objectives and measures for the Medicare Promoting Interoperability Program from paragraph (e) under 42 CFR 495.24 beginning in CY 2023. We note that this proposal does not include any changes in policy for the Medicare Promoting Interoperability Program, including changes to the objectives and measures. We refer readers to section IX.H.3., section IX.H.4., and section IX.H.5. of this proposed rule for proposed changes in policy related to the objectives and measures. We also emphasize that this proposal does not change our view that the objectives and measures are rules intended to bind regulated parties, nor does it change our intention to enforce the objectives and measures. Specifically, we are proposing to modify the introductory paragraph to 42 CFR 495.24 and paragraph (e) and to establish a new paragraph (f) under 42 CFR 495.24 as described in Table IX.H.–06. In the event these proposals are not finalized, we would update the regulatory text to reflect any policy changes to the objectives and measures for the Medicare Promoting Interoperability Program in the final rule. We refer readers to Table IX.H.–06 for detailed information on these proposed changes and for information on the paragraphs we are proposing to modify due to the proposed changes to regulatory text.

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TABLE IX.H.-06: PROPOSED MODIFICATIONS AND ADDITIONS TO THE REGULATORY TEXT UNDER 42 CFR 495.24

Objectives and Measures	Regulatory Text Impacted	Proposed Regulatory Text Modifications and Aadditions
§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years	§ 495.24 – (Introductory text)	Modification--To remove "for 2019 and subsequent years" and add "for 2019 through 2022. Addition—Add the following sentence to the end of the introductory paragraph: "The criteria specified in paragraph (f) of this section are applicable for eligible hospitals and CAHs attesting to CMS for 2023 and subsequent years."
Stage 3 objectives and measures for eligible hospitals and CAHs attesting to CMS for 2019 and subsequent years	§ 495.24(e) – (Heading)	Modification--In paragraph heading: delete "for 2019 and subsequent years" and to add "for 2019 through 2022."
General rule	§ 495.24(e)(1)(i)(C)	Modification--Delete "In 2022 and subsequent years, earn" and to add "In 2022, earn" at § 495.24(e)(1)(i)(C).
Protect Patient Health Information	§ 495.24(e)(4)(ii)	Modification--Remove "In 2022 and subsequent years" and to add "In 2022" at § 495.24(e)(4)(ii).
Electronic Prescribing	§ 495.249(e)(5)(ii)(B)	• Modification--Delete "In 2020 and subsequent years" and to add "In 2020 through 2022" at § 495.24(e)(5)(ii)(B).
Electronic Prescribing	§ 495.249(e)(5)(iii)(A)	• Modification--Delete "in CY 2019 and subsequent years" and to add "in CY 2019 through CY 2022".
Electronic Prescribing	§ 495.249(e)(5)(v)	• Modification--Delete "Beginning with the EHR reporting period in CY 2019" and to add "For the EHR reporting periods in CY 2019 through CY 2022".
Provider to Patient Exchange	§ 495.24(e)(7)(ii)	• Modification--Delete "beginning in CY 2019" and to add "for CY 2019 through CY 2022." at § 495.24(e)(7)(ii)
Public Health and Clinical Data Exchange	§ 495.24(e)(8)	• Modification--Delete "For CY 2022 and subsequent years" and to add "For CY 2022" at § 495.24(e)(8)(ii) introductory text; (e)(8)(ii)(A); (e)(8)(iii) introductory text; (e)(8)(iii)(A)(*2*); (e)(8)(iii)(D)(*2*); and (e)(8)(iii)(E)(*2*).
Stage 3 objectives and measures for eligible hospitals and CAHs attesting to CMS for 2023 and subsequent years	§ 495.24(f) –	Addition--Adds new paragraph (f) that would set forth the Stage 3 objectives and measures for eligible hospitals and CAHs attesting to CMS for 2023 and subsequent years. (See § 495.24(f) of the regulations text for the proposed requirements.)

We are inviting public comment on our proposed modifications and additions to the regulatory text at 42 CFR 495.24 beginning in CY 2023.

9. Overview of Objectives and Measures for the Medicare Promoting Interoperability Program for the EHR Reporting Period in CY 2023

For ease of reference, Table IX.H.–07. lists the objectives and measures for the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2023 as revised to reflect the proposals made in this proposed rule. Due to our proposed modifications to the regulatory text at 42 CFR 495.24(e) (described in section IX.H.8. of the preamble of this proposed rule), we are adding a column to Table IX.H.–07. indicating whether the measure may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT or must be calculated by reviewing all patient records, which is intended to reflect the policy codified at 42 CFR 495.24(e)(3). Table IX.H.–08. lists the 2015 Edition certification criteria required to meet the objectives and measures.

TABLE IX.H.-07.: SUMMARY OF PROPOSED AND PREVIOUSLY FINALIZED OBJECTIVES AND MEASURES FOR THE MEDICARE PROMOTING INTEROPERABILITY PROGRAM FOR THE EHR REPORTING PERIOD IN CY 2023

Objective	Measure	Numerator	Denominator	Exclusion	Calculation Considerations Related to Unique Patients or Actions
Electronic Prescribing	e-Prescribing:* At least one hospital discharge medication order for permissible prescriptions (for new and changed prescriptions) is queried for a drug formulary and transmitted electronically using certified electronic health record technology (CEHRT).	The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically.	The number of new or changed prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances for patients discharged during the EHR reporting period.	Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their EHR reporting period.	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
Electronic Prescribing	Query of Prescription Drug Monitoring Program (PDMP):* For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period. Any eligible hospital or CAH that could not report on this measure in accordance with applicable law.	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.

Health Information Exchange	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care: (1) Creates a summary of care record using CEHRT; and (2) Electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.	Number of transitions of care and referrals during the EHR reporting period for which the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the transitioning or referring provider.	N/A	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
Health Information Exchange	Support Electronic Referral Loops by Receiving and Reconciling Health Information: For at least one electronic summary of care record received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, medication allergy, and current problem list using CEHRT.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication Allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using certified electronic health record technology (CEHRT) for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the reconciling party of a transition of care or referral, and for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient.	N/A	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.

Health Information Exchange	HIE Bi-Directional Exchange The eligible hospital or CAH must attest to the following: (*1*) Participating in an HIE in order to enable secure, bi-directional exchange of information to occur for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy. (*2*) Participating in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners. (*3*) Using the functions of CEHRT to support bi-directional exchange with an HIE.	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A (measure is Y/N)	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.

Health Information Exchange	Enabling Exchange under TEFCA* The eligible hospital or CAH must attest to the following: (1) Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the Federal Register and on ONC's website) in good standing (that is not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy. (2) Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A (measure is Y/N)	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.

Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information: For at least one unique patient discharged from the eligible hospital or CAH inpatient or emergency department (POS 21or 23): (1) the patient (or patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) the eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the application programming interface (API) in the eligible hospital or CAH's CEHRT.	The number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download and transmit to a third party and to access using an application of their choice that is configured to meet the technical specifications of the API in the eligible hospitals or CAH's CEHRT.	The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.	N/A	Measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

Public Health and Clinical Data Exchange	Immunization Registry Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the eligible hospital or CAH: (1) Does not administer any immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or IIS during the EHR reporting period; (2) Operates in a jurisdiction for which no immunization registry or IIS is capable of accepting the specific standards required to meet the certified electronic health record technology (CEHRT) definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no immunization registry or IIS has declared readiness to receive immunization data as of six months prior to the start of the EHR reporting period.	Measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting: The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an emergency department (POS 23).	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH: (1) Does not have an emergency department; (2) Operates in a jurisdiction for which no PHA is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the certified electronic health record technology (CEHRT) definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of six months prior to the start of the EHR reporting period.	Measure must be calculated by reviewing all patient records, not just those maintained using CEHRT

Public Health and Clinical Data Exchange	Electronic Case Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit case reporting of reportable conditions.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the eligible hospital or CAH: (1) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period; (2) Operates in a jurisdiction for which no PHA is capable of receiving electronic case reporting data in the specific standards required to meet the certified electronic health record technology (CEHRT) definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHS has declared readiness to receive electronic case reporting data as of six months prior to the start of theEHR reporting period.	Measure must be calculated by reviewing all patient records, not just those maintained using CEHRT

Public Health and Clinical Data Exchange	Electronic Reportable Laboratory (ELR) Result Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit ELR results.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the eligible hospital or CAH: (1) Does not perform or order laboratory tests that are reportable in their jurisdiction during (EHR reporting period; (2) Operates in a jurisdiction for which no PHA is capable of accepting the specific ELR standards required to meet the certified electronic health record technology (CEHRT) definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive ELR results from an eligible hospital or CAH as of six months prior to the start of the EHR reporting period.	Measure must be calculated by reviewing all patient records, not just those maintained using CEHRT .
Public Health and Clinical Data Exchange	Public Health Registry Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit data to public health registries.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	Measure must be calculated by reviewing all patient records, not just those maintained using CEHRT
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting: The eligible hospital or CAH is in active engagement to submit data to a clinical data registry (CDR).	N/A (measure is Y/N)	N/A (measure is Y/N)	None	Measure must be calculated by reviewing all patient records, not just those maintained using CEHRT

Public Health and Clinical Data Exchange	AUR Surveillance Reporting*	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the eligible hospital or CAH 1) Does not have any patients in any patient care location for which data are collected by NHSN during the EHR reporting period; 2) Does not have electronic medication administration records (eMAR)/barcoded medication administration (BCMA) records or electronic admission discharge transfer (ADT) system; 3)Does not have electronic laboratory information system (LIS) or electronic admission discharge transfer (ADT) system; 4) For the EHR reporting period in CY 2023, uses CEHRT that is not certified to the ability to transmit to public health agencies for antimicrobial use and resistance reporting certification criterion at 45 CFR 170.315(f)(6).	Measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

Protect Patient Health Information	Security Risk Analysis Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process. Actions included in the security risk analysis measure may occur any time during the calendar year in which the EHR reporting period occurs.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	Measure must be calculated by reviewing all patient records, not just those maintained using CEHRT
Protect Patient Health Information	Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) Conduct an annual self- assessment using all nine SAFER Guides at any point during the calendar year in which the EHR reporting period occurs.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	Measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

* Signifies a proposal made in this FY 2023 IPPS/LTCH PPS proposed rule

TABLE IX.H.-08: MEDICARE PROMOTING INTEROPERABILITY PROGRAM OBJECTIVES AND MEASURES AND 2015 EDITION CERTIFICATION CRITERIA

Objective	Measure	2015 Edition (CY 2022 EHR Reporting Period)*
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§ 170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
Health Information Exchange (alternative)	Health Information Exchange (HIE Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(8) Application access — data category request
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Health Information Exchange (alternative)	Participation in TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(8) Application access — data category request
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	§ 170.315(e)(1) View, download, and transmit to 3rd party
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(8) Application access — data category request
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization registry reporting	§ 170.315(f)(1) Transmission to immunization registries
	Syndromic surveillance reporting	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance

	Electronic case reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting
		§ 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.
	Electronic reportable laboratory result reporting	§ 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results
	AUR Surveillance Reporting	§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting
Electronic Clinical Quality Measures (eCQMs)	eCQMs for eligible hospitals and CAHs	§ 170.315(c)(1)
		§ 170.315(c)(2)
		§ 170.315(c)(3)(i) and (ii)
		§ 170.315(c)(4) (optional)
Protect Patient Health Information	Security Risk Assessment	The requirements are a part of CEHRT specific to each certification criterion.
	Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)	No 2015 health IT certification criteria at this time.

*The ONC Cures Act final rule made changes to the existing 2015 Edition Health IT Certification Criteria by introducing new criteria, revising and removing existing criteria (85 FR 25667 through 25668). These changes are required for the CY2023 EHR reporting period.

10. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare Promoting Interoperability Program

a. Proposed Changes to Clinical Quality Measures in Alignment With the Hospital IQR Program

(1) Background

Under sections 1814(l)(3)(A) and 1886(n)(3)(A) of the Act and the definition of ''meaningful EHR user'' under 42 CFR 495.4, eligible hospitals and CAHs must report on clinical quality measures selected by CMS using CEHRT (also referred to as electronic clinical quality measures, or eCQMs), as part of being a meaningful EHR user under the Medicare Promoting Interoperability Program.

Tables IX.H.–09. through IX.H.–11. summarize the previously finalized eCQMs available for eligible hospitals and CAHs to report under the Medicare Promoting Interoperability Program for the CY 2022 reporting period, the CY 2023 reporting period, and the CY 2024 reporting period and subsequent years (86 FR 45496 through 45497). The tables include the Safe Use of Opioids—Concurrent Prescribing measure (NQF #3316e), which we finalized as mandatory for reporting beginning with the CY 2022 reporting period (84 FR 42598 through 42600).

TABLE IX.H.-09: PREVIOUSLY FINALIZED ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2022 REPORTING PERIOD

Short Name	Measure Name	NQF No.
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids*	Safe Use of Opioids – Concurrent Prescribing	3316e

*Reporting the Safe Use of Opioids-Concurrent Prescribing eCQM is mandatory beginning with the CY 2022 reporting period.

TABLE IX.H.-10.: PREVIOUSLY FINALIZED ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2023 REPORTING PERIOD

Short Name	Measure Name	NQF No.
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
HH-02	Hospital Harm–-Severe Hyperglycemia Measure	3533e
HH-01	Hospital Harm-Severe Hypoglycemia Measure	3503e
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids*	Safe Use of Opioids – Concurrent Prescribing	3316e

*Reporting the Safe Use of Opioids-Concurrent Prescribing eCQM is mandatory beginning with the CY 2022 reporting period.

TABLE IX.H.11: PREVIOUSLY FINALIZED ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2024 REPORTING PERIOD AND SUBSEQUENT YEARS

Short Name	Measure Name	NQF No.
HH-02	Hospital Harm-Severe Hyperglycemia Measure	3533e
HH-01	Hospital Harm-Severe Hypoglycemia Measure	3503e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids*	Safe Use of Opioids – Concurrent Prescribing	3316e

*Reporting the Safe Use of Opioids-Concurrent Prescribing eCQM is mandatory beginning with the CY 2022 reporting period.

(2) Proposed eCQM Adoptions

As we have stated previously in rulemaking (82 FR 38479), we intend to continue to align the eCQM reporting requirements for the Promoting Interoperability Program with similar requirements under the Hospital IQR Program to the extent feasible. Section 1886(n)(3)(B)(i)(I) of the Act provides in part that in selecting clinical quality measures for the Promoting Interoperability Program, the Secretary shall provide preference to such measures that have been selected for purposes of the Hospital IQR Program (section 1886(b)(3)(B)(viii) of the Act). In addition, section 1886(n)(3)(B)(iii) of the Act provides that in selecting clinical quality measures for the Promoting Interoperability Program, and in establishing the form and manner for reporting, the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under the Hospital IQR Program. To minimize redundant or duplicative reporting, while maintaining a set of meaningful clinical quality measures that continue to incentivize improvement in the quality of care provided to patients, we are proposing to adopt four new eCQMs for the Medicare Promoting Interoperability Program in alignment with the Hospital IQR Program, as further discussed in this section of the proposed rule.

In alignment with proposals for the Hospital IQR Program eCQM measure set, we are proposing two new eCQMs that address factors contributing to maternal mortality and morbidity, beginning with the CY 2023 reporting period. Specifically, we are proposing to add the following eCQMs in the Medicare Promoting Interoperability Program eCQM measure set beginning with the CY 2023 reporting period: (1) Severe Obstetric Complications eCQM (NQF NA); and (2) Cesarean Birth eCQM (NQF NA). Table IX.H.–10 summarizes previously finalized and proposed eCQMs in the Medicare Promoting Interoperability Program for the CY 2023 reporting period and subsequent years. We also are proposing to require mandatory reporting of the Severe Obstetric Complications eCQM and Cesarean Birth eCQM for the CY 2024 reporting period and for subsequent years. We refer readers to the discussion of the same proposals for the Hospital IQR Program in sections IX.E.5.d. and IX.E.5.c. of the preamble of this proposed rule for more information about these proposed measures and our policy reasons for proposing them.

We are inviting public comments on these proposed measures for the Medicare Promoting Interoperability Program.

TABLE IX.H.-12.: PROPOSED AND PREVIOUSLY FINALIZED ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2023 REPORTING PERIOD AND SUBSEQUENT YEARS

Short Name	Measure Name	NQF No.
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids*	Safe Use of Opioids – Concurrent Prescribing	3316e
ePC-07/SMM**	Severe Obstetric Complications	NA
ePC-02**	Cesarean Birth	NA

*Reporting the Safe Use of Opioids-Concurrent Prescribing eCQM is mandatory beginning with the CY 2022 reporting period.

**Newly proposed in this proposed rule to add to the eCQM measure set, beginning with the CY 2023 reporting period.

We also are proposing, in alignment with proposals for the Hospital IQR Program eCQM measure set, to adopt two new eCQMs on which hospitals can self-select to report for the CY 2024 reporting period and subsequent years that focus on opioid-related adverse events during an admission to an acute care hospital and on malnutrition. Specifically, we are proposing to add the following eCQMs to the Medicare Promoting Interoperability Program eCQM measure set on which hospitals can self-select to report beginning with the CY 2024 reporting period: Hospital Harm-Opioid-Related Adverse Event eCQM (NQF #3501e) and Global Malnutrition Composite Score eCQM (NQF #3592e). Table IX.H.–11 summarizes previously finalized and proposed eCQMs in the Medicare Promoting Interoperability Program for the CY 2024 reporting period and subsequent years. We refer readers to the discussion of the same proposals for the Hospital IQR Program in sections IX.E.5.e. and IX.E.5.f. of the preamble of this proposed rule for more information about these proposed measures and our policy reasons for proposing them.

We are inviting public comments on these proposed measures for the

Medicare Promoting Interoperability Program.

TABLE IX.H.-13: PROPOSED AND PREVIOUSLY FINALIZED ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2024 REPORTING PERIOD AND SUBSEQUENT YEARS

Short Name	Measure Name	NQF No.
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids*	Safe Use of Opioids – Concurrent Prescribing	3316e
ePC-07/SMM***	Severe Obstetric Complications	NA
ePC-02***	Cesarean Birth	NA
HH-ORAE****	Hospital Harm-Opioid Related Adverse Event	3501e
GMCS****	Global Malnutrition Composite Score	3592e

*Reporting the Safe Use of Opioids-Concurrent Prescribing eCQM is mandatory beginning with the CY 2022 reporting period.

*** If finalized as proposed, reporting Severe Obstetric Complications and Cesarean Birth (ePC-02) will be mandatory beginning with the CY 2024 reporting period.

****Newly proposed in this proposed rule to add to the eCQM measure set, beginning with the CY 2024 reporting period.

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b. Proposed eCQM Reporting and Submission Requirements for the CY 2024 Reporting Period and Subsequent Years

Consistent with our goal to align the eCQM reporting periods and criteria in the Medicare Promoting Interoperability Program and the Hospital IQR Program, we previously finalized the requirement that eligible hospitals and CAHs reporting eCQMs for the Medicare Promoting Interoperability Program must report four calendar quarters of data from CY 2023 and each subsequent year for: (a) Three self-selected eCQMs from the set of available eCQMs for CY 2023 and each subsequent year, and (b) the Safe Use of Opioids-Concurrent Prescribing eCQM (NQF #3316e), for a total of four eCQMs (85 FR 58975). We are not proposing to change the data reporting and submission requirements for the CY 2023 reporting period.

In this proposed rule, in alignment with proposals for the Hospital IQR Program, we are proposing to modify the eCQM reporting and submission requirements under the Medicare Promoting Interoperability Program for eligible hospitals and CAHs beginning with the CY 2024 reporting period such that hospitals would be required to report four calendar quarters of data for each required eCQM: (1) Three self-selected eCQMs; (2) the Safe Use of Opioids—Concurrent Prescribing eCQM; (3) the proposed Severe Obstetric Complications eCQM; and (4) the proposed Cesarean Birth eCQM, for a total of six eCQMs, beginning with the CY 2024 reporting period and for subsequent years. We note that the number of calendar quarters of data required and the number of self-selected eCQMs would remain the same, but we are proposing to increase the number of eCQMs that all eligible hospitals and CAHs would be required to report from one to three. This proposal is made in conjunction with our proposals discussed in sections IX.D.10.e. of the preamble of this proposed rule, in which we are proposing to adopt the Severe Obstetric Complications eCQM and Cesarean Birth eCQM, respectively. We believe by 2024, eligible hospitals and CAHs will have had sufficient experience with eCQM reporting to propose an increase in the number of required eCQMs from four to six eCQMs. In addition, we believe in light of the maternal health crisis as described in sections IX.E.5.d.(1) and IX.E.5.c.(1) of this proposed rule, and our commitment to reducing unacceptably high maternal morbidity and mortality rates, it is important to collect and utilize quality measure data focused on maternal health to incentive improved quality of care.

As detailed in sections IX.E.10.e. of the preamble of this proposed rule, we are proposing that if our proposals to adopt the Severe Obstetric Complications eCQM and the Cesarean Birth eCQM are finalized, these measures would be available for eligible hospitals and CAHs to select as one of their three self-selected eCQMs for the CY 2023 reporting period, and then beginning with the CY 2024 reporting period, all eligible hospitals and CAHs would be required to report these two eCQMs. We refer readers to section IX.E.10.e of the preamble of this proposed rule for the reporting and submission requirements associated with the proposal to modify the eCQM reporting requirements for the Hospital IQR Program. We invite public comments on these proposed eCQM reporting requirements.

11. Patient Access to Health Information Measure—Request for Information (RFI)

Patient use of portals to access their health information has been tied to

benefits such as improvements in access, quality of care, and health outcomes, and reductions in healthcare expenditures.[1434] In particular, access to health information has been shown to enable the discovery of medical errors, to improve medication adherence, and to promote communication between the patient and health care provider.[1435] However, despite the fact that surveyed patients experiencing shared access to notes with health care providers has been largely positive,[1436] voluntary uptake and use of patient portals has been low, with nearly two-thirds of hospitals having less than 25 percent of patients activate access to the hospital's patient portal in 2017.[1437] Health care provider encouragement (and other facilitating conditions), perceived usefulness, ease of use, control of health information, and enhanced communication are demonstrated as facilitators, while concerns of privacy, security, and lack of awareness have been tied to barriers of use.[1438] [1439]

The Health Information National Trends Survey (HINTS), a large, nationally representative survey operated by the National Cancer Institute (with support from ONC), is conducted routinely and contains key utilization data on consumer access and use of their online medical record through patient portals. The HINTS results showed the rates of individuals being offered and subsequently using their health information through a patient portal, as well as use of mobile health applications (apps) and the role health care providers play in encouraging use.[1440] Results showed that health care providers and staff have a substantial role in influencing patient use of the portal.

In the past for the Medicare Promoting Interoperability Program, we attempted to promote patient access to their health information through measuring the number of patients who actively engaged with the electronic health record through the View, Download, or Transmit (VDT) measure at 42 CFR 495.24(c)(6)(ii)(A). In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636 through 41668), we renamed the Patient Electronic Access Objective to the Provider to Patient Exchange Objective and updated the measures within the Provider to Patient Exchange Objective. Specifically, we removed the standalone VDT measure from the Medicare Promoting Interoperability Program in response to stakeholder feedback, including hospitals and hospital associations detailing the significant challenges they faced in implementing measures that require patient action (83 FR 41665). These challenges included, but were not limited to, patients who have limited knowledge of, proficiency with, or access to information technology; patients declining to access the portals provided by the eligible hospital or CAH to view, download, and transmit their health information via this platform; as well as the lack of availability of user-friendly portals and the immaturity of the health IT infrastructure needed to facilitate useful access and use of their own health information. We also noted that data analysis of the VDT measure showed low percentages of patients taking action to view, download, and transmit their health information (83 FR 41665). Additionally, in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41661 through 41663) we changed the name of the Provide Patient Access measure at 42 CFR 495.24(c)(5)(ii)(A) to Provide Patients Electronic Access to Their Health Information at 42 CFR 495.24(e)(7)(ii) and finalized changes to the measure description. These measure changes included a requirement for eligible hospitals or CAHs to provide timely access for viewing, downloading or transmitting their health information for at least one unique patient discharged using any application of the patient's choice (83 FR 41661 through 41663). This change emphasized timely electronic access of patient health information rather than requiring health care providers to be accountable for patient actions.

Through the current Provide Patients Electronic Access to Their Health Information measure in the Provider to Patient Exchange Objective, we are ensuring that patients have access to their health information through any application of their choice that is configured to meet the technical specifications of the Application Programing Interface (API) in the CEHRT of the eligible hospital or CAH. Promoting the use of API-enabled applications that provide timely access to updated information whenever the patient needs that information is an integral step in enhancing patient access and use of their health information. These API-enabled applications should be configured using standardized technology and contain the information the patient needs to make informed decisions about their care in a way the patient understands, and that recognizes the community's level of access to devices and internet connectivity. While we removed the VDT measure holding eligible hospitals and CAHs responsible for patient action (83 FR 41665), we still require that the technical capabilities be in place within an eligible hospital's or CAH's CEHRT through the Provide Patients Electronic Access to Their Health Information measure should patients choose to access and use their health information (83 FR 41661 through 41663).

We continue to believe in the importance of taking a patient-centered approach to health information access and moving to a system in which patients have immediate access to their electronic health information and can be assured that their health information will follow them as they move throughout the health care system. Recognizing the concerns and barriers with the previous VDT measure discussed previously, but acknowledging the advancements made within the health IT industry over the past few years, this request for information is seeking a broad array of public comments regarding how to further promote equitable patient access and use of their health information without adding unnecessary burden on the hospital or health care provider. Specifically, we are seeking public comment on the following questions:

- Moving beyond providing the information and technical capabilities to

[1434] Ronda MC, Dijkhorst-Oei LT, Rutten GE. Reasons and barriers for using a patient portal: survey among patients with diabetes mellitus. J Med Internet Res. 2014 Nov 25;16(11):e263. doi: 10.2196/jmir.3457. PMID: 25424228; PMCID: PMC4260081.

[1435] Wildenbos GA, Peute L, Jaspers M. Facilitators and Barriers of Electronic Health Record Patient Portal Adoption by Older Adults: A Literature Study. Stud Health Technol Inform. 2017;235:308–312. PMID: 28423804.

[1436] Walker J, Leveille S, Bell S, Chimowitz H, Dong Z, Elmore JG, Fernandez L, Fossa A, Gerard M, Fitzgerald P, Harcourt K, Jackson S, Payne TH, Perez J, Shucard H, Stametz R, DesRoches C, Delbanco T. OpenNotes After 7 Years: Patient Experiences With Ongoing Access to Their Clinicians' Outpatient Visit Notes. J Med Internet Res.

[1437] Henry J, Barker W, Kachay L. Office of the National Coordinator for Health Information Technology (ONC) Data Brief No. 45 (April 2019). Electronic Capabilities for Patient Engagement among U.S. Non-Federal Acute Care Hospitals: 2013–2017. Available at: *https://www.healthit.gov/sites/default/files/page/2019-04/AHApatientengagement.pdf.*

[1438] Powell KR. Patient-Perceived Facilitators of and Barriers to Electronic Portal Use: A Systematic Review. Comput Inform Nurs. 2017 Nov;35(11):565–573. doi: 10.1097/CIN.0000000000000377. PMID: 28723832.

[1439] Alaa A. Abd-alrazaq, Bridgette M. Bewick, Tracey Farragher, Peter Gardner, Factors that affect the use of electronic personal health records among patients: A systematic review, International Journal of Medical Informatics, Volume 126, 2019, Pages 164–175, ISSN 1386–5056, *https://doi.org/10.1016/j.ijmedinf.2019.03.014.*

[1440] Johnson C, Richwine C, Patel V. Office of the National Coordinator for Health Information Technology (ONC) Data Brief, No. 57 (September 2021). Individuals' Access and Use of Patient Portals and Smartphone Health Apps, 2020.

access their data, are there additional approaches to promote patient access and use of their health information? Are there examples of successful approaches or initiatives that have enhanced patient access and use of their health information?

++ Would allowing patients to add information to their records be useful in promoting patient access and utilization? Are there other incentives that would promote patient access?

++ Are there potential unintended consequences in allowing patients to add information to their records? What could be done to mitigate any potential unintended consequences?

++ Are there certain tools found to be useful in promoting patient access and use of their health information?

• Recent studies have raised concerns about the presence of racial bias and stigmatizing language within EHRs that could lead to unintended consequences if patients were to obtain disparaging notes regarding their medical care.[1441] [1442]

++ What policy, implementation strategies, or other considerations are necessary to address existing racial bias or other biases and prevent use of stigmatizing language?

• Additional analysis of HINTS data provides insights into common barriers to patient portal access and use as well as characteristics that can help predict which individuals are more likely to experience certain barriers (for example, preference for in-person communication with their provider is one of the most prevalent barriers experienced more often by older adults and women).[1443]

++ What are the most common barriers to patient access and use of their health information that have been observed? Are there differences by populations or individual characteristics?

• Patients' health information may be found in multiple patient portals. How could CMS or HHS facilitate individuals' ability to access all their health information in one place?

++ If patient portals connected to a network participating in the recently launched TEFCA,[1444] [1445] would this enable more seamless access to individual health information across various patient portals?

• With the advancement of HIT, EHRs and other health-related communication technologies, there are concerns of equity to health outcomes and access with populations who could receive greater benefits from these technologies but are less likely to adopt them.[1446] [1447] What policy, governance and implementation strategies or other considerations are necessary to ensure equal access to patient portals, equitable portal implementation, appropriate design and encouragement of use?

• What challenges do eligible hospitals and CAHs face when addressing patient questions and requests resulting from patient access of patient portals or access of data through use of a mobile app? What can be done to mitigate potential burden?

• For patients who access their health information, how could CMS, HHS, and health care providers help patients manage their health through the use of their personal health information?

• Do you believe the API and app ecosystem is at the point where it would be beneficial to revisit adding a measure of patient access to their health information which assesses providers on the degree to which their patients actively access their health information ? What should be considered when designing a measure of patient access of their health information through portals or apps?

We welcome input on how we can encourage and enable patient access to and use of their health information to manage and improve their care across the care continuum.

[1441] Sun M, Oliwa T, Peek ME, Tung EL. Negative Patient Descriptors: Documenting Racial Bias in the Electronic Health Record. Health Affairs 41, No. 2 (2022): 203–211. doi:10.1377/hlthaff.2021.01423.

[1442] Himmelstein G, Bates D, Zhou L. Examination of Stigmatizing Language in the Electronic Health Record. JAMA Netw Open. 2022;5(1):e2144967. doi:10.1001/jamanetworkopen.2021.44967.

[1443] Turner K, Clary A, Hong Y, Alishahi Tabriz A, Shea CM. Patient Portal Barriers and Group Differences: Cross-Sectional National Survey Study. J Med internet Res 2020;22(9):e18870.

[1444] The Trusted Exchange Framework (TEF): Principles for Trusted Exchange. ONC January 2022: *https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf.*

[1445] Common Agreement for Nationwide Health Information Interoperability V1. ONC. January 2022: *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[1446] Sarkar U, Karter AJ, Liu JY, et al. The literacy divide: health literacy and the use of an internet-based patient portal in an integrated health system—results from the diabetes study of Northern California (DISTANCE). J Health Commun 2010; 15 (Suppl 2): 183–96.

[1447] Ackerman SL, Sarkar U, Tieu L, et al. Meaningful use in the safety net: a rapid ethnography of patient portal implementation at five community health centers in California. J Am Med Inform Assoc 2017; 24 (5): 903–12.

X. Changes for Hospitals and Other Providers

A. Codification of the Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans

1. Background

Currently, certain costs incurred on behalf of Deferred Compensation Plans may be allowable costs under Medicare to the extent such costs are related to the reasonable and necessary cost of providing patient care and represent costs actually incurred. Reasonable cost reimbursement is addressed in section 1861(v)(1)(A) of the Act. Section 1861(v)(1)(A) defines ''reasonable cost,'' in part, as the cost actually incurred, excluding costs found to be unnecessary in the efficient delivery of needed health services. Section 1861(v)(1)(A) does not specifically address the determination of reasonable costs, but authorizes the Secretary to promulgate regulations and principles to be applied in determining reasonable costs.

We have issued regulations implementing this provision of the Act, including 42 CFR 413.9(a), which provides that the payments ''must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries.'' In addition, § 413.9(c)(2) states that ''[t]he provision in Medicare for payment of reasonable cost of services is intended to meet the actual costs.'' Further, § 413.9(c)(3) provides that ''[r]easonable cost includes all necessary and proper expenses incurred in furnishing services . . . .'' Therefore, in accordance with the statute, the regulations include two principles that help guide the determination of which expenses may be considered allowable reasonable costs that can be paid under Medicare; that is, such costs must be ''related'' to the care of Medicare beneficiaries, and such costs must actually be ''incurred.''

Consistent with these provisions, we have issued instructions in sections 2140 through 2142 of the Medicare Provider Reimbursement Manual, Part I (PRM–I) for determining and reporting the policies that govern how providers of services are to determine and report the allowable costs of Deferred Compensation Plans. Section 2140.1 of PRM–I defines Deferred Compensation as ''remuneration currently earned by an employee but which is not received until a subsequent period, usually after retirement. Accordingly, a Deferred Compensation Plan defers the receipt of income beyond the year in which it is earned.'' The policies for Deferred Compensation plans that we have established in sections 2140 through

2142 of PRM–I vary depending on whether a plan is funded using an allowable funding mechanism or unfunded, and whether a plan is a Defined Contribution plan or a Defined Benefit plan. The term funded essentially means that funds are set aside to protect payment of future benefits for plan participants, and not simply paid out of current revenues, as is the case with unfunded plans. Allowable Non-Qualified Deferred Compensation Plan costs that are considered unfunded are based on reasonable benefits that providers of services paid to participating employees.

Allowable Defined Contribution plan costs are based on reasonable contributions made by providers of services to Defined Contribution accounts. Prior to August 2011, allowable funded Defined Benefit plan costs were based on Employee Retirement Income Security Act of 1974 (ERISA) components of accrued pension costs (for example, Normal Cost, Actuarial Accrued Liability, Actuarial Value of Assets) if the resulting computation of costs was funded into an approved account. In August 2011, the FY 2012 IPPS/LTCH PPS final rule (76 FR 51693 through 51697), established regulations for reporting costs of Qualified Defined Benefit plans for Medicare cost-finding purposes. Specifically, for cost reporting periods beginning on or after October 1, 2011, a provider of services cost equals the cash basis contribution deposits plus any carry forward contributions, subject to a limitation (§ 413.100(c)(2)(vii)(D)(*1*)). Providers of services with current contributions and carry forward contributions that exceed the limit may request approval of excess contributions, which are reviewed by the contractor on a case-by-case basis (§ 413.100(c)(2)(vii)(D)(*3*)).

At the time the FY 2012 IPPS/LTCH final rule was issued, the regulations at §§ 413.24 and 413.100 specified that pension costs of Qualified Defined Benefit plans were reported on an accrual basis of accounting method. To conform this accrual requirement in the regulations with the cash-basis methodology for reporting pension costs finalized in the FY 2012 IPPS/LTCH PPS final rule, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53448), we amended the general cost reporting rules under §§ 413.24(a)(2) and 413.100(c)(2)(vii)(D) to note the exception for recognizing actual contributions funded during the cost reporting period on a cash basis.

We are proposing to codify and clarify additional policies relating to Deferred Compensation in a new section in part 413, subpart F. We are not proposing to change our current policies for allowable Deferred Compensation costs associated with Qualified and Non-Qualified Deferred Compensation Plans (the plans) that are included in Medicare cost reports. Nor are we proposing to change the way in which Deferred Compensation costs are to be audited by the Medicare Administrative Contractors (MACs).

2. Proposed Qualified and Funded Non-Qualified Deferred Compensation Plans (§ 413.99)

In accordance with section 1861(v)(1)(A) of the Act, we are proposing to add a new § 413.99 in subpart F of part 413 of title 42, titled ''Qualified and Funded Non-Qualified Deferred Compensation Plans,'' to establish rules for allowable and non-allowable costs incurred for the plans, by providers of services, under the program. Our proposals, which we discuss in more detail throughout this section of this proposed rule, set forth general requirements; definitions; requirements for costs of the plans to be allowable under the program; additional requirements for payments to funded defined benefit plans; data and documentation requirements to support payments/contributions to the plans; and allowable administrative and other costs associated with the plans, including costs related to the Pension Benefit Guaranty Corporation (PBGC).

3. Proposed Statutory Basis, Scope, and Definitions (§ 413.99(a))

In accordance with section 1861(v)(1)(A) of the Act, we are proposing to establish the ''Basis,'' ''Scope,'' and ''Definitions'' of these regulations that determine the allowable and non-allowable costs of the plans under the program at proposed new § 413.99(a)(1), (2), and (3), respectively. Specifically, we are proposing at new § 413.99(a)(1) to specify that all payments to providers of services must be based on the ''reasonable cost'' of services covered under Title XVIII in accordance with section 1861(v) of the Act and the regulations in 42 CFR part 413. In addition, we are proposing at new § 413.99(a)(2) to specify that this section and § 413.100(c)(2)(vii) will apply to Medicare's treatment of the costs incurred for Qualified and Non-Qualified Deferred Compensation Plans.

CMS has previously defined certain terms related to the program's policies on Deferred Compensation and the plans in sections 2140 through 2142 of PRM–I. In this proposed rule, we are proposing to codify these definitions, with clarifications where appropriate, at new § 413.99(a)(3). We are also proposing to add definitions for several new terms to ensure clarity and consistent application. Specifically, we are proposing at new § 413.99(a)(3) to specify that as used in this section the following definitions apply: *Deferred Compensation, Employee Retirement Income Security Act of 1974 (ERISA), Funded Plan, Non-Qualified Deferred Compensation Plan (NQDC), Non-Qualified Defined Benefit Plan (NQDB), Pension Benefit Guaranty Corporation (PBGC), Qualified Defined Benefit Plan (QDBP), Qualified Defined Contribution or Individual Account Plan (QDCP),* and *Unfunded plan* (see the defintions in the proposed regulatory text in the regulations text section of this proposed rule).

4. Proposed Principle Requirements (§ 413.99(b))

We propose to establish at new § 413.99(b) the ''Principle requirements'' that must be satisfied by all Deferred Compensation Plans in order for costs incurred by a provider of services in connection with such plans to be allowable under the program. A formal Deferred Compensation Plan is an agreement between the provider of services and its participating employees, in which the agreeing parties can make contributions to the plan for the exclusive benefit of its participating employees. Proposed § 413.99(b)(1) would specify that amounts be contributed by a provider of services, or an employee of the provider of services, to a Qualified or Non-Qualified Deferred Compensation Plan, established and maintained by the provider of services to provide retirement income to employees or to result in the deferral of income by employees for periods extending to the termination of covered employment or beyond. Contributions or payments made by a provider of services for the benefit of its employees to a Qualified or Non-Qualified Deferred Compensation Plan are allowable when, and to the extent that, such costs are actually incurred by the provider of services and found to be reasonable and necessary under the principles of reasonable cost.

Contracts or agreements between hospital-based physicians and hospitals involve a variety of arrangements under which the physician is compensated by the hospital for the full range of services within the institution. We are proposing to include requirements for recognition of the costs incurred to fund the plans for hospital-based physician patient care services and guarantee arrangements for physician emergency room services.

Deferred compensation paid for physician services to hospitals and SNFs is part of physician compensation under § 415.60(a) and is directly attributable to an employee's salary. Deferred compensation is salary earned in the current period that is not received until a subsequent period, usually after retirement. Defined Contribution plans and Defined Benefit plans generally specify contributions and benefits as a percentage of employee salary. Deferred compensation based on unallowable compensation is also unallowable. Consistent with the policies in PRM–I, we propose in § 413.99(b)(2) to specify that costs incurred by a hospital or SNF to fund a Qualified or Non-Qualified Deferred Compensation Plan for a provider-based physician must meet certain requirements to be allowable. These proposed requirements at § 413.99(b)(2)(i) through (iii) would establish that (i) the allocation of physician compensation costs required under § 415.60 does not attribute the provider-based physician's Deferred Compensation entirely to one category of service and his current compensation to another; (ii) contributions or payments toward the Qualified or Non-Qualified Deferred Compensation Plan do not include any cost excluded from the definition of physician compensation at § 415.60(a); and (iii) the amount of Deferred Compensation does not exceed the amount specified in the agreement required by § 415.60(g).

In situations where the provider is merely acting as the billing agent for the physician whose remuneration is derived from billing for patient care services, the Medicare program will not recognize such remuneration. As a result, these proposed requirements would also specify that an arrangement between a physician and a provider of services under which the physician is reimbursed for patient charges, but the provider of services does the billing as a Deferred Compensation agreement, is not allowed. We propose to codify this policy at § 413.99(b)(2)(iv).

We propose to codify at § 413.99(b)(2)(v) that the costs incurred for physician guarantee arrangements for hospital emergency room availability services must also meet the additional requirements that (1) the terms of both the guarantee arrangement and the Deferred Compensation plan establish the amounts to be included at the beginning of the hospital's cost reporting period; (2) the amount of Deferred Compensation is included in the guaranteed amount; (3) the hospital contributes to the fund established under the Deferred Compensation Plan from its own funds; (4) the amount of Deferred Compensation that is allowable is limited to the amount by which the guarantee, including Deferred Compensation, exceeds the total billed by the hospital to all patients for the physician's patient care services; and (5) when the physician's charges to all patients equal or exceed the amount guaranteed by the hospital, the program does not recognize a Deferred Compensation contribution/payment.

5. Proposed Requirements for Non-Qualified and Qualified Deferred Compensation Plans (§ 413.99(c))

We are proposing to codify the guidance from sections 2140 through 2142 of PRM–I regarding the requirements that must be met in order for costs incurred by providers of services to be allowable for inclusion as Deferred Compensation in the Medicare cost report. The requirements vary based on the type of plan established by the provider of services. The plans currently recognized by the program include Deferred Compensation Plans, currently set forth in section 2140 of PRM–I, Qualified Defined Contribution Deferred Compensation Plans set forth in section 2141 of PRM–I, and Qualified Defined Benefit Pension Plans set forth in section 2142 of PRM–I. As discussed previously in section X.A.1 of this proposed rule, we are proposing to codify the definitions of these types of plans and related terms, with clarifications where appropriate, in proposed new § 413.99(a)(3). We propose to establish at new § 413.99(c) the plan-specific requirements that each type of Qualified or Non-Qualified Deferred Compensation Plan must meet in order for a provider of servicers contributions or payments to the plan to be allowable under the program.

Employer contributions for the benefit of employees under a Deferred Compensation Plan are allowable when, and to the extent that, such costs are actually incurred by the provider or services. Contributions to a funded Deferred Compensation Plan are allowable costs when they are made to the plan, to the extent they fall under the computed limit. Benefits paid for an unfunded Deferred Compensation Plans are allowable costs only when actually paid to the participating employees (or their beneficiaries), and only to the extent considered reasonable.

First, we propose to codify at § 413.99(c)(1) the requirements for NQDCs, which can be funded or unfunded. Proposed § 413.99(c)(1)(i) would establish that an NQDC must meet the requirements for document compliance and operational compliance set forth in Internal Revenue Code (IRC) section 409A. Proposed paragraph (c)(1)(ii) would specify that a funded NDQC must meet the proposed definition of a Funded Plan in § 413.99(a)(3) and comply with the requirements in proposed § 413.99(c)(5) (discussed later in this section of this proposed rule). Proposed paragraph (c)(1)(iii) would provide that an unfunded NQDC must meet the definition of an Unfunded Plan as proposed in § 413.99(a)(3), and there must be no constructive receipt of income for employees from the NQDC as a result of contributions made by a provider of services.

Second, we propose to codify at § 413.99(c)(2) the requirements for QDCPs. Consistent with our existing policies for Defined Contribution Deferred Compensation Plans found in section 2141.1 of PRM–I, proposed paragraph (c)(2)(i) would specify that a QDCP must meet the applicable requirements of ERISA, as amended, and the requirements set forth in IRC section 401(a), and, if applicable, section 401(k). In addition, proposed paragraph (c)(2)(ii) would specify that a QDCP must meet the proposed definition for a Funded Plan in § 413.99(a)(3) and comply with the requirements in proposed § 413.99(c)(5).

Third, we propose to codify at § 413.99(c)(3) the requirements for QDBPs. Specifically, proposed § 413.99(c)(3)(i) would establish that a QDBP must meet the applicable requirements of ERISA, as amended, and the requirements for a QDBP under IRC section 401(a). Proposed paragraph (c)(3)(ii) would specify that a QDBP must meet the definition of a Funded Plan as proposed in § 413.99(a)(3) and comply with the requirements in proposed § 413.99(c)(5).

Fourth, we propose to codify at § 413.99(c)(4) the requirements for NQDBs, which may be funded or unfunded. Proposed § 413.99(c)(4)(i) would establish that an NQDB must meet the requirements for document compliance and operational compliance set forth in Internal Revenue Code (IRC) section 409A. Proposed paragraph (c)(4)(ii) would specify that a funded NQDB must meet the definition of a Funded Plan as proposed in § 413.99(a)(3) and comply with the requirements in proposed § 413.99(c)(5). Proposed paragraph (c)(4)(iii) would provide that an unfunded NQDB must meet the definition of an Unfunded Plan as proposed in § 413.99(a)(3), and there must be no constructive receipt of income for employees from the NQDC as a result of contributions made by a provider of services.

We are proposing to codify at § 413.99(c)(5) certain requirements for Funded Plans. We propose to establish at paragraph (c)(5)(i) the types of funding mechanisms that Funded Plans must use in order for provider of services contributions and employee contributions to such plans to be included in allowable costs. Specifically, a Funded Plan would be required to use either to purchase an insured plan with a commercial insurance company, to establish a custodial bank account, or to establish a trust fund administered by a trustee. Proposed paragraph (c)(5)(ii) would codify our longstanding policy, set forth in section 2140.3.B of PRM–I, disallowing the use of an ordinary life insurance contract as a funding mechanism for a Funded Plan. Specifically, proposed paragraph (c)(5)(ii) would specify that the purchase of an ordinary life insurance contract (for example, whole life, straight life, or other) is not a deferral of compensation and is not recognized as a funding mechanism, even where it is convertible at the normal retirement date specified in the policy to an annuity payable over the remaining life of the employee. Proposed paragraph (c)(5)(iii) would establish that, regardless of the funding mechanism utilized, all provider of services and employee contributions to the fund established under the Deferred Compensation Plan and income therefrom must be used for the sole benefit of the participating employees.

The proposed requirements for a Funded Plan are based on the generally accepted definition of a Funded Plan, along with existing CMS policies on the funding of Deferred Compensation Plans found in section 2140.3 of PRM–I.

6. Proposed Recognition of Contributions or Payments to Qualified and Non-Qualified Deferred Compensation Plans (§ 413.99(d))

At proposed § 413.99(d), we propose to codify rules and requirements that determine when payments or contributions by a provider to Qualified or Non-Qualified Deferred Compensation Plans that meet the applicable plan-specific requirements at proposed § 413.99(c) are recognized and included in allowable costs under the program. In general, the rules in proposed § 413.99(d) vary depending on whether a plan is qualified or non-qualified. In addition, certain special rules apply to contributions to QDBPs and NQDBs that are deposited into trusts.

First, for unfunded Deferred Compensation Plan (which include unfunded NQDBs), we propose to codify at proposed § 413.99(d)(1)(ii) that payments made to such plans are included in allowable costs only during the cost reporting period in which an actual payment is made to the participating employees (or their beneficiaries) and only to the extent considered reasonable in accordance with § 413.100(c)(2)(vii)(A). This proposed requirement incorporates the existing regulatory requirement for payments to unfunded Deferred Compensation Plans at § 413.100(c)(2)(vii)(A), to aid the reader in understanding related policies that appear in other sections of this part that affect unfunded NQDCs and unfunded NQDBs.

Second, regarding certain funded Deferred Compensation Plans (specifically funded Defined Contribution Plans, but excluding QDBPs and funded NQDBs), we propose to include at § 413.99(d)(1)(ii) a cross reference to § 413.100(c)(2)(vii)(B), which requires that accrued costs related to matching or non-elective contributions to a funded Deferred Compensation Plan must be liquidated within 1 year after the end of the cost reporting period in which the liability is incurred. Under § 413.100(c)(2)(viii)(B), an extension, not to exceed 3 years beyond the end of the cost reporting year in which the liability was incurred, may be granted for good cause if the provider of services, within the 1-year time limit, furnishes to the contractor sufficient written justification for non-payment of the liability. Applying this requirement to QDCPs is consistent with § 413.100(c)(2)(vii)(B) and with policies established in section 2141.2 of PRM–I.

Third, contributions into a protected trust for QDBPs and funded NQDBs are allowable. We require that these assets be protected solely for the plan participants and to pay reasonable plan administrative expenses. Contributions or payments must be made by the provider into a protected trust and accounted for on a cash basis. For these plans, we are proposing to establish at § 413.99(d)(1)(iii) that contributions by providers must satisfy the following four requirements to be allowable: First, the contributions must be paid to the plan participants or the plan trust; second, contributions are accounted for on a cash basis; third, money refunded from a plan must be treated as a negative contribution; and fourth, the allowable cost must be computed in accordance with the calculation defined in § 413.100(c)(2)(vii)(D). We describe each of these proposed requirements in greater detail in the paragraphs that follow.

First, we propose to establish at § 413.99(d)(1)(iii)(A) that QDBP or funded NQDB contributions are found to have been incurred only if paid directly to participants or beneficiaries under the terms of the plan or to the QDBP or NQDB. Proposed paragraph (d)(1)(iii)(A) codifies our existing policy, which is described in section 2142.6.A of PRM–I. Section 2142.6 states that provider contributions or payments made to a defined benefit pension plan are allowable only to the extent that costs are actually incurred by the provider. Such costs are found to have been incurred only if paid directly to participants or beneficiaries under the terms of the plan or paid to a pension fund which meets the applicable tax qualification requirements under IRC section 401(a).

Second, we propose to codify at § 413.99(d)(1)(iii)(B) the existing regulatory requirement at § 413.100(c)(2)(vii)(D) for contributions to a QDBP or funded NQDB. Specifically, proposed § 413.99(d)(1)(iii)(B) would require that payments to a QDBP or funded NQDB for a cost reporting period be measured on a cash basis. A contribution or payment would be deemed to occur on the date it is credited to the fund established for the QDBP or funded NQDB, or for provider of services payments made directly to a plan participant or beneficiary, on the date the provider of services account is debited.

Third, we propose to clarify the treatment of pension contributions when a QDBP or funded NQDB is terminated at § 413.99(d)(1)(iii)(C) as payments/contributions made to fully fund a terminating QDBP or funded NQDB are to be included as funding on the date they are paid. Excess assets withdrawn from a QDBP or funded NQDB are to be treated as negative contributions on the date that they are withdrawn. We believe our proposal to recognize negative contributions by reference to the date of withdrawal provides greater clarity than the standard under our current guidance under section 2140.3 of PRM–I, which refers to the ''year of plan termination,'' which is less specific and subject to interpretation.

Fourth, we propose to specify at § 413.99(d)(1)(iii)(D) that QDBP and funded NQDB costs and limits are computed in accordance with the existing regulatory requirements at § 413.100(c)(2)(vii)(D). For purposes of determining the QDBP or funded NQDB cost limit under § 413.100(c)(2)(vii)(D)(*2*), we propose that provider of services contribution

payments for each applicable cost reporting period shall be determined on a cash basis in accordance with proposed § 413.99(d)(1)(iii)(B), without regard to any limit determined for the period during which the contributions were made, and excluding any contributions deposited in a prior period and treated as carry forward contributions. We are proposing that the averaging period used to determine the QDBP or funded NQDB cost limit shall be determined without regard to a provider of services period of participation in the Medicare program. Periods that are not Medicare cost reporting periods (for example, periods prior to the hospital's participation in the Medicare program) shall be defined as consecutive twelve-month periods ending immediately prior to the provider of services initial Medicare cost reporting period. We are proposing that the averaging period used to determine the QDBP or funded NQDB cost limit shall exclude all periods ending prior to the initial effective date of the plan (or a predecessor plan in the case of a merger). Lastly, we are proposing that in general, the current period defined benefit cost and limit shall be computed and applied separately for each QDBP or funded NQDB offered by a provider of services. In the case of a plan merger, the contribution payments made by a provider of services to a predecessor QDBP or funded NQDB and reflected in the assets subsequently transferred to a successor plan shall be treated as contribution payments made to the successor plan.

In the FY 2012 IPPS/LTCH PPS final rule, we established separate methodologies for measuring pension costs for Medicare cost-finding purposes (76 FR 51693 through 51697) and for purposes of updating the hospital wage index (76 FR 51586 through 51590). Under the methodology we established for the wage index, the pension costs that are to be included in the wage index equal a hospital's average cash contributions deposited to its defined benefit pension plan over a 3-year period or, if less than a 3-year period, the number of years that the hospital has sponsored a defined benefit plan. The 3-year average was centered on the base cost reporting period for the wage index. For example, the FY 2013 wage index is based on Medicare cost reporting periods beginning during Federal FY 2009 and reflects the average pension contributions made in hospitals' cost reporting periods beginning during Federal FYs 2008, 2009, and 2010. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49505 through 49508), we modified the policy such that the 3-year average is based on pension contributions made during the base cost reporting period plus the prior 2 cost reporting years. For example, the FY 2017 wage index is based on Medicare cost reporting periods beginning during Federal FY 2013. Therefore, the FY 2017 wage index reflects the average pension contributions made in hospitals' cost reporting periods beginning during Federal FYs 2011, 2012, and 2013 (rather than Federal FYs 2012, 2013, and 2014 under the prior policy established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590)). While the QDBP cost for cost-finding purposes is computed using the cost period annual contributions limited by a cap (as codified in § 413.100(c)(2)(vii)(D)), the wage index QDBP cost is a 3-year average of annual plan contributions without adjustment or cap.

7. Proposed Documentation Requirements (§ 413.99(e))

We propose to codify at § 413.99(e) that a provider of services must maintain and make available upon request documentation to substantiate the costs incurred for the plans included in its Medicare cost report. These proposed requirements for documentation are based on the existing regulatory requirements at § 413.20, which require providers of services to maintain sufficient financial records and statistical data for proper determination of costs payable under the program.

In addition, these requirements are based in part on the policy established when CMS revised the calculation for a QDBP and funded NQDB in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51693 through 51697). Section 2142.5.F of PRM–I states that the provider must have available data to show the amount(s) and date(s) of contribution payments made to a defined benefit pension plan during the current reporting period and any applicable prior periods. If the pension costs included in the cost report for a period differ from the pension contribution payments made during the reporting period (for example, as a result of carry forward contributions), the provider must also have data available to track and reconcile the difference.

Specifically, we are proposing at § 413.99(e) that documentation must be maintained by the provider of services in accordance with § 413.20 to substantiate the allowability of the payments or contributions to Qualified or Non-Qualified Deferred Compensation Plans (or both) that it has included in its cost reports. With respect to *required documentation,* we are proposing to specify at § 413.99(e)(1) that the provider of services must maintain and make available, upon request from the contractor or CMS, certain specified documentation, to substantiate the allowability of payments or contributions made by the provider of services to a Qualified or Non-Qualified Deferred Compensation Plan. Under proposed § 413.99(e)(1), the following documentation would be required: Documentation that demonstrates that the provider of services is in compliance with IRC section 409A and IRC section 409A(a), and if applicable IRC section 457; ledger accounts/account statements for each plan participant noting current year deferrals, distributions, and loans, including any deferral election forms completed by employees, any change requests, and the approval of such requests; documentation that demonstrates the amount(s) and date(s) of actual payment/contributions made to the Non-Qualified or Qualified Deferred Compensation Plan during the current cost reporting period; Schedule SB of Form 5500 (tri-agency form (Department of Labor (DOL), Internal Revenue Service (IRS), PBGC) that plans file with the DOL's ''EFAST'' electronic filing system. The ''Form 5500'' is the Annual Return/Report of Employee Benefit Plan for a QDBP for the current cost reporting period, or any applicable prior periods; and, in the case of a system wide (multiple employer) plan, the home office shall identify the contributions attributed to each participating provider of services. If the costs included in the cost report for a period differ from the contributions made during the reporting period (for example, as a result of carry forward contributions), the provider of services must also have data available to track and reconcile the difference.

We are also proposing to establish at § 413.99(e)(2) that the following additional documentation must be made available, upon request by the contractor or CMS, to substantiate the allowability of payments or contributions made by a provider of services to a Qualified or Non-Qualified Deferred Compensation Plan: The plan document, the trust document and all amendments related to the current cost reporting period; if applicable, any Form 5330, Return of Excise Taxes Related to Employee Benefit Plans, for the cost reporting period; supporting documents for all plan assets and

liabilities, such as broker's statements, bank statements, insurance contracts, loan documents, deeds, etc., and verification of how assets are valued; trustee or administrator reports; ledgers; journals; trustee, administrator and investment committee minutes; certified audit report; and other financial reports for the trust. Any other financial reports, including receipt and disbursement statements, a detailed income statement and a detailed balance sheet; and, for each covered QDBP, documentation of the certified premium information and payments to the PBGC.

8. Proposed Administrative and Other Costs Associated With Qualified and Non-Qualified Deferred Compensation Plans (§ 413.99(f))

In proposed § 413.99(f), we propose to codify our current policies, as set forth in sections 2140, 2141, and 2142 of PRM–I, regarding the treatment of certain administrative and other costs related to Deferred Compensation Plans as allowable or non-allowable under the program. In the paragraphs that follow, we discuss our proposed treatment of various administrative costs related to Deferred Compensation Plans. First, we propose to establish at § 413.99(f) that the provider of services shall file a cost report required under §§ 413.20 and 413.24(f) that is consistent with the proposed policies set forth in proposed § 413.99.

a. Trustee and Custodial Fees

We propose to codify at § 413.99(f)(1) that reasonable trustee or custodial fees, including PBGC premiums, paid by the provider of services are allowed as an administrative cost, except where the plan provides that such fees are paid out of the corpus or earnings of the fund. Fees paid out of the corpus or earnings of the fund would not be allowed, based on the rationale that, because contributions into the plan trust pay for benefits and expenses that are paid from the trust, that means administrative costs paid out of the plan trust have already been accounted for through the allowance of contributions made by the provider of services. This proposal would codify our current policy, which is set forth in section 2140.3.B.1.d of PRM–I.

b. Vested Benefits

We propose to codify at § 413.99(f)(2) that the forfeiture of an employee's benefits for cause (as defined in the plan) is recognized as an allowable cost provided that such forfeited amounts are used to reduce the provider of services contributions or payments to the plan during the cost reporting period in which the forfeiture occurs. This proposal would codify our policy on the effects of a forfeiture of vested benefits on the plan costs that are allowable under the program, as set forth at section 2140.3.D of PRM–I, with the added clarification that the reduction must occur in the cost reporting period in which the forfeiture occurs.

We propose to codify at § 413.99(f)(3) our existing policy on the effects of employees' termination of participation in a plan before their rights are vested in the contributions/payments to the plan that are allowable under the program. Specifically, proposed § 413.99(f)(3) would specify that if an employee terminates participation in the Deferred Compensation Plan before their rights are vested, the applicable non-vested contributions/payments cannot be applied to increase the benefits of the surviving participants. Instead, the non-vested contributions/payments should be used to reduce the provider of services contributions/payments to the Deferred Compensation Plan, in the cost reporting period wherein the employee terminated participation in the Deferred Compensation Plan. Otherwise, the contributions/payments made by the provider of services must be applied to reduce the subsequent contributions/payments to the Deferred Compensation Plan in the next cost reporting period. If subsequent provider of services contributions/payments to the Deferred Compensation Plan are not made, then provider of services costs will be reduced by the contractor to the extent of such non-vested funds.

c. DOL, IRS, and PBGC Penalties

Providers of services who maintain a Deferred Compensation Plan are required to comply with regulatory requirements related to the plan that are established by the Department of Labor (DOL), the IRS and the PBGC. Where providers of services fail to follow these requirements, a penalty may be levied. For example, the IRS levies an excise tax when payments are not timely filed. section 1861(v)(8) of the Act sets forth items unrelated to patient care that are not considered reasonable under the program. In other words, these items are unallowable, and therefore cannot be included in the allowable costs of the provider of services. One of these items is the cost for fines and penalties resulting from violations of Federal, State, or local laws. Accordingly, we are proposing at § 413.99(f)(4) to specify that if the provider of services is assessed an excise tax or other remedy by DOL or IRS or PBGC for failure to follow the DOL, IRS, or PBGC requirements under ERISA, or any other penalty fee or penalty interest applicable to its Deferred Compensation Plan, the associated cost is unallowable, in accordance with section 1861(v)(8)(iv) of the Act.

d. Loans Made From a Deferred Compensation Plan

Under our current policy, as set forth in section 2140.3.C of PRM–I providers of services are able to make a loan to themselves out of either corpus or income from their Qualified or Non-Qualified Deferred Compensation Plan on the conditions that the fund receive adequate security and a reasonable rate of interest on the loan. This existing policy is inconsistent with ERISA section 406 (29 U.S.C. 1106(1)(B)) which specifically prohibits lending of money or other extension of credit between the plan and a party in interest, unless found to be excepted under 29 U.S.C. 1108. The definition of a ''party in interest'' includes an employer any of whose employees are covered by such plan. The same provision exists in the IRC at 26 U.S.C. 4975. We believe that the policy we codify in new § 413.99 should reflect these provisions in ERISA and the IRS rules that are designed to protect Deferred Compensation Plans and the plans' participants and beneficiaries. Accordingly, we are proposing at § 413.99(f)(5) to specify that a provider of services cannot make a loan to itself from a Deferred Compensation Plan where ERISA or IRS rules prohibit such a transaction, except where specifically excepted. In cases where an exception applies, our existing policy on allowable interest expense at § 413.153 continues to apply.

e. Termination/Discontinuation of a Deferred Compensation Plan

Sections 2140.3.D and 2141.3.D of PRM–I set forth CMS's policy on the effect of a provider of services declining to vest its outstanding required contributions/payments as a result of a termination, in full or in part, or a discontinuation of contributions or payments to a Deferred Compensation Plan. Under this policy, which we propose to codify at § 413.99(f)(6), where the provider of services declines to vest its outstanding required contributions/payments (that is, matching and non-elective or both) to a Deferred Compensation Plan, as a result of a termination, in full or in part, or a discontinuation of contributions or payments to a Deferred Compensation Plan, then the provider of services total outstanding required contributions or payments to the Deferred Compensation

Plan during the cost reporting period wherein such termination is initiated cannot be included in the provider of services allowable cost for the cost reporting period in which the termination is initiated, nor any future period.

f. Required Offset Against Interest Expense

In section 2140.3.D of PRM–I, CMS has established a policy that investment income earned on a fund after its termination but prior to liquidation of the fund's assets and distribution to the provider is offset against the provider's allowable interest expense. We are proposing to adopt the current policy in section 2140.3 of PRM–I at proposed § 413.99(f)(7), which would state that investment income earned on a Deferred Compensation Plan after its termination but prior to liquidation of the plan's assets and distribution to the provider of services must be offset against the provider of services allowable interest expense under § 413.153.

g. Treatment of Residual Assets Following Termination of a Funded Plan

In section 2140.3.D of PRM–I, CMS has established a policy describing how residual assets arising from the termination of a funded plan are to be handled on the Medicare cost report. We are proposing to adopt the current policy, as it appears in section 2140.3.D of PRM–I, at new § 413.99(f)(8). Specifically, proposed § 413.99(f)(8) would specify that residual assets arising from the termination of a funded plan must be recouped in the year of the plan termination only against the cost center(s) in which the provider of services reported its plan contributions/payments, usually the administrative and general cost center. Residual assets exceeding the amount in the administrative and general (or other) cost center are not further offset in the current or subsequent years. The Medicare share of the reversion is based on the Medicare utilization rate in the year the reversion occurs (or the year the actuarial surplus is determined), and not Medicare's utilization in the years the contributions to the plan were made.

9. Proposed Treatment of Costs Associated With the Pension Benefit Guaranty Corporation (PBGC) (§ 413.99(g))

Since 1974, the PBGC has protected retirement security and the retirement incomes of over 33 million American workers, retirees, and their families in private sector defined benefit pension plans. A Qualified Defined Benefit Plan (defined previously as a QDBP) provides a specified monthly benefit at retirement, often based on a combination of salary and years of service. The PBGC was created by ERISA to encourage the continuation and maintenance of private sector defined benefit pension plans, provide timely and uninterrupted payment of pension benefits, and keep pension insurance premiums at a minimum.

General tax revenues do not fund the PBGC Single-Employer Program. The PBGC collects insurance premiums from employers that sponsor insured pension plans, earns money from investments, and receives funds from pension plans it takes over (see *https://www.pbgc.gov/about/how-pbgc-operates*).

Providers of services who offer a QDBP may incur costs related to the PBGC premiums. The proposed regulations outlined in this section of this proposed rule establish which costs incurred by providers of services who maintain a QDBP and pay premiums for basic benefits to the PBGC are allowable under the program. We propose to include these provisions on the treatment of costs associated with the PBGC in paragraph (g) of proposed § 413.99.

In 29 U.S.C. 1306 the schedule for the premium rates, and the bases for application of those rates are set forth. Under 29 U.S.C. 1306, premiums are established for basic benefits, non-basic benefits, and reimbursement for uncollectible withdrawal liability. We are proposing at § 413.99(g)(1) that PBGC premiums and costs paid out of the corpus or earnings of the trust are included in the contributions allowed by § 413.99(d)(3)(ii), and therefore are not allowable as separate costs. We are also proposing at § 413.99(g)(2) that the amount of PBGC premiums paid for basic benefits (that is, flat rate or variable, excluding amounts paid out of the corpus or earnings of the trust) by a provider of services who sponsors a QDBP are allowable under the program. Similar to allowance of Administrative Costs as stated in proposed § 413.99(f)(1), while PBGC premiums are an allowable cost, they are not allowed if they are paid from the plan trust.

In 29 CFR part 4050, the rules for PBGC's program that holds retirement benefits for missing participants and beneficiaries of terminated retirement plans and pays those benefits to participants and beneficiaries when found, are provided. A Missing Participant is a former employee of a provider of services who has a liability remaining with the plan but cannot be located or is unresponsive when the plan terminates and closes out. Transfers of funds to the PBGC by the provider of services to cover this liability under the PBGC Missing Participant Program are allowable as long as they are not paid out of the corpus or earnings of the trust. We are proposing at new § 413.99(g)(3) that the total amount paid to the PBGC by a provider of services who sponsors a QDBP (excluding amounts paid out of the corpus or earnings of the trust) of the benefit transfer amount (see 29 CFR 4050.103(d)) for all missing participants or beneficiaries of the QDBP is allowable under the program.

After entering into a trusteeship agreement with the employer or after receiving an order issued by a U.S. district court approving termination, the PBGC guarantees employee plan benefits will be paid up to a certain limit if the QDBP has insufficient assets as part of a Distress Termination (as described in 29 CFR part 4041) or as part of a PBGC-initiated termination under 29 U.S.C. 1342. We are proposing at § 413.99(g)(4) that for terminated plans with insufficient assets to pay all of the plan benefits, where the PBGC guarantees the payment of vested benefits up to limits defined by law, only contributions to the QDBP made by a provider of services are allowable. Benefits paid to the participants and beneficiaries of the QDBP by the PBGC are unallowable.

In 29 CFR part 4047, PBGC is given the authority to restore a plan from terminated status to ongoing. Contributions and benefits paid by the provider of services to the PBGC or the plan or its participants and beneficiaries are allowable in this situation. We are proposing at § 413.99(g)(5) that where the PBGC issues or has issued a plan restoration order as described in 29 CFR part 4047, the amounts that the provider of services repays to the PBGC for guaranteed benefits and related expenses under the plan while the plan was in terminated status, and any administrative costs assessed by the PBGC, excluding penalties, are allowable.

B. Condition of Participation (CoP) Requirements for Hospitals and CAHs To Report Data Elements To Address Any Future Pandemics and Epidemics as Determined by the Secretary

Under sections 1866 and 1902 of the Act, providers of services seeking to participate in the Medicare or Medicaid program, or both, must enter into an agreement with the Secretary or the state Medicaid agency, as appropriate. Hospitals (all hospitals to which the requirements of 42 CFR part 482 apply,

including short-term acute care hospitals, LTC hospitals, rehabilitation hospitals, psychiatric hospitals, cancer hospitals, and children's hospitals) and CAHs seeking to be Medicare and Medicaid providers of services under 42 CFR part 485, subpart F, must be certified as meeting Federal participation requirements. Our conditions of participation (CoPs), conditions for coverage (CfCs), and requirements set out the patient health and safety protections established by the Secretary for various types of providers and suppliers. The specific statutory authority for hospital CoPs is set forth in section 1861(e) of the Act; section 1820(e) of the Act provides similar authority for CAHs. The hospital provision at section 1861(e)(9) of the Act authorizes the Secretary to issue any regulations he or she deems necessary to protect the health and safety of patients receiving services in those facilities; the CAH provision at section 1820(e)(3) of the Act authorizes the Secretary to issue such other criteria as he or she may require. The CoPs are codified in the implementing regulations at part 482 for hospitals, and at 42 CFR part 485, subpart F, for CAHs.

Our CoPs at § 482.42 for hospitals and § 485.640 for CAHs require that hospitals and CAHs, respectively, have active facility-wide programs, for the surveillance, prevention, and control of healthcare-associated infections (HAIs) and other infectious diseases and for the optimization of antibiotic use through stewardship. Additionally, the programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the required hospital and CAH programs must also be addressed in coordination with facility-wide quality assessment and performance improvement (QAPI) programs.

Infection prevention and control is a primary goal of hospitals and CAHs in their normal day-to-day operations, and these programs have been at the center of initiatives taking place in hospitals and CAHs during the PHE for COVID–19. Our regulations at §§ 482.42(a)(3) and 485.640(a)(3) require infection prevention and control program policies to address any infection control issues identified by public health authorities. On March 4, 2020, we issued guidance [1448] stating that hospitals should inform infection prevention and control services, local and state public health authorities, and other healthcare facility staff as appropriate about the presence of a person under investigation for COVID–19. CMS followed this guidance with an interim final rule with comment (IFC), published on September 2, 2020 (85 FR 54820), that now requires hospitals and CAHs to report important data critical to support the fight against COVID–19. The CoP provisions require that hospitals and CAHs report this information in accordance with a frequency as specified by the Secretary on COVID–19 as well as in a standardized format specified by the Secretary (42 CFR 482.42(e) and 485.640(d), respectively). Examples of data elements that may be required to be reported include things such as the number of staffed beds in a hospital and the number of those that are occupied, information about its supplies, and a count of patients currently hospitalized who have laboratory-confirmed COVID–19. This list is not exhaustive of those data items that we may require hospitals and CAHs to submit, as specified by the Secretary (see *https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf* for the current list of data items specified). These elements are essential for planning, monitoring, and resource allocation during the COVID–19 Public Health Emergency (PHE). The rules make reporting a requirement of participation in the Medicare and Medicaid programs. This reporting is needed to support broader surveillance of, and response to, COVID–19.

Following the publication of the September 2, 2020 IFC, we set forth a second set of reporting requirements for hospitals and CAHs in an IFC published on December 29, 2020 (85 FR 85866). This IFC added additional requirements for hospitals and CAHs to report data elements that must include, but not be limited to, their current inventory supplies of any COVID–19-related therapeutics that have been distributed and delivered to the hospital (or CAH) under the authority and direction of the Secretary as well as the hospital's (or the CAH's) current usage rate for these COVID–19-related therapeutics (§§ 482.42(e) and 485.640(d), respectively, as amended). The December 2020 IFC also requires hospitals and CAHs to report information in accordance with a frequency, and in a standardized format, as specified by the Secretary during the PHE, for Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) (§§ 482.42(f) and 485.640(e), respectively). As with the COVID–19 reporting, examples of data elements that may be required to be reported include things such as the number of staffed beds in a hospital and the number of those that are occupied, information about its supplies, and a count of patients currently hospitalized who have diagnoses of Acute Respiratory Illnesses (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection). And as with the COVID–19 reporting requirements, we firmly believe these elements are essential for planning, monitoring, and resource allocation during the COVID–19 PHE, especially during seasonal influenza season and when hospitals and CAHs are likely to see an increase in the number of patients presenting with the signs and symptoms of a variety acute respiratory illnesses along with a continuing and unknown number of patients presenting with both suspected and confirmed COVID–19.

The current acute respiratory illness reporting requirements, in tandem with those for COVID–19 reporting, by all hospitals and CAHs, have been, and continue to be, important in supporting surveillance of, and response to, the PHE for COVID–19. Similarly, they play an important role when considering future planning to prevent the spread of respiratory viruses and infections, including, but not limited to, COVID–19. However, current regulatory language specifically ties the aforementioned reporting requirements to the current PHE declaration for COVID–19. Consequently, these reporting requirements will no longer be required through the CoPs once the PHE declaration ends. Additionally, we are concerned that the current requirements while appropriately focused on the current COVID–19 pandemic, are too limited in scope for potential future use. Given our experience throughout the PHE for COVID–19, CMS, in conjunction with other Federal partners, particularly the CDC and ASPR, are considering ways to ensure a more flexible regulatory framework to ensure a nimble and informed response to the next potential pandemic or epidemic, so that we are able to immediately respond to the situation at hand. Therefore, we propose to revise the hospital and CAH infection prevention and control and antibiotic stewardship programs CoPs to

[1448] *https://www.cms.gov/files/document/qso-20-13-hospitalspdf.pdf-2.*

extend the current COVID–19 reporting requirements and to establish new reporting requirements for any future PHEs related to a specific infectious disease or pathogen. For COVID–19 reporting, these proposed requirements would take effect after the COVID–19 PHE declaration expires, but no earlier than the effective date of the final rule implementing these proposals. Therefore, if the COVID–19 PHE declaration is still in effect at the time of the final rule, it is our intention that these proposals would not be implemented and enforced until the current COVID–19 PHE declaration concludes and we issued guidance indicating such a transition. We welcome public comment on strategies to mitigate challenges and support an informed transition.

Specifically, we propose to revise the COVID–19 and Seasonal Influenza reporting standards for hospitals and CAHs (at §§ 482.42(e)–(f) and 485.640(d)–(e), respectively) to require that, beginning at the conclusion of the current COVID–19 PHE declaration and continuing until April 30, 2024, a hospital (or a CAH) must electronically report information about COVID–19 and Seasonal Influenza in a standardized format specified by the Secretary.

For COVID–19 reporting, the categories of data elements that this report would, to the extent as determined by the Secretary, include are as follows: Suspected and confirmed COVID–19 infections o among patients and staff; total COVID–19 deaths among patients and staff; personal protective equipment and testing supplies in the facility; ventilator use, capacity and supplies in the facility; total hospital bed and intensive care unit bed census and capacity; staffing shortages; COVID–19 vaccine administration data of patients and staff; and relevant therapeutic inventories and/or usage. For seasonal influenza, the categories of data elements that this report would, to the extent as determined by the Secretary, include are as follows: Confirmed influenza infections among patients and staff; total influenza deaths among patients and staff; and confirmed co-morbid influenza and COVID–19 infections among patients and staff. We note that the proposed categories of data elements align closely with those COVID–19 reporting requirements for long-term care (LTC) facilities that were finalized on November 9, 2021 (86 FR 62421) and are representative of the guidance provided to hospitals and CAHs for reporting. Therefore, we do not expect that these categories of data elements would require hospitals and CAHs to report any information beyond that which they have already been reporting (OMB control numbers 0938–0328 for hospitals and 0938–1043 for CAHs). Furthermore, similar to the requirements for LTC facilities, this proposal would also allow for the scope and frequency of data collection to be reduced and limited responsive to the evolving clinical and epidemiological circumstances. These requirements would also sunset April 30, 2024, unless the Secretary establishes an earlier ending date. To the extent possible, we have sought to align the proposed sunset date in this rule with the sunset date finalized in the CY 2022 Home Health Prospective Payment System (HH PPS) final rule for nursing homes' COVID–19 reporting requirements. However, this rule also includes a provision to continue influenza reporting (which has been part of the broader COVID–19 reporting requirements, given the risk of concurrently or sequentially occurring influenza outbreaks and the associated additional pressure on hospital capacity during flu season). Accordingly, we did not beleive it would be appropriate to set a sunset date in the middle of a flu season (December 2024). Therefore, we elected to set the sunset date at the end of a typical flu season (April). And, given our preference to maximize alignment with the NH sunset date, we were left with the option of April 2024 or April 2025. We are proposing a date to sunset the requirement that we believe is in the interest of health and safety and avoids imposing unnecessary burden on providers.

We believe that additional reporting requirements are necessary to protect the health and safety of hospital and CAH patients as well as the communities that these facilities serve. The possible resurgence in COVID–19 cases, the uncertain virulence of annual seasonal influenza, and the emergence of other infectious disease pathogens that may lead to future epidemics and pandemics may all pose significant risks to patients and communities in the future. Past experiences with outbreaks, epidemics, and pandemics, along with the lessons learned from the current COVID–19 pandemic, have demonstrated that such scenarios can lead to surges of inpatient admissions that often negatively impact hospital capacity to accept and treat patients. To more effectively respond to future crises, we seek to ensure timely and complete surveillance, on an ''as needed'' basis, through broadening reporting requirements beyond COVID–19 and the current PHE. Establishing such requirements would enable HHS and the Federal Government to continue to respond to hospitals and CAHs in need of additional support and guidance. Therefore, at §§ 482.42(g) and 485.640(f), for hospitals and CAHs respectively, we are proposing additional requirements to address future PHEs related to epidemics and pandemics. Specifically, when the Secretary has declared a PHE, we propose to require hospitals and CAHs to report specific data elements to the CDC's National Health Safety Network (NHSN), or other CDC-supported surveillance systems, as determined by the Secretary. The proposed requirements of this section would apply to local, state, and national PHEs as declared by the Secretary. We note that we would anticipate a nominal lag time between the declaration of the PHE and the start of the collection to allow for CMS to notify regulated entities and provide guidance regarding the necessary reporting. We would expect the method of notification to follow a model similar to that which we used to inform regulated entities at the beginning of the COVID–19 PHE (see QSO–21–03–Hospitals/CAHs at *https://www.cms.gov/files/document/qso-21-03-hospitalscahs.pdf-0*). Relevant to the declared PHE, the categories of data elements that this report would include are as follows: Suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff; total deaths attributed to the relevant infectious disease pathogen among patients and staff; personal protective equipment and other relevant supplies in the facility; capacity and supplies in the facility relevant to the immediate and long term treatment of the relevant infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies; total hospital bed and intensive care unit bed census, capacity, and capability; staffing shortages; vaccine administration status of patients and staff for conditions monitored under this section and where a specific vaccine is applicable; relevant therapeutic inventories and/or usage; isolation capacity, including airborne isolation capacity; and key co-morbidities and/or exposure risk factors of patients being treated for the pathogen or disease of interest in this section that are captured with interoperable data standards and elements. We acknowledge that there are uncertainties in planning for future emergencies, and CMS understands that there are lots of incentives and pathways to consider with regard to preparedness. Therefore, we are

soliciting public comment on how to best align and incentivize preparedness, while also reducing burden and costs on regulated entities, and ensuring flexibility.

In identifying categories of data elements to propose, we considered the data elements that proved most informative and actionable over the course of the COVID–19 PHE (elements that, over time, supported early identification and response to stress at facility, system, community, state, and Federal levels) as well as lessons learned from preparedness for, and response to, other epidemiological threats that have emerged over recent decades (Ebola, SARS, MERS, seasonal influenza). The inclusion of vaccine administration data, in particular, is informed by the current inability of the required data elements to match patient COVID–19 vaccination status with hospitalization or ICU admission status. In short, the categories proposed here provide the flexibility for CMS and CDC to gather actionable data that would close many of the gaps identified throughout the COVID–19 pandemic and answer the call for U.S. public health agencies to have much more timely, complete, and consistent data for future pathogens of concern.[1449] We believe that the proposed requirements provide a regulatory framework for the reporting of relevant infectious disease data by hospitals and CAHs with regard to future pandemics and epidemics. As such, we expect these requirements will complement, not supplant existing Federal, state, local, territorial, or tribal reporting requirements. We return to, and expand upon, these points further later in this section.

In this rule, we are also proposing at §§ 482.42(g)(2) and 485.640(f)(2) to require that a hospital (or a CAH) must report each applicable infection (confirmed and suspected) and the applicable vaccination data in a format that provides person-level information, to include medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients, unless the Secretary specifies an alternative format by which the hospital (or CAH) would be required report these data elements. We are also proposing in this provision to limit any person-level, directly or potentially individually identifiable, information for affected patients to items outlined in this section or otherwise specified by the Secretary. Lastly, §§ 482.42(g)(3) and 485.640(f)(3), we are proposing that a hospital (or a CAH) would provide the information specified on a daily basis, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) or other CDC-supported surveillance systems as determined by the Secretary. We note that while we have proposed a maximum reporting frequency of daily during PHEs, this may be reduced at the discretion of the Secretary contingent on the state of the PHE and ongoing risks. Furthermore, we do not want these collections to overlap information being collected elsewhere, thus, we are soliciting comment on the potential that this data collection may duplicate elements already reported elsewhere, and if so, which data elements and through what data collection mechanism.

The term ''person-level data'' encompasses both ''directly identifiable information'' (information that identifies an individual, such as a record number) and ''potentially identifiable information'' (information that could be used with other available information to identify an individual but is not directly tied to one individual—for example, race/ethnicity). As a guiding principle, HHS would limit any data collection under this provision to the minimum necessary collection cadence and data elements, including individual data, necessary to protect patient health and safety. We are committed to ensuring the provisions proposed here incorporate lessons from, and correct for limitations identified during, the PHE.

We believe that individual data elements such as race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients are necessary to address issues of health equity and response management. In the absence of these data, it can be challenging to take action to reduce disparities in disease incidence and severity, as well as access to, receipt of, and effectiveness of relevant preventive and therapeutic services (for example, vaccines) among vulnerable or otherwise marginalized populations (for example, racial/ethnic minorities; individuals with intellectual or developmental disabilities). An important gap raised during the COVID–19 pandemic was the inability to follow patients with COVID–19 through the health care system, especially the important transfers that often occur between acute and long-term care facilities. A medical record identifier would allow tracking transfers between facilities, which could provide important and actionable information on COVID–19 outcomes and health care facility capacities. Similarly, medical record identifiers enable data and encounters to be connected in order to assess the full scope of disease burden for an individual and determine appropriate course of therapeutic action.

As previously noted, CMS has proposed that hospitals would report any data required under this provision (§§ 482.42(g) and 485.640(f)) to CDC's NHSN or other CDC-supported surveillance systems as determined by the Secretary. Hospitals reporting to NHSN in fulfillment of the CMS quality reporting program requirements are already familiar with reporting patient-level data to NHSN, including medical record identifiers, gender, birthdate, and date of event. CDC protects those elements with strong security and privacy measures and tightly restricts access to these data. Access to NHSN data is restricted to the uses described in the NHSN Agreement to Participate and Consent, and all NHSN users must abide by the NHSN Rules of Behavior, which safeguard against unwarranted or inadvertent misuse or disclosure of NHSN data. CDC's Secure Data Network also requires use of a 128-bit encryption digital certificate for authentication into NHSN. The provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with sections 304, 306, and 308(d) of the Public Health Service Act (42 U.S.C. 242b, 242k, and 242m(d)).

CMS recognizes that the health and safety benefits associated with any reporting requirements must be carefully weighed against the potential burden these impose on facility operations—particularly in situations, like a PHE, where staff resources are already stretched to provide required services. The proposal balances these imperatives by not specifying what and how often specific data elements would be required. Specifically, the proposed requirements would allow for reporting frequency to be adjusted in response to specific triggers and signals. For example, if case counts nationally are low and have been for some time, it may be reasonable to reduce reporting frequency—potentially even to ''zero,'' which would effectively ''turn off'' reporting—for a given element or category. At the same time, if case

[1449] Michaels D., Emanuel EJ, Bright RA. A National Strategy for COVID–19: Testing, Surveillance, and Mitigation Strategies. JAMA. Published online January 06, 2022. doi:10.1001/jama.2021.24168.

counts were increasingly rapidly, it may be necessary to increase the scope and frequency of data collected.

As previously noted, CMS does not intend to supplant or duplicate existing requirements and mechanisms for reporting of public health surveillance data to other Federal, state, territorial, local, and tribal agencies. The health care facility reporting requirements proposed in this rule are distinct from and serve a different purpose than case surveillance of notifiable diseases and conditions that is conducted by state and local health departments. Specifically, this proposed rule aims to create a framework for hospital and CAH reporting that would ensure HHS and the Federal Government have the information necessary to identify and respond to hospitals and CAHs in need of additional support and guidance and to monitor and assess the capacity of hospitals and CAHs to provide safe care during a declared PHE (national, regional, or local). To that end, we propose reporting to CDC's NHSN because it is a vendor-neutral, federally owned system. As such, it can and does accept data submitted by outside vendors contracted either by hospitals, jurisdictions, or other Federal entities to submit data on behalf of hospitals and which meets data quality standards defined by CDC. CDC's NHSN also provides ready access to data to state and many local public health agencies for the facilities in their jurisdictions via their NHSN accounts and contributes aggregate data to multiple public-facing platforms, including HHS Protect and CMS Care Compare. This proposed rule aims to minimize reporting burden while maintaining transparency [1450] and ensuring public health agencies, researchers, and the public have sufficient visibility [1451] of overall health system capacity amid evolving epidemiological conditions in order to rapidly direct preventive and response actions. Additionally, aligning these proposed hospital and CAH reporting requirements with the existing reporting in NHSN, and other mechanisms of reporting required public health data, may decrease reporting burden and allow for analysis of health care data across these patient safety and health care facility capacity domains by the CDC.

At the same time, we recognize the value of and support hospital engagement with public health authorities to report public health surveillance data. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45470 through 45479), we finalized the requirement for eligible hospitals and CAHs participating in the Promoting Interoperability Program to report four of the six of the measures associated with the Public Health and Clinical Data Exchange Objective, beginning with the EHR reporting period in CY 2022: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting. And elsewhere in this rule, we've proposed changes to the duration and level of engagement that will further strengthen incentives for eligible hospitals and CAHs to engage in these essential reporting activities. To ensure CMS has the necessary flexibility to take advantage of these other reporting streams, CMS has proposed that hospitals would report any data required under this provision to CDC's NHSN or other CDC-supported surveillance systems, as specified by the Secretary.

Ultimately, CMS expects reporting requirements under this section will become increasingly automated and real-time as data systems and standards continue to mature and become more interoperable. Through resources provided by the American Rescue Plan Act and its Data Modernization Initiative, CDC is investing in increasing the automation capabilities of the surveillance systems like NHSN and its ability to connect with other data submission techniques, vendors, and systems.[1452] Nevertheless, the glidepath to this future state may differ across regions, facilities, and even required data elements—particularly those captured and reported at the person level. To accommodate variable reporting capabilities, the person-level reporting requirements under this provision would leverage established national standards and interoperability requirements of ONC to reduce burden and promote standardization, and would include minimal data elements necessary for public health, safety, and infection control purposes.

We recognize that this transition may come with certain tradeoffs and are soliciting comments on any challenges or unintended consequences that this may impose on facilities. We firmly believe that the proposed reporting requirements support our responsibility to protect and ensure the health and safety of hospital and CAH patients by, among other things, ensuring that these facilities follow infection prevention and control protocols based on recognized standards of practice. We believe that these proposed reporting requirements are necessary for CMS to monitor whether individual hospitals and CAHs are appropriately tracking, responding to, and mitigating the spread and impact of viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential on patients, the staff who care for them, and the general public. We believe that this action reaffirms our commitment to protecting the health and safety of all patients who receive care at the approximately 6,200 Medicare- and Medicaid-certified hospitals and CAHs nationwide. We welcome public comments on our proposal and have noted specific areas of interest for feedback throughout the discussion.

C. Request for Public Comments on IPPS and OPPS Payment Adjustments for Wholly Domestically Made NIOSH-Approved Surgical N95 Respirators

1. Introduction and Overview

On January 20, 2021, President Biden issued Executive Order (E.O.) 13987, titled ''Organizing and Mobilizing the United States Government To Provide a Unified and Effective Response To Combat COVID–19 and To Provide United States Leadership on Global Health and Security'' (86 FR 7019). This order launched a whole-of-government approach to combat the coronavirus disease 2019 (COVID–19) and prepare for future biological and pandemic threats. This response has continued over the past year. In March 2022, President Biden released the *National COVID–19 Preparedness Plan* that builds on the progress of the prior 13 months and lays out a roadmap to fight COVID–19 in the future.[1453] Both the ongoing threat of COVID–19 and the potential for future pandemics necessitate significant investments in pandemic preparedness.

Availability of personal protective equipment (PPE) in the health care sector is a critical component of this preparedness, and one that displayed significant weakness in the beginning of the COVID–19 pandemic. In spring of 2020, supply chains for PPE faced severe disruption due to lockdowns that limited production, and unprecedented demand spikes across multiple industries. Supply of surgical N95 respirators—a specific type of filtering

[1450] *https://obamawhitehouse.archives.gov/the-press-office/2013/05/09/executive-order-making-open-and-machine-readable-new-default-government-.*

[1451] *https://digital.gov/open-data-policy-m-13-13/.*

[1452] *https://www.cdc.gov/surveillance/data-modernization/index.html.*

[1453] White House, *National COVID–19 Preparedness Plan,* March 2022; *https://www.whitehouse.gov/wp-content/uploads/2022/03/NAT-COVID-19-PREPAREDNESS-PLAN.pdf*

facepiece respirator used in clinical settings—was one type of PPE that was strained in hospitals. So-called ''just-in-time'' supply chains that minimize stockpiling, in addition to reliance on overseas production, left U.S. hospitals unable to obtain enough surgical N95 respirators to protect health care workers. Prices for surgical N95s soared, from an estimated $0.25–$0.40 range [1454] to $5.75 [1455] or even $12.00 in some cases.[1456] Unable to obtain surgical N95s regulated by the National Institute for Occupational Safety and Health (NIOSH), hospitals had to turn to KN95s—a Chinese standard of respirator—and other non-NIOSH-approved disposable respirators that were authorized under Emergency Use Authorization (EUA). Concerns were raised during the COVID–19 pandemic regarding counterfeit respirators. NIOSH evaluates and approves surgical N95s to meet efficacy standards for air filtration and protection from fluid hazards present during medical procedures. KN95 respirators, on the other hand, are not regulated by NIOSH. KN95s have faced particular counterfeit and quality risks—with NIOSH finding that about 60% of KN95 respirators that it evaluated during the COVID–19 pandemic in 2020 and 2021 did not meet the particulate filter efficiency requirements that they intended to meet.[1457] Failure to meet these requirements compromises safety of health care personnel and patients.

Over the course of the pandemic, U.S. industry responded to the shortages and dramatically increased production of N95s. Today, the majority of surgical N95s purchased by hospitals are assembled in the U.S., and prices have returned to rates closer to $0.70 per respirator.[1458] However, risks remain to maintain preparedness for COVID–19 and future pandemics. It is important to maintain this level of domestic production for surgical N95s, which provide the highest level of protection from particles when worn consistently and properly, protecting both health care personnel and patients from the transfer of microorganisms, body fluids, and particulate material—including the virus that causes COVID–19. Additionally, it is important to ensure that a sufficient share of those surgical N95s are *wholly* made in the U.S.—that is, including raw materials and components. The COVID–19 pandemic has illustrated how overseas production shutdowns, foreign export restrictions, or ocean shipping delays can jeopardize availability of raw materials and components needed to make critical public health supplies. In a future pandemic or COVID–19-driven surge, hospitals need to be able to count on PPE manufacturers to deliver the equipment they need on a timely basis in order to protect health care workers and their patients. Sustaining a level of wholly domestic production of surgical N95 respirators is integral to maintaining that assurance.

This policy goal—ensuring that quality PPE is available to health care personnel when needed by maintaining production levels of wholly domestically made PPE—is emphasized in the *National Strategy for a Resilient Public Health Supply Chain,* published in July 2021 as a deliverable of President Biden's Executive Order 14001 on ''A Sustainable Public Health Supply Chain.'' To help achieve this goal, the U.S. Government is committing to purchase wholly domestically made PPE in line with new requirements in section 70953 of the Infrastructure Investment and Jobs Act. These new contract requirements stipulate that PPE purchased by covered departments must be wholly domestically made—that is, the products as well as their materials and components must be grown, reprocessed, reused, or produced in the U.S.

The Federal Government's procurement of wholly domestically made PPE will *help* achieve the above policy goal. However, the U.S. Government alone cannot sustain the necessary level of production. As outlined in the previously mentioned *National Strategy for a Resilient Public Health Supply Chain,* the U.S. Government is only one small part of the market for PPE. Hospitals are the primary purchasers and users of medical PPE including surgical N95 respirators. Sustaining a strong domestic industrial base for PPE—in order to be prepared for future pandemics or COVID–19-driven surges and protect Americans' health during such times—therefore, requires hospitals' support.

Surgical N95 respirators are a particularly critical type of PPE needed to protect personnel and beneficiaries from the SARS–CoV–2 virus and future respiratory pandemic illnesses. However, wholly domestically made NIOSH-approved surgical N95 respirators are generally more expensive than foreign-made ones. Therefore, we believe a payment adjustment that reflects, and offsets, the additional marginal costs that hospitals face in procuring wholly domestically made NIOSH-approved surgical N95 respirators might be appropriate. These marginal costs are due to higher prices for wholly domestically made NIOSH-approved surgical N95s, which, in turn, primarily stem from higher costs of manufacturing labor in the U.S. compared to costs in countries such as China, where many N95 and other respirators are made. Such a payment adjustment might provide sustained support over the long term to hospitals that purchase wholly domestically made NIOSH-approved surgical N95 respirators, and could help safeguard personnel and beneficiary safety over the long term by sustaining production and availability of these respirators.

For the IPPS, the Secretary could potentially make such a payment adjustment under section 1886(d)(5)(I) of the Social Security Act, which specifically authorizes the Secretary to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate.

For the OPPS, the Secretary could potentially make such a payment adjustment under section 1833(t)(2)(E) of the Social Security Act, which authorizes the Secretary to establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments.

2. Request for Public Comments on Potential Payment Adjustments Under the IPPS and OPPS

As discussed earlier in this section, given the importance of NIOSH-approved surgical N95 respirators in protecting personnel and beneficiaries from the SARS–CoV–2 virus and future respiratory pandemic illnesses, we are considering whether it might be appropriate to provide payment adjustments to hospitals to recognize the additional resource costs they incur to acquire NIOSH-approved surgical N95 respirators that are wholly domestically made. NIOSH-approved surgical N95 respirators, which faced

[1454] Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Supply Chain Control Tower analysis.

[1455] Society for Healthcare Organization Procurement Professionals, *COVID–19 PPD Cost Analysis,* April 2020; *http://cdn.cnn.com/cnn/2020/images/04/16/shopp.covid.ppd.costs.analysis_.pdf.*

[1456] Washington Post, ''U.S. sent millions of face masks to China early this year, ignoring pandemic warning signs,'' April 2020; *https://www.washingtonpost.com/health/us-sent-millions-of-face-masks-to-china-early-this-year-ignoring-pandemic-warning-signs/2020/04/18/aaccf54a-7ff5-11ea-8013-1b6da0e4a2b7_story.html.*

[1457] U.S. Centers for Disease Control and Prevention ''Types of Masks and Respirators''; *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html.*

[1458] Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Supply Chain Control Tower analysis.

severe shortage at the onset of the COVID–19 pandemic, are essential for the protection of patients and hospital personnel that interface with patients. The Department of Health and Human Services (HHS) recognizes that procurement of NIOSH-approved surgical N95 respirators that are wholly domestically made, while critical to pandemic preparedness and protecting health care workers and patients, can result in additional resource costs for hospitals.

We are interested in feedback and comments on the appropriateness of payment adjustments that would account for these additional resource costs. We believe such payment adjustments could help achieve a strategic policy goal, namely, sustaining a level of supply resilience for NIOSH-approved surgical N95 respirators that is critical to protect the health and safety of personnel and patients in a public health emergency. We are considering such payment adjustments to apply to 2023 and potentially subsequent years. This rule outlines for feedback and comments two possible frameworks to do so.

One potential framework for payment adjustments might be to provide biweekly interim lump-sum payments to hospitals that would be reconciled at cost report [1459] settlement. Under this framework, a hospital would separately report on its cost report the aggregate cost and total quantity of NIOSH-approved surgical N95 respirators it purchased that were wholly domestically made and those that were not—for cost reporting periods beginning on or after January 1, 2023. This information, along with existing information already collected on the cost report, could be used to calculate a Medicare payment for the estimated cost differential, specific to each hospital, incurred due to the purchase of NIOSH-approved surgical N95 respirators that are wholly domestically made vs. those that are foreign-assembled or include foreign-sourced components. In accordance with the principles of reasonable cost as set forth in section 1861(v)(1)(A) of the Act and in 42 CFR 413.1 and 413.9, Medicare could make a lump-sum payment for Medicare's share of these additional inpatient and outpatient costs at cost report settlement.

Alternatively, a second potential framework on which we seek comment is the development of a claims-based approach wherein Medicare could establish a MS–DRG add-on payment that could be applied to each applicable Medicare IPPS discharge. Under this alternative, hospitals would have to meet or exceed a ''domestic sourcing threshold'' of 50 percent for wholly domestically sourced surgical N95 respirators purchased by or for the hospital in 2023. We could establish a unique billing code that eligible hospitals would append to their claim attesting to the fact that they met or exceeded the domestic sourcing threshold for the year. If we were to adopt a claims-based approach for IPPS, we believe it would be appropriate to adopt a similar claims-based approach for face-to-face Medicare encounters under the OPPS. Similar to the MS–DRG add-on payment approach, for OPPS, Medicare could establish an Ambulatory Payment Classification (APC) add-on payment for each non-telehealth OPPS service.

There are several considerations for either a potential framework of lump-sum interim biweekly periodic payments reconciled at cost report settlement; or a potential framework of claims-based payment adjustments for IPPS and OPPS. Accordingly, we seek comment on the following questions.

- Which of the potential frameworks would be a more appropriate approach to provide payment adjustments for purchased wholly domestically made NIOSH-approved surgical N95 respirators? Please explain why.
- How can hospitals determine if the surgical N95 respirators they purchase are wholly domestically made NIOSH-approved surgical N95 respirators and eligible for these payment adjustments?
- For the lump-sum payment framework, what would be the most appropriate methodology to determine Medicare's share of costs for purchased wholly domestically made NIOSH-approved surgical N95 respirators? One potential methodology could use the ratio of Medicare inpatient cases to total inpatient hospital cases for all payers reported on the Medicare cost report.
- For the lump-sum payment framework, a hospital might use only wholly domestically made NIOSH-approved surgical N95 respirators. Such a hospital would not have any cost information to report for NIOSH-approved surgical N95 respirators that were not wholly domestically made. Strictly for purposes of calculating a cost differential in such situations, should a national minimum cost be established for a NIOSH-approved surgical N95 respirator that is not wholly domestically made?
- For the claims-based payment framework, how should Medicare calculate the per claim add-on amount prospectively given the varying costs of NIOSH-approved surgical N95 respirators, and how should it be updated given year-by-year cost changes for NIOSH-approved surgical N95 respirators?
- For the claims-based payment framework, what are reasonable usage assumptions upon which to base the payment adjustments? For example, for OPPS, should the payment adjustments be based on assumption of one wholly domestically made NIOSH-approved surgical N95 respirator worn per face-to-face, in-person encounter? What assumptions should be made for IPPS? Should the claims-based payment adjustment differ by MS–DRG and by APC?
- Given that the OPPS authority that would potentially be used for an OPPS payment adjustment is required by law to be budget neutral, should the IPPS payment adjustment also be budget neutral or should it be applied in a non-budget neutral manner?
- What program integrity safeguards should Medicare institute in effectuating this policy? What documentation should hospitals be required to maintain? [1460] How can the policy mitigate price increases for wholly domestically made NIOSH-approved surgical N95 respirators and preserve incentives for hospitals to negotiate fair prices with N95 mask suppliers?
- For hospitals that meet the domestic sourcing threshold, should the submission of the claim be deemed sufficient for attestation of compliance with meeting or exceeding the domestic sourcing threshold or is a separate attestation process necessary? For what time period should a hospital be attesting that it met the domestic sourcing threshold?
- Do special considerations for certain hospitals exist, such as hospitals with low-volume of Medicare patients or those in a rural or urban safety net setting?

[1459] Medicare-certified providers, such as Medicare-certified hospitals, are required to submit an annual cost report (CMS–2552–10 (OMB control number 0938–0050)) to their Medicare Administrative Contractor (MAC). The Medicare cost report contains provider information such as facility characteristics, cost and charges by cost center, in total and for Medicare, Medicare settlement data, and financial statement data. CMS will provide the opportunity for the public to comment on any information collection associated with a future proposal.

[1460] We note if a hospital does not maintain adequate documentation regarding its wholly domestically made NIOSH-approved surgical N95 respirators for its cost report under the lump-sum payment framework or its domestic sourcing threshold attestation under the claims-based payment framework, CMS could recoup any additional payments.

- For Group Purchasing Organizations (GPOs) that purchase wholly domestically made NIOSH-approved surgical N95 respirators on behalf of health systems, what considerations, if any, are needed to inform a payment adjustment policy?
- Other than information obtained from hospital cost reports or claims, what additional data sources should CMS consider to inform future adjustments?
- What data or circumstances should be taken into consideration to determine continuation of these payments beyond 2023?
- Are there other types of respiratory devices and PPE that should be considered for payment adjustments?

We realize there may be different ways a payment adjustment to recognize the additional resource costs hospitals incur when purchasing wholly domestically made NIOSH-approved surgical N95 respirators could be implemented and seek comment on these or other frameworks.

XI. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2022 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the proposed policies set forth in this proposed rule. MedPAC recommendations for the IPPS for FY 2023 are addressed in Appendix B to this proposed rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's website at *https://www.medpac.gov.*

XII. Other Required Information

A. Publicly Available Files

IPPS-related data are available on the internet for public use. The data can be found on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.* Following is a listing of the IPPS-related data files that are available.

As discussed in section II.A. of this proposed rule, we are proposing to use the FY 2021 data for FY 2023 ratesetting, with certain proposed modifications to our relative weight and outlier methodologies. As discussed in section I.F. of the preamble of this proposed rule, we are also considering, as an alternative to our proposed approach, the use of the FY 2021 MedPAR claims for purposes of FY 2023 ratesetting but without these proposed modifications to our usual methodologies. In order to facilitate comments on this alternative approach, which we may consider finalizing for FY 2023 based on consideration of comments received, we are making available supplemental information, including the relative weights calculated both with and without COVID–19 cases as described in section I.F. of the preamble of this proposed rule as well as other proposed rule supporting data files including the IPPS and LTCH PPS Impact Files, supporting MS–DRG files (such as the AOR/BOR File, the Case Mix Index File, and the Standardizing File) and a file that contains Operating and Capital National Standardized Amounts as well as other factors (such as budget neutrality factors and the fixed-loss outlier threshold), determined under the alternatives considered for this proposed rule. We refer the reader to section I.O. of Appendix A of this proposed rule for a discussion of the files that we are making available with regard to our alternative approach.

Commenters interested in discussing any data files used in construction of this proposed rule should contact Michael Treitel at (410) 786–4552.

1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet S–3, parts II and III from FY 2019 Medicare cost reports used to create the proposed FY 2023 IPPS wage index. Multiple versions of this file are created each year. For a discussion of the release of different versions of this file, we refer readers to section III.L. of the preamble of this proposed rule.

Media: Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Periods Available: FY 2007 through FY 2023 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the CY 2019 occupational mix survey data to be used to compute the occupational mix adjusted wage indexes. Multiple versions of this file are created each year. For a discussion of the release of different versions of this file, we refer readers to section III.L. of the preamble of this proposed rule.

Media: Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Period Available: FY 2023 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year to support the rulemaking.

Media: Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Period Available: FY 2023 IPPS Update.

4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed and final rule.

Media: Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Periods Available: FY 2005 through FY 2023.

5. FY 2023 IPPS FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Federal Information Processing Standards (FIPS), county name, and a list of Core Based Statistical Areas (CBSAs).

Media: Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2023 proposed rule home page or the FY 2023 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2023 IPPS Update.

6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal years ending on or after September 30, 1996. These data files contain the highest level of cost report status.

Media: Internet at *https://www.cms.gov/Research-Statistics-Dataand-Systems/Downloadable-Public-UseFiles/Cost-Reports/Cost-Reports-byFiscal-Year.html.*

(We note that data are no longer offered on a CD. All of the data collected

are now available free for download from the cited website.)

7. Provider-Specific File

This file is a component of the PRICER program used in the MAC's system to compute DRG/MS–DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

Media: Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspMedicareFeeSvcPmtGen/psf_text.*

Period Available: Quarterly Update.

8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number based on the MS–DRGs assigned to the hospital's discharges using the GROUPER version in effect on the date of the discharge. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS–DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year to support the rulemaking.

Media: Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html,* or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 1985 through FY 2023.

9. MS–DRG Relative Weights (Also Table 5—MS–DRGs)

This file contains a listing of MS–DRGs, MS–DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay for each fiscal year. Two versions of this file are created each year to support the rulemaking.

Media: Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html,* or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or the fiscal year final rule home page desired).

Periods Available: FY 2005 through FY 2023 IPPS Update.

10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital inpatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, HCRIS Cost Report Data, MedPAR Limited Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the **Federal Register**. Two versions of this file are created each year to support the rulemaking.

Media: Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Historical-Impact-Files-for-FY-1994-through-Present,* or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 1994 through FY 2023 IPPS Update.

11. AOR/BOR File

This file contains data used to develop the MS–DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS–DRG for length of stay and standardized charges. The BOR file are ''Before Outliers Removed'' and the AOR file is ''After Outliers Removed.'' (Outliers refer to statistical outliers, not payment outliers.) Two versions of this file are created each year to support the rulemaking.

Media: Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html,* or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 2005 through FY 2023 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-Based Statistical Area (CBSA). The file supports the rulemaking.

Media: Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2023 proposed rule home page or the FY 2023 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2023 IPPS Update.

13. MS–DRG Relative Weights Cost Centers File

This file provides the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center cost-to-charge ratios (CCRs) that we used in the relative weight calculation.

Media: Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2023 proposed rule home page or the FY 2023 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2023 IPPS Update.

14. Hospital Readmissions Reduction Program Supplemental File

The Hospital Readmissions Reduction Program Supplemental File is only available and updated for the final rule, when the most recent data is available. Therefore, we refer readers to the FY 2022 IPPS/LTCH PPS final rule supplemental file, which has the most recent finalized payment adjustment factor components and is the same data as would have been used to create the FY 2023 IPPS/LTCH PPS proposed rule supplemental file.

Media: Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation

panel on the left side of the page, click on the FY 2023 proposed rule home page or the FY 2023 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2023 IPPS Update.

15. Medicare Disproportionate Share Hospital (DSH) Supplemental File

This file contains information on the calculation of the uncompensated care payments for FY 2023. Variables include the data used to determine a hospital's share of uncompensated care payments, total uncompensated care payments and estimated per claim uncompensated care payment amounts. The file supports the rulemaking.

Media: Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2023 proposed rule home page or the FY 2023 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2023 IPPS Update.

16. New Technology Thresholds File

This file contains the cost thresholds by MS–DRG that are generally used to evaluate applications for new technology add-on payments for the fiscal year that follows the fiscal year that is otherwise the subject of the rulemaking. (As discussed in section II.G. of this proposed rule, we use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS–DRG for that same fiscal year.) Two versions of this file are created each year to support rulemaking. (We note that the information in this file was previously provided in Table 10 of the annual IPPS proposed and final rules (83 FR 41739).)

Media: Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the applicable fiscal year's proposed rule or final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Periods Available: For FY 2023 and FY 2024 applications.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs for the Hospital Wage Index for Acute Care Hospitals

Section III.E.1. of the preamble of this proposed rule, use of 2019 Medicare wage index occupational mix survey for the FY 2023 wage index, references the information collection request currently approved under 0938–0907. There are no proposed changes to the currently approved information collection request associated with this rulemaking; however, we note that the information collection expires September 30, 2022.

Section III.I.2.a. of the preamble of this proposed rule, FY 2023 Reclassification Application Requirements and Approvals, references the information collection request 0938–0573 which expired on January 31, 2021. A reinstatement of the information collection request is currently being developed. The public will have an opportunity to review and submit comments regarding the reinstatement of this PRA package through a public notice and comment period separate from this rulemaking.

3. ICRs for Payments for Low-Volume Hospitals

As discussed in section V.C. of this proposed rule, in accordance with section 1886(d)(12) of the Act, beginning with FY 2023, the low-volume hospital definition and payment adjustment methodology will revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act and subsequent legislation. Therefore, effective for FY 2023 and subsequent years, under current policy at § 412.101(b), in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges during the fiscal year. In that section we also discuss the process for requesting and obtaining the low-volume hospital payment adjustment under § 412.101. Specifically, a hospital makes a written request to its MAC that contains sufficient documentation to establish that the hospital meets the applicable statutory mileage and discharge criteria. While this information collection requirement would normally be subject to the PRA, we believe in this instance it is exempt. Based on historical data, we estimate there are fewer than 5 hospitals among all subsection (d) hospitals that will meet the applicable mileage and discharge criteria for FY 2023. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(c)(4), the proposed requirement would be exempt as it affects less than 10 entities in a 12-month period.

4. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

a. Background

The Hospital IQR Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. OMB has currently approved 1,572,810 hours of burden and approximately $65 million under OMB control number 0938–1022 (expiration date December 31, 2022), accounting for information collection burden experienced by approximately 3,300 IPPS hospitals and 1,100 non-IPPS hospitals for the FY 2024 payment determination. In this proposed rule, we describe the burden changes regarding collection of information under OMB control number 0938–1022 (expiration date December 31, 2022) for IPPS hospitals.

For more detailed information on our proposed policies for the Hospital IQR Program, we refer readers to section IX.E. of the preamble of this proposed rule. We are proposing the adoption of four measures that we expect to affect our collection of information burden estimates: (1) The Hospital Commitment to Health Equity structural measure, beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years; (2) the Screening for Social Drivers of Health measure, beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (3) the Screen Positive Rate for Social Drivers of Health measure, beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; and (4) the Hospital-level THA/TKA PRO–PM, beginning with voluntary reporting across two periods, followed by mandatory reporting of the measure for the reporting period which runs from July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination. We are also proposing a modification to our eCQM reporting and submission requirements whereby we would increase the total number of eCQMs to be reported from four to six eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination, which would additionally affect our collection of information burden. The estimated collection of burden associated with these proposals is discussed in this section of this proposed rule.

We are also proposing policies which would not affect the information collection burden associated with the Hospital IQR Program. As discussed in section IX.E. of the preamble of this proposed rule, we are proposing to adopt four eCQMs: (1) Cesarean Birth electronic clinical quality measure (eCQM), beginning with the CY 2023 reporting period/FY 2025 payment determination, followed by mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (2) Severe Obstetric Complications eCQM, beginning with the CY 2023 reporting period/FY 2025 payment determination, followed by mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (3) Hospital-Harm—Opioid-Related Adverse Events eCQM, beginning with the CY 2024 reporting period/FY 2026 payment determination; and (4) Global Malnutrition Composite Score eCQM, beginning with the CY 2024 reporting period/FY 2026 payment determination. We are also proposing the adoption of two claims-based measures beginning with the FY 2024 payment determination: (1) MSPB Hospital; and (2) the Hospital-Level RSCR Following Elective Primary THA/TKA. We are proposing refinements to current Hospital IQR Program claims-based measures beginning with the FY 2024 payment determination: (1) Hospital-Level, Risk-Standardized Payment Associated with an Episode of Care for Primary Elective THA/TKA; and (2) The Acute Myocardial Infarction (AMI) Excess Days in Acute Care (EDAC). Lastly, we are proposing to: (1) Establish a hospital designation related to patient care to be publicly-reported on a public-facing website beginning in Fall 2023; (2) modify our case threshold exemptions and zero denominator declaration policies for hybrid measures as we believe they are not applicable for this measure type beginning with the FY 2026 payment determination; and (3) modify our eCQM validation policy to increase the reporting of medical requests from 75 percent of records to 100 percent of records, beginning with the validation of CY 2022 eCQM data affecting the FY 2025 payment determination.

The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $21.20 per hour for a medical records and health information technician professional.[1461] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($21.20 × 2 = $42.40) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to hospitals using a wage plus benefits estimate of $42.40 per hour throughout the discussion in this section of this rule for the Hospital IQR Program.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45507), our burden estimates were based on an assumption of approximately 3,300 IPPS hospitals. For this proposed rule, we are updating our assumption to 3,150 IPPS hospitals based on recent data from the FY 2022 Hospital IQR Program payment determination which reflects a closer approximation of the total number of hospitals reporting data to the Hospital IQR Program.

b. Information Collection Burden Estimate for the Hospital Commitment to Health Equity Structural Measure Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination

In section IX.E.5.a. of the preamble of this proposed rule, we are proposing the adoption of the Hospital Commitment to Health Equity structural measure beginning with the CY 2023 reporting period/FY 2025 payment determination. Hospitals would report data through the Hospital Quality Reporting (HQR) System.

We are proposing to require hospitals to submit the response on an annual basis during the submission period. We estimate the information collection burden associated with this proposed structural measure to be, on average across all 3,150 IPPS hospitals, no more than 10 minutes per hospital per year, as it involves attesting to as many as five questions one time per year for a given reporting period. While we understand some hospitals may require more than 10 minutes to research the information needed to respond, we believe that the majority of hospitals will have the information readily available to respond to the questions listed in section IX.E.5.a. of the preamble of this proposed rule and will require less than 10 minutes. In addition, we believe that many hospitals would be able to submit similar responses in future years, thereby reducing the actual time to respond in subsequent reporting periods. Using the estimate of 10 minutes (or 0.167 hours) per hospital per year, and the updated wage estimate as described previously, we estimate that this policy will result in a total annual burden increase of 525 hours across all participating IPPS hospitals (0.167 hours × 3,150 IPPS hospitals) at a cost of $22,260 (525 hours × $42.40). With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.K. of Appendix A of this proposed rule).

[1461] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records and Health Information Technicians. Accessed on January 13, 2022; available at: *https://www.bls.gov/oes/current/oes292098.htm.*

c. Information Collection Burden Estimate for the Screening for Social Drivers of Health Measure Beginning With Voluntary Reporting in the CY 2023 Reporting Period and Mandatory Reporting in the CY 2024 Reporting Period/FY 2026 Payment Determination

In section IX.E.5.b.(1). of the preamble of this proposed rule, we are proposing the adoption of the Screening for Social Drivers of Health measure beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination. Hospitals would report data through the HQR System.

As discussed in the preamble of this proposed rule, hospitals would be able to collect data and report the measure via multiple methods. We believe that most hospitals would likely collect data through a screening tool incorporated into their electronic health record (EHR) or other patient intake process.

We believe the Outcome and Assessment Information Set (OASIS), which is currently used in the Home Health Quality Reporting Program, is a reasonable comparison for estimating the information collection burden for the Screening for Social Drivers of Health measure due to analogous assessment of patient-level need. The OASIS is a core standard assessment data set home health agencies integrate into their own patient-specific, comprehensive assessment to identify each patient's need for home care that meets the patient's medical, nursing, rehabilitative, social, and discharge planning needs. For OASIS, the currently approved information collection burden under OMB 0938–1279 (expiration date November 30, 2024) is estimated to be 0.3 minutes per data element (18 seconds). For the five HRSN domains screened for by the proposed Social Drivers of Health measure under the Hospital IQR Program, we estimate a total of 2 minutes (0.033 hours) per patient to conduct this screening. The most recent data from the Bureau of Labor Statistics reflects an Average Hourly Earnings of $31.31.[1462] Based on information collected by the American Hospital Association,[1463] we estimate approximately 21,000,000 patients (34,251,159 total admissions in U.S. community hospitals × 3,150 IPPS hospitals ÷ 5,198 total U.S. community hospitals) will be screened annually across all participating IPPS hospitals. For the purposes of calculating burden, we estimate that during the voluntary period, 50 percent of hospitals will survey 50 percent of patients. We estimate during the mandatory period, hospitals would submit for 100 percent of patients. For the CY 2023 voluntary reporting period, we estimate a total burden of 175,000 hours (21,000,000 respondents × 50 percent of patients × 50 hospitals of hospitals × 0.033 hours) at a cost of $5,479,250 (175,000 hours × $31.31) across all participating IPPS hospitals. For the CY 2024 reporting period and subsequent years, we estimate a total annual burden of 700,000 hours (21,000,000 respondents × 0.033 hours) at a cost of $21,917,000 (700,000 hours × $31.31) across all participating IPPS hospitals.

Measure data would be submitted via the HQR System annually. Similar to the currently approved data submission and reporting burden estimate for eCQMs in the Hospital IQR Program and web-based measures for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program (OMB control number 0938–1270; expiration date July 31, 2024) reported via the HQR System, we estimate a burden of 10 minutes per hospital response to transmit the measure data. Therefore, we estimate that each participating facility will spend 10 minutes (0.1667 hours) annually to collect and submit the data via this portal. For the purposes of calculating burden, we estimate that during the voluntary period, 50 percent of hospitals will submit data. For the CY 2023 voluntary reporting period, we estimate a total burden of 263 hours (0.1667 hours × 3,150 hospitals × 50 percent of hospitals) at a cost of $11,151 (263 hours × $42.40) across all participating IPPS hospitals. For the CY 2024 reporting period and subsequent years, we estimate a total annual burden for all participating IPPS hospitals of 525 hours (0.1667 hours × 3,150 hospitals) at a cost of $22,260 (525 hours × $42.40).

With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.K. of Appendix A of this proposed rule).

d. Information Collection Burden Estimate for the Screen Positive Rate for Social Drivers of Health Process Measure Beginning With Voluntary Reporting in the CY 2023 Reporting Period and Mandatory Reporting Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

In section IX.E.5.b.(2). of the preamble of this proposed rule, we are proposing the adoption of the Screen Positive Rate for Social Drivers of Health measure beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination. Hospitals would report data through the HQR System. For this measure, hospitals would be required to report on an annual basis the number of patients who screen positive for one or more of the five domains (reported as five separate rates) divided by the total number of patients screened.

We previously included the burden associated with screening patients in our discussion of the Screening for Social Drivers of Health measure. For this measure, we estimate only the additional burden for a hospital reporting via the HQR System since patients would not need to provide any additional information for this measure. We estimate that each participating facility will spend 10 minutes (0.1667 hours) annually to collect and submit the data. For the purposes of calculating burden, we estimate that during the voluntary period, 50 percent of hospitals would submit data. For the CY 2023 voluntary reporting period, we estimate a total burden of 263 hours (0.1667 hours × 3,150 hospitals × 50 percent of hospitals) at a cost of $11,130 (263 hours × $42.40) across all participating IPPS hospitals. For the CY 2024 reporting period and subsequent years, we estimate a total annual burden estimate for all IPPS hospitals of 525 hours (0.1667 hours × 3,150 hospitals) at a cost of $22,260 (525 hours × $42.40).

[1462] U.S. Bureau of Labor Statistics. Economy at a Glance, Average Hourly Earnings. Accessed on January 24, 2022; available at: *https://www.bls.gov/eag/eag.us.htm.*

[1463] *https://www.aha.org/system/files/media/file/2020/01/2020-aha-hospital-fast-facts-new-Jan-2020.pdf.*

e. Information Collection Burden Estimate for the Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Beginning With Two Voluntary Reporting Periods Followed by Mandatory Reporting for Eligible Elective Procedures Occurring July 1, 2025 Through June 30, 2026, Impacting the FY 2028 Payment Determination, and for Subsequent Years

In section IX.E.5.g. of the preamble of this proposed rule, we are proposing the adoption of the THA/TKA PRO–PM beginning with voluntary reporting across two periods (July 1, 2023 through June 30, 2024 and July 1, 2024 through June 30, 2025), followed by mandatory reporting of the measure beginning with the reporting period which runs from July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination.

The THA/TKA PRO–PM uses four sources of data for the calculation of the measure: (1) PRO data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. We estimate no additional burden associated with claims data, Medicare enrollment and beneficiary data, and U.S. Census Bureau survey data as these data are already collected via other mechanisms.

Many hospitals have already incorporated patient-reported outcome (PRO) data collection into their workflows. While we are not proposing to require how hospitals collect data, hospitals new to collecting PRO data have multiple options for when and how they would collect this data so they can best determine the mode and timing of collection that works best for their patient population. The possible patient touchpoints for pre-operative PRO data collection include the doctor's office, pre-surgical steps such as education classes, or medical evaluations that can occur in an office or at the hospital. The modes of PRO data collection can include completion of the pre-operative surveys using electronic devices (such as an iPad or tablet), pen and paper, mail, phone call, or through the patient's portal. Post-operative PRO data collection modes are similar to pre-operative modes. The possible patient touchpoints for post-operative data collection can occur before the follow-up appointment, at the doctor's office, or after the follow-up appointment. The potential modes of PRO data collection for post-operative data are the same as for pre-operative data. If the patient does not or cannot attend a follow-up appointment, the modes of collection can include completion of the post-operative survey using email, mail, phone, or through the patient portal. Use of multiple modes would increase response rates as it allows for different patient preferences.

For the THA/TKA PRO–PM data, we are proposing that hospitals would be able to submit data during two voluntary periods, followed by mandatory reporting for eligible elective procedures occurring July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination and for subsequent years. Hospitals would need to submit data twice (pre-operative data and post-operative data). For the purposes of calculating burden, we estimate that during the voluntary periods, 50 percent of hospitals that perform at least one THA/TKA procedure would submit data, and would do so for 50 percent of THA/TKA patients. We estimate during the mandatory period, hospitals would submit for 100 percent of patients. While we are proposing that hospitals would be required to submit, at minimum, 50 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data, we are conservative in our estimate for the mandatory period in case hospitals exceed this currently proposed threshold.

Under OMB control number 0938–0981 (expiration date September 30, 2024), the currently approved burden per respondent to complete the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure is 7.25 minutes (0.120833 hours). We estimate that the time to complete both the preoperative and post-operative surveys is analogous to completing the HCAHPS Survey once. The most recent data from the Bureau of Labor Statistics reflects an Average Hourly Earnings of $31.31.[1464] For burden estimating purposes, we assume that most hospitals will likely undertake PRO data collection through a screening tool incorporated into their EHR or other patient intake process. We estimate that approximately 330,000 THA/TKA procedures occur in the inpatient setting each year, and that many patients could complete both the pre-operative and postoperative questionnaires, although from our experience with using this measure in the Comprehensive Joint Replacement model, we are also aware that not all patients who complete the pre-operative questionnaire would complete the post-operative questionnaire. Due to the performance period for the first voluntary reporting period being 6 months, we assume 41,250 patients will complete the survey (165,000 patients × 0.50 × 0.50 of hospitals) for a total of 4,984 hours annually (41,250 respondents × 0.120833 hours) at a cost of $156,049 (4,984 hours × $31.31) across all IPPS hospitals. For the second voluntary reporting periods, we assume 82,500 patients will complete the survey (330,000 patients × 0.50 × 0.50 hospitals) for a total of 9,969 hours annually (82,500 respondents × 0.120833 hours) at a cost of $312,122 (9,969 hours × $31.31) across all IPPS hospitals. Beginning with mandatory reporting for the FY 2028 payment determination, we estimate a total of 39,875 hours (330,000 patients × 0.120833 hours) at a cost of $1,248,486 (39,875 hours × $31.31) across all IPPS hospitals.

For the data submission, which would be reported via the HQR System, we estimate a burden of 10 minutes per response. For each of the two voluntary reporting periods, we estimate that each hospital will spend 20 minutes (0.33 hours) annually (10 minutes × 2 surveys) to collect and submit the data via this tool. We estimate a resulting burden for all participating IPPS hospitals of 525 hours (0.33 hours × 3,150 hospitals × 50 percent) at a cost of $22,260 (525 hours × $42.40). Beginning with mandatory reporting for the FY 2028 payment determination, we estimate a total of 1,050 hours (0.33 hours × 3,150 hospitals) at a cost of $44,520 (1,050 hours × $42.40).

With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.K. of Appendix A of this proposed rule).

f. Information Collection Burden Estimate for the Modification of the eCQM Reporting and Submission Requirements Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

In section IX.E.10.e. of the preamble of this proposed rule, we are proposing a modification to our eCQM reporting and submission requirements whereby we are increasing the total number of eCQMs to be reported from four to six eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination.

We previously finalized in the FY 2020 IPPS/LTCH PPS final rule that, for the CY 2021 reporting period/FY 2023

[1464] U.S. Bureau of Labor Statistics. Economy at a Glance, Average Hourly Earnings. Accessed on January 24, 2022; available at: *https://www.bls.gov/eag/eag.us.htm.*

payment determination, hospitals are required to submit data for four self-selected eCQMs each year (84 FR 42503). Additionally, for the CY 2022 reporting period/FY 2024 payment determination, hospitals are required to submit data for three self-selected eCQMs and the Safe Use of Opioids-Concurrent Prescribing eCQM for a total of four eCQMs (84 FR 42505). We also finalized in the FY 2021 IPPS/LTCH PPS final rule to require hospitals to submit four quarters of eCQM data beginning in the CY 2023 reporting period/FY 2025 payment determination (85 FR 59008 through 59009). We continue to estimate the information collection burden associated with the eCQM reporting and submission requirements to be 10 minutes per measure per quarter. For the increase in submission from four to six eCQMs, we estimate a total of 20 minutes or 0.33 hours (10 minutes × 2 eCQMs) per hospital per quarter. We estimate a total burden increase of 1,050 hours across all participating IPPS hospitals (0.33 hour × 3,150 IPPS hospitals) for each quarter of eCQM data or 4,200 hours annually (1,050 hours × 4 quarters) at a cost of $178,080 (4,200 hours × $42.40).

g. Information Collection Burden Estimate for the Adoption of Four eCQMs: Two Perinatal eCQMs Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination; One Opioid-Related Hospital-Harm eCQM and One Malnutrition eCQM Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

In sections IX.E.5.c. and IX.E.5.d. of the preamble of this proposed rule, we are proposing to adopt two perinatal eCQMs—Cesarean Birth and Severe Obstetric Complications—beginning with the CY 2023 reporting period/FY 2025 payment determination, followed by mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. Also, in sections IX.E.5.e. and IX.E.5.f. of the preamble of this proposed rule, we are proposing to adopt the Hospital-Harm—Opioid-Related Adverse Events eCQM and the Global Malnutrition Composite Score eCQM, respectively, beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

We do not believe that these proposals to add four eCQMs will affect the information collection burden of submitting eCQMs under the Hospital IQR Program. Current Hospital IQR Program policy requires hospitals to select four eCQMs from the eCQM measure set on which to report (84 FR 42503 through 4250). In other words, while these provisions will result in new eCQMs being added to the eCQM measure set, hospitals will not be required to report more than a total of four eCQMs as is currently required (84 FR 42603) or six eCQMs, if the proposal discussed in section IX.E.10.e. of the preamble of this proposed rule is finalized. In the previous section XII.B.4.f. (of the Collection of Information section of this proposed rule), we account for the burden of reporting six eCQMs.

With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.K. of Appendix A of this proposed rule).

h. Information Collection Burden Estimate for the Adoption or Refinement of Four Claims-Based Measures

In sections IX.E.5.h., IX.E.5.i., IX.E.6.a., and IX.E.6.b. of the preamble of this proposed rule, we are proposing to adopt two claims-based measures—MSPB Hospital and Hospital-Level RSCR Following Elective Primary THA/TKA—and refine two claims-based measures currently in the Hospital IQR Program measure set—Hospital-Level, Risk-Standardized Payment Associated with an Episode of Care for Primary Elective THA/TKA and AMI EDAC. We are proposing to adopt the Hospital MSPB measure and the Hospital-Level RSCR Following Elective Primary THA/TKA beginning with the FY 2024 payment determination and are proposing refinements to the other two measures beginning with the FY 2024 payment determination and for subsequent years. Because these measures are calculated using data that are already reported to the Medicare program for payment purposes, adopting and refining these measures will not result in a change to the burden estimates provided in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45507 through 45512).

i. Information Collection Burden Estimate for Addition of the Publicly-Reported Hospital Designation To Capture Hospital Commitment to the Quality and Safety of Maternal Health Beginning Fall 2023

In section IX.E.8. of the preamble of this proposed rule, we are proposing to establish the publicly-reported hospital designation to capture hospital commitment to the quality and safety of maternity care on a CMS website, for hospitals who qualify for the designation, beginning in Fall 2023. In the FY 2022 IPPS/LTCH PPS final rule, we finalized adoption of the Maternal Morbidity Structural measure (86 FR 45365) and accounted for that burden under OMB control number 0938–1022 (expiration date December 31, 2022). We expect that our policy will not yield a change in burden as it does not require any additional information collection nor affect the requirements for data submission for hospitals.

j. Information Collection Burden Estimate for the Modification of the Case Threshold Exemptions and Zero Denominator Declaration Policies for Hybrid Measures Beginning With the FY 2026 Payment Determination

In section IX.E.10.f.(4). of the preamble of this proposed rule, we are proposing to modify our case threshold exemptions and zero denominator declaration policies for hybrid measures as we believe they are not applicable for those measure types, beginning with the FY 2026 payment determination and for subsequent years.

In the FY 2020 IPPS/LTCH PPS final rule, we finalized the adoption of the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (Hybrid HWR) (84 FR 42505 through 42508) and in the FY 2022 IPPS/LTCH PPS final rule, we finalized the Hybrid Hospital-Wide Mortality Measure with Claims and Electronic Health Record Data (Hybrid HWM) (86 FR 45508). For each hybrid measure, all IPPS hospitals are required to submit one of three things: Data via QRDA I file, a zero denominator declaration, or a case threshold exemption. Of these three options, submission of data via QRDA I file is the most burden-intensive. For both hybrid measures, our currently approved burden estimates assume data submission via QRDA I file for all IPPS hospitals; therefore, we do not believe this proposal will result in an increase in burden.

k. Information Collection Burden Estimate for the Modification of the eCQM Validation Policy Medical Record Requests Beginning With the FY 2025 Payment Determination

In section IX.E.11.b. of the preamble of this proposed rule, we are proposing to modify our eCQM validation policy to increase the reporting of medical requests from at least 75 percent of records to 100 percent of records beginning with the FY 2025 payment determination and for subsequent years.

In the FY 2017 IPPS/LTCH PPS final rule, we finalized to require submission of at least 75 percent of sampled eCQM medical records in a timely and complete manner (81 FR 57181). While we adopted a policy to require

submission of at least 75 percent of sampled records, we estimated the burden associated with this finalized policy with the assumption that hospitals would submit 100 percent of sampled eCQM medical records (81 FR 57261). Based on this estimate, we believe the currently approved burden already encompasses burden associated with our proposed policy.

l. Information Collection Burden Estimate To Add Reporting and Submission Requirements for PRO–PMs Beginning With the FY 2026 Payment Determination

In section IX.E.10.k. of the preamble of this proposed rule, we are proposing reporting and submission requirements for PRO–PMs beginning with the FY 2026 payment determination. We expect that our policy will not yield a change in burden beyond that which is discussed in section X.B.6.e. of the preamble of this proposed rule for the THA/TKA PRO–PM.

m. Summary of Information Collection Burden Estimates for the Hospital IQR Program

In summary, under OMB control number 0938–1022 (expiration date December 31, 2022), we estimate that the policies promulgated in this proposed rule will result in a total increase of 746,300 hours annually for 3,150 IPPS hospitals from the CY 2023 reporting period/FY 2025 payment determination through the CY 2026 reporting period/FY 2028 payment determination. The total cost increase related to this information collection is approximately $23,437,906. The subsequent tables summarize the total burden changes for each respective FY payment determination compared to our currently approved information collection burden estimates (the table for the FY 2028 payment determination reflects the total burden change associated with all proposals). For the THA/TKA PRO–PM, only one survey would be administered during the CY 2023 reporting period due to the start of reporting occurring in 3Q and the beginning of mandatory reporting would take place in 3Q of the CY 2025 reporting period. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1022 which expires December 31, 2022.

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SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2023 REPORTING PERIOD/FY 2025 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2023 Reporting Period / FY 2025 Payment Determinations							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of respondents reporting**	**Average number records per respondent per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across hospitals**	**Previously finalized annual burden (hours) across hospitals**	**Net difference in annual burden hours**
Add Hospital Commitment to Health Equity Structural Measure	10	1	3,150	1	.167	525	N/A	+525
Add Screening for Social Drivers of Health Measure (Survey)	2	N/A	5,250,000	N/A	111.1	175,000	N/A	+175,000
Add Screening for Social Drivers of Health Measure (Reporting)	10	1	1,575	1	0.167	273	N/A	+263
Add Screen Positive Rate for Social Drivers of Health	10	1	1,575	1	0.167	273	N/A	+263
Add THA/TKA PRO-PM Measure (Survey Completion)	7.25	N/A	1,575	N/A	1.58	2,492	N/A	+2,492
Add THA/TKA PRO-PM Measure (Data Submission)	10	1	1,575	1	0.167	263	N/A	+263
	Total Change in Information Collection Burden Hours: +178,568							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+178,568) = **+$5,602,913**							

SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2024 REPORTING PERIOD/FY 2026 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2024 Reporting Period / FY 2026 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of respondents reporting**	**Average number records per respondent per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across respondents**	**Previously finalized annual burden (hours) across respondents**	**Net difference in annual burden hours**
Add Hospital Commitment to Health Equity Structural Measure	10	1	3,150	1	.167	525	N/A	+525
Add Screening for Social Drivers of Health Measure (Survey)	2	N/A	21,000,000	N/A	222.2	700,000	N/A	+700,000
Add Screening for Social Drivers of Health Measure (Reporting)	10	1	3,150	1	0.167	525	N/A	+525
Add Screen Positive Rate for Social Drivers of Health	10	1	3,150	1	0.167	,525	N/A	+525
Add THA/TKA PRO-PM Measure (Survey)	7.25	N/A	1,575	N/A	4.75	7,477	N/A	+7,477
Add THA/TKA PRO-PM Measure (Reporting)	10	2	1,575	1	0.33	525	N/A	+525
Modify eCQM Reporting	60	4	3,150	1	1	12,600	8,800	+3,800
	Total Change in Information Collection Burden Hours: +713,377							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+713,377) = **+$22,401,251**							

SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/FY 2027 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2025 Reporting Period / FY 2027 Payment Determinations							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of respondents reporting**	**Average number records per respondent per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across respondents**	**Previously finalized annual burden (hours) across respondents**	**Net difference in annual burden hours**
Add Hospital Commitment to Health Equity Structural Measure	10	1	3,150	1	.167	525	N/A	+525
Add Screening for Social Drivers of Health Measure (Survey)	2	N/A	21,000,000	N/A	222.2	700,000	N/A	+700,000
Add Screening for Social Drivers of Health Measure (Reporting)	10	1	3,150	1	0.167	525	N/A	+525
Add Screen Positive Rate for Social Drivers of Health	10	1	3,150	1	0.167	525	N/A	+525
Add THA/TKA PRO-PM Measure – Voluntary Reporting (Survey)	7.25	N/A	1,575	N/A	3.16	4,984	N/A	+4,984
Add THA/TKA PRO-PM Measure – Voluntary Reporting (Reporting)	10	1	1,575	1	0.167	262.5	N/A	+262.5
Add THA/TKA PRO-PM Measure – Mandatory Reporting (Survey)	7.25	N/A	3,150	N/A	6.33	19,938	N/A	+19,938
Add THA/TKA PRO-PM Measure – Mandatory Reporting (Reporting)	10	1	3,150	1	0.33	525	N/A	+525
Modify eCQM Reporting	60	4	3,150	1	1	12,600	8,800	+3,800
	Total Change in Information Collection Burden Hours: +731,084							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+731,084) = **+$22,958,594**							

SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2026 REPORTING PERIOD/FY 2028 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2026 Reporting Period / FY 2028 Payment Determinations							
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of respondents reporting	Average number records per respondent per quarter	Annual burden (hours) per hospital	Proposed annual burden (hours) across respondents	Previously finalized annual burden (hours) across respondents	Net difference in annual burden hours
Add Hospital Commitment to Health Equity Structural Measure	10	1	3,150	1	.167	525	N/A	+525
Add Screening for Social Drivers of Health Measure (Survey)	2	N/A	21,000,000	N/A	222.2	700,000	N/A	+700,000
Add Screening for Social Drivers of Health Measure (Reporting)	10	1	3,150	1	0.167	525	N/A	+525
Add Screen Positive Rate for Social Drivers of Health	10	1	3,150	1	0.167	525	N/A	+525
Add THA/TKA PRO-PM Measure (Survey)	7.25	N/A	3,150	N/A	12.66	39,875	N/A	+39,875
Add THA/TKA PRO-PM Measure (Reporting)	10	2	3,150	1	0.33	1,050	N/A	+1,050
Modify eCQM Reporting	60	4	3,150	1	1	12,600	8,800	+3,800
	Total Change in Information Collection Burden Hours: +746,300							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+746,300) = **+$23,437,906**							

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5. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

OMB has currently approved 0 hours of burden under OMB control number 0938–1175 (expiration date January 31, 2025), accounting for the information collection requirements for 11 PCHs for the FY 2024 program year.

For more detailed information on our proposed policies for the PCHQR Program, we refer readers to section IX.F. of the preamble of this proposed rule. We are proposing to: (1) Adopt and codify a patient safety exemption for the measure removal policy; (2) begin public display of the End-of-Life (EOL) measures beginning with FY 2024 program year data; and (3) begin public display of the 30-Day Unplanned Readmissions for Cancer Patients measure beginning with FY 2024 program year data. We do not expect that any of these proposals will impact our currently approved information collection burden estimates.

6. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section V.I. of the preamble of this proposed rule, we discuss proposed requirements for the Hospital VBP Program. Specifically, in this proposed rule, with respect to quality measures, we are proposing to suppress to suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey and the five healthcare-associated infection (HAI) measures for the FY 2023 program year. We are also proposing to continue requiring hospitals to report data for all measures, including measures we are proposing to suppress for FY 2023. Because the FY 2023 Hospital VBP Program will use data that are also used to calculate quality measures in other programs and Medicare fee-for-service claims data that hospitals are already submitting to CMS for payment purposes, we do not anticipate any change in burden associated with this proposed rule.

7. ICRs Relating to the Hospital-Acquired Condition (HAC) Reduction Program

In this proposed rule, we are not proposing to remove any measures, adopt any new measures into the HAC Reduction Program, or update our validation procedures.[1465] The HAC

[1465] Burden associated with the validation procedures in the HAC Reduction Program are

Continued

Reduction Program has previously adopted six measures: The CMS PSI 90 measure and five CDC NHSN HAI measures. We do not believe that the claims-based CMS PSI 90 measure in the HAC Reduction Program creates additional burden for hospitals because the measure is calculated using the Medicare FFS claims that hospitals have submitted to the Medicare program for payment purposes. Accordingly, we do not believe that our proposed policies in sections V.J.3.c.(1). and V.J.2.b.(2). to increase the minimum volume threshold and suppress the CMS PSI 90 measure from the FY 2023 HAC Reduction program change any information collection burden for hospitals.

We note the burden associated with collecting and submitting data for the HAI measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA bacteremia, and CDI) via the CDC's NHSN system is captured under a separate OMB control number, 0920–0666 (expiration January 1, 2025). As discussed in sections V.J.2.b.(2). and V.J.2.b.(3). of the preamble of this proposed rule, we are proposing to suppress the five NHSN measures, in addition to the claims-based CMS PSI 90 measure, from the FY 2023 HAC Reduction Program. We propose to suppress CY 2021 CDC NHSN HAI data from the FY 2024 program year. Because hospitals would continue to report data for the HAI measures, this proposal would not change information collection burden for hospitals as accounted for under CDC's OMB control number 0920–1066.

In section V.J.7. of the preamble of this proposed rule, we clarify the removal of the No Mapped Locations (NML) policy beginning in FY 2023. Hospitals will be required to appropriately submit data to the NHSN or, if hospitals do not have the applicable locations for the CLABSI and CAUTI measures, the hospital must submit an IPPS Measure Exception Form to be exempt from CLABSI and CAUTI reporting for CMS programs. The burden for all hospitals to submit data to the NHSN is already accounted for under OMB control number 0920–0666, therefore there is no increase in burden for hospitals which submit data as a result of this clarification. In addition, the burden associated with completion of forms (including the IPPS Measure Exception Form) is already accounted for under OMB control number 0938–1022, therefore there is no increase in burden for hospitals which elect to submit this form as a result of this clarification. We are currently assessing whether this clarification will necessitate changes to the IPPS Measure Exception Form, however we believe that if changes are necessary, the change in burden will be negligible and our currently approved burden estimates under OMB control number 0938–1022 are conservative enough to accommodate the change. If the IPPS Measure Exception Form is revised, we will submit the new version for approval under OMB control number 0938–1022.

8. ICRs Relating to the Hospital Readmissions Reduction Program

In section V.H. of the preamble of this proposed rule, we discuss proposed requirements for the Hospital Readmissions Reduction Program. In this proposed rule, we are not proposing to remove or adopt any new measures into the Hospital Readmissions Reduction Program for FY 2023. All six of the current Hospital Readmissions Reduction Program's measures are claims-based measures. We believe that continuing to use these claims-based measures would not create or reduce any information collection burden for hospitals because they will continue to be collected using Medicare FFS claims that hospitals are already submitting to the Medicare program for payment purposes.

9. ICRs for the Promoting Interoperability Program

a. Historical Background

In section IX.H. of the preamble of this proposed rule, we discussed several proposals for the Medicare Promoting Interoperability Program. An information collection request under OMB control number 0938–1278 (expiration date March 31, 2022) reflecting program policies finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45514) is pending approval, which includes an estimated total burden of 21,450 hours and $879,450, accounting for information collection burden experienced by approximately 3,300 eligible hospitals that attest to CMS under the Medicare Promoting Interoperability Program. We will be submitting an updated information collection request under OMB control number 0938–1278 in connection with the proposals in this FY 2023 IPPS/LTCH PPS proposed rule that will reflect the inclusion of CAHs and additional new information pertinent to the collection requirements. The collection of information burden analysis in this proposed rule focuses on all eligible hospitals and CAHs that could participate in the Medicare Promoting Interoperability Program and attest to the objectives and measures, and report eCQMs, under the Medicare Promoting Interoperability Program for the EHR reporting periods in CY 2023, CY 2024, and CY 2025.

For more detailed information on our proposed policies for the Medicare Promoting Interoperability Program, we refer readers to section IX.H. of the preamble of this proposed rule. We are proposing the following changes for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program that we expect to affect our collection of information burden estimates: (1) To require the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program (PDMP) measure beginning in the CY 2023 electronic health record (EHR) reporting period while maintaining its associated points at 10 points and adding exclusions; (2) to adopt a new Antimicrobial Use and Resistance (AUR) Surveillance measure that would be required for eligible hospitals and CAHs under the Medicare Promoting Interoperability Program's Public Health and Clinical Data Exchange Objective with associated exclusions beginning with the CY 2023 EHR reporting period and (3) to require eligible hospitals and CAHs to submit their level of active engagement in addition to submitting responses for the Public Health and Clinical Data Exchange Objective required measures and the optional measures beginning with the CY 2023 EHR reporting period. We are also proposing a modification to our eCQM reporting and submission requirements whereby we are increasing the total number of eCQMs to be reported from four to six eCQMs beginning with the CY 2024 reporting period. Details on these policies as well as the expected burden changes are discussed further in this section of this proposed rule.

We are also proposing several policies which would not affect the information collection burden associated with the Medicare Promoting Interoperability Program. As discussed in section IX.H.10.a.(2) of the preamble to this proposed rule, we are proposing to adopt four eCQMs: (1) Severe Obstetric Complications eCQM beginning with the CY 2023 reporting period, followed by mandatory reporting beginning with the CY 2024 reporting period; (2) Cesarean Birth (ePC–02) eCQM beginning with the CY 2023 reporting period, followed by mandatory reporting beginning with the CY 2024 reporting period; (3) Hospital-Harm—

accounted for under OMB Control Number 0938–1352.

Opioid-Related Adverse Events eCQM beginning with the CY 2024 reporting period; and (4) Global Malnutrition Composite Score eCQM beginning with the CY 2024 reporting period. We are also proposing: (1) To expand the Query of PDMP measure to include Schedule II, III, and IV drugs beginning with the CY 2023 EHR reporting period; (2) to add the Enabling Exchange Under TEFCA measure to the Health Information Exchange Objective as an optional alternative to the three existing measures and to update the scoring methodology for the Health Information Exchange Objective beginning in the CY 2023 EHR reporting period; (3) to reduce the active engagement options for the Public Health and Clinical Data Exchange Objective from three to two options beginning with the CY 2023 EHR reporting period; (4) to modify the scoring methodology for the Medicare Promoting Interoperability Program beginning in the CY 2023 EHR reporting period; (5) to institute public reporting of certain Medicare Promoting Interoperability Program data beginning with data from the CY 2023 EHR reporting period; and (6) to remove regulation text for the objectives and measures under 42 CFR 495.24(e) and add new paragraph (f) beginning in CY 2023.

The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $21.20 per hour for a medical records and health information technician professional.[1466] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in publicly available literature. Nonetheless, we believe that doubling the hourly wage rate ($21.20 × 2 = $42.40) to estimate total cost is a reasonably accurate estimation method and is consistent with OMB guidance. Accordingly, we will calculate cost burden to hospitals using a wage plus benefits estimate of $42.40 per hour throughout the discussion in this section of this rule for the Medicare Promoting Interoperability Program.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45514), our burden estimates were based on an assumption of 3,300 eligible hospitals and CAHs. We have determined that our assumption was in error as we inadvertently omitted the number of CAHs in our estimate. For this proposed rule, we are updating our assumption to 3,150 eligible hospitals and 1,350 CAHs based on data from the CY 2020 EHR reporting period, for a total number of 4,500 respondents. These estimates differ from those of the information collection request under OMB control number 0938–1278 as they are based on updated data from the CY 2020 EHR reporting period and reflect the addition of the number of CAHs. As indicated earlier, an updated information collection request will be submitted with updated numbers inclusive of CAHs. We are making this adjustment to reflect the total number of potential eligible hospitals and CAHs that could report under the Medicare Promoting Interoperability Program.

b. Information Collection Burden Estimate for the Electronic Prescribing Objective's Query of PDMP Measure Beginning With the CY 2023 EHR Reporting Period

In section IX.H.3.c.(2) of the preamble of this proposed rule, we are proposing to require the Query of PDMP measure for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program beginning in CY 2023 and maintain the associated points at 10 points.

In the FY 2020 IPPS/LTCH PPS final rule, we estimated the burden associated with reporting the Electronic Prescribing Objective and associated measures to be 10 minutes (84 FR 42608) coinciding with the finalized change to the Query of PDMP measure to require a ''yes/no'' response instead of a numerator/denominator calculation. However, the burden associated with the Query of PDMP measure was not accounted for in the burden estimate of 10 minutes for the Electronic Prescribing Objective in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42608 through 42609), the FY 2021 IPPS/LTCH PPS final rule (85 FR 59014), or the FY 2022 IPPS/LTCH PPS final rule (86 FR 45516). In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45464), we finalized that the Query of PDMP measure will remain optional. As a result of the proposal to require the Query of PDMP measure beginning with the EHR reporting period in CY 2023, and considering the burden estimate of 30 seconds (0.5 minutes) for similar ''yes/no'' response measures for the Public Health and Clinical Data Exchange Objective as reflected in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45515), we are updating our burden estimate for the Electronic Prescribing Objective to 10.5 minutes to reflect the additional burden of reporting the Query of PDMP measure. Therefore, we estimate a total increase in burden of 38 hours across all eligible hospitals and CAHs (0.5 minutes × 4,500 eligible hospitals and CAHs) annually at a cost of $1,590 (38 hours × $42.40).

In addition, in section IX.H.3.c.(3) of the preamble of this proposed rule, we are proposing expanding the Query of PDMP measure to include Schedule II, III, and IV drugs beginning with the CY 2023 EHR reporting period. We expect that our policy will not yield a change in burden as it does not affect the requirements for data submission for eligible hospitals or CAHs as we continue to assume all eligible hospitals and CAHs would report this measure once per year.

c. Information Collection Burden Estimate for the Antimicrobial Use and Resistance (AUR) Surveillance Measure Beginning With the CY 2023 EHR Reporting Period

In section IX.H.5.b. of the preamble of this proposed rule, we are proposing to require new Antimicrobial Use and Resistance (AUR) Surveillance measure for eligible hospitals and CAHs under the Medicare Promoting Interoperability Program's Public Health and Clinical Data Exchange Objective beginning with the CY 2023 EHR reporting period. Eligible hospitals and CAHs would be required to attest to active engagement with CDC's National Healthcare Safety Network (NHSN) to submit AUR data and receive a report from NHSN indicating their successful submission of AUR data for the EHR reporting period.

In the FY 2022 IPPS/LTCH PPS final rule, we finalized that eligible hospitals and CAHs are required to report four measures for the Public Health and Clinical Data Exchange Objective with a total estimated burden of 2 minutes annually (30 seconds × 4 measures) (86 FR 45516). Therefore, we estimate the burden associated with this new measure to be 30 seconds or 0.5 minutes per eligible hospital or CAH annually. We estimate a total increase in burden of 38 hours across all eligible hospitals and CAHs (0.5 minutes × 4,500 eligible hospitals and CAHs) annually at a cost of $1,611 (38 hours × $42.40).

While the burden associated with attesting to active engagement with NHSN to submit data will be accounted for under OMB control number 0938–1278 (expiration date March 31, 2022), the burden associated with the actual submission of AUR data to NHSN is accounted for under OMB control

[1466] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records and Health Information Technicians. Accessed on January 13, 2022; available at: *https://www.bls.gov/oes/current/oes292098.htm.*

number 0920–0666 (expiration date January 31, 2025).

d. Information Collection Burden Estimate for the Proposal To Require Eligible Hospitals and CAHs To Submit Their Level of Active Engagement for the Public Health and Clinical Data Exchange Objective Beginning With the CY 2023 EHR Reporting Period

In section IX.H.5.c.(3) of the preamble of this proposed rule, we are proposing to require eligible hospitals and CAHs to submit their level of engagement for the measures under the Public Health and Clinical Data Exchange Objective, either Pre-production and Validation or Validated Data Production. This requirement would be in addition to submitting responses for the required measures and the optional measures, if applicable.

We believe the burden associated with this requirement is similar to the burden associated with the attestation that eligible hospitals and CAHs must complete for the four previously finalized measures under this objective and the proposed AUR Surveillance measure. Therefore, we estimate the burden associated with this new requirement to be 30 seconds or 0.5 minutes per eligible hospital or CAH annually. We estimate a total increase in burden of 38 hours across all eligible hospitals and CAHs (0.5 minutes/hospital × 4,500 eligible hospitals and CAHs) annually at a cost of $1,611 (38 hours × $42.40).

In addition, in section IX.H.c.(2) of the preamble of this proposed rule, we are proposing to reduce the active engagement options for the Public Health and Clinical Data Exchange Objective from three to two options beginning with the CY 2023 EHR reporting period and require eligible hospitals and CAHs to spend only one EHR reporting period at the pre-production and validation phase. We expect that our policy will not yield a change in burden as it does not affect the requirements for data submission for eligible hospitals or CAHs but instead will motivate EHR vendors to implement these capabilities in their products and encourage healthcare organizations to engage in these reporting activities.

e. Information Collection Burden Estimate for the Modification of the eCQM Reporting and Submission Requirements Beginning With the CY 2024 Reporting Period

In section IX.H.10.b of the preamble of this proposed rule, we are proposing a modification to our eCQM reporting and submission requirements whereby we would increase the total number of eCQMs to be reported from four to six eCQMs beginning with the CY 2024 reporting period. We are also proposing that the six eCQMs must be comprised of: (1) Three self-selected eCQMs; (2) the Safe Use of Opioids—Concurrent Prescribing eCQM; (3) the proposed Severe Obstetric Complications eCQM; and (4) the proposed Cesarean Birth eCQM, for a total of six eCQMs.

We previously finalized in the FY 2021 IPPS/LTCH PPS final rule that, for the CY 2023 reporting period, eligible hospitals and CAHs are required to submit data for three self-selected eCQMs each year and the Safe Use of Opioids-Concurrent Prescribing eCQM for a total of four eCQMs (85 FR 58975). We also finalized in the FY 2021 IPPS/LTCH PPS final rule to require eligible hospitals and CAHs to submit four quarters of eCQM data beginning in the CY 2023 reporting period (85 FR 58975). We continue to estimate the information collection burden associated with the eCQM reporting and submission requirements to be 10 minutes per measure per quarter. As discussed in the section IX.E.4.f. of the preamble of this proposed rule, we already account for the burden associated with the reporting of eCQM measures for eligible hospitals as part of the Hospital Inpatient Quality Reporting program, therefore the burden for the 3,150 eligible hospitals is included there. For the submission of six eCQM measures for CAHs, we estimate a total of 1 hour (0.167 hours/eCQM × 6 eCQMs) per CAH per quarter. We estimate a total burden of 1,350 hours across all CAHs (1 hour × 1,350 CAHs) for each quarter of eCQM data or 5,400 hours annually (1,350 hours × 4 quarters) at a cost of $228,960 (5,400 hours × $42.40).

f. Information Collection Burden Estimate for the Adoption of Two eCQMs Beginning With the CY 2023 Reporting Period and Two eCQMs Beginning With the CY 2024 Reporting Period

In section IX.H.10.a. of the preamble of this proposed rule, we are proposing to adopt four eCQMs: (1) Severe Obstetric Complications eCQM beginning with the CY 2023 reporting period, followed by mandatory reporting beginning with the CY 2024 reporting period; (2) Cesarean Birth (ePC–02) eCQM beginning with the CY 2023 reporting period, followed by mandatory reporting beginning with the CY 2024 reporting period; (3) Hospital-Harm—Opioid-Related Adverse Events eCQM beginning with the CY 2024 reporting period; and (4) Global Malnutrition Composite Score eCQM beginning with the CY 2024 reporting period.

We do not believe that these proposals to add four eCQMs would affect the information collection burden of submitting eCQMs under the Medicare Promoting Interoperability Program beyond the burden described in section IX.B.4.f. of the preamble of this proposed rule. Current Medicare Promoting Interoperability Program policy requires hospitals to submit data for three self-selected eCQMs each year and the Safe Use of Opioids—Concurrent Prescribing eCQM for a total of four eCQMs (85 FR 58975). In other words, while these proposals would result in new eCQMs being added to the eCQM measure set, hospitals would not be required to report more than a total of four eCQMs as is currently required (84 FR 42603) or six eCQMs if the proposal discussed in section IX.10. of the preamble of this proposed rule is finalized.

With respect to any costs unrelated to data submission, we refer readers to section I.K. of Appendix A of this proposed rule.

g. Information Collection Burden Estimate for the Proposal To Add the Enabling Exchange Under TEFCA Measure to the Health Information Exchange Objective Beginning With the CY 2023 EHR Reporting Period

In section IX.H.4.c. of the preamble of this proposed rule, we are proposing to add the Enabling Exchange Under TEFCA measure to the Health Information Exchange Objective as an optional alternative to the three existing measures (Support Electronic Referral Loops by Sending Health Information measure, Support Electronic Referral Loops by Receiving and Reconciling Health Information measure, and the HIE Bi-Directional Exchange measure) and to update the scoring methodology for the Health Information Exchange Objective beginning with the CY 2023 EHR reporting period. We expect that our policy will not yield a change in burden as eligible hospitals and CAHs may choose to report the two Support Electronic Referral Loop measures, or may choose to report the HIE Bi-Directional Exchange measure, or may choose to report the proposed new Enabling Exchange Under TEFCA measure.

h. Information Collection Burden Estimate for the Proposal To Modify the Scoring Methodology for the Medicare Promoting Interoperability Program Beginning With the CY 2023 EHR Reporting Period

In section IX.H.6. of the preamble of this proposed rule, we are proposing the following changes to the scoring methodology:

- Increasing the points allocated to the Public Health and Clinical Data Exchange Objective from 10 points to 25 points.
- Increasing the points allocated to the Electronic Prescribing Objective from 10 points to 20 points.
- Decreasing the points allocated to the Health Information Exchange Objective from 40 points to 30 points.
- Decreasing the points allocated to the Provide to Patient Exchange Objective from 40 points to 25 points.

We expect that our policy will not yield a change in burden as it does not affect the requirements for data submission for eligible hospitals or CAHs but only changes the scoring methodology.

i. Information Collection Burden Estimate for the Proposal To Institute Public Reporting of Medicare Promoting Interoperability Program Data Beginning With Data From the CY 2023 EHR Reporting Period

In section IX.H.7. of the preamble of this proposed rule, we are proposing to publicly report certain Medicare Promoting Interoperability Program data submitted by eligible hospitals and CAHs beginning with CY 2023 EHR reporting period. Specifically, we are proposing to publish eligible hospitals' and CAHs' final scores and the CMS EHR certification ID, beginning with data submitted for the CY 2023 EHR reporting period. We expect that our policy will not yield a change in burden as it does not affect the requirements for data submission for eligible hospitals or CAHs.

j. Information Collection Burden Estimate for Proposed Modifications to Regulatory Text

In section IX.H.8. of the preamble of this proposed rule, we are proposing remove references to objectives and measures and to make modifications to regulatory text at 42 CFR 495.24 beginning in CY 2023. We expect that our policy will not yield a change in burden as it does not affect the requirements for data submission for eligible hospitals or CAHs since the changes only seek to modify regulatory text.

k. Summary of Estimates Used To Calculate the Collection of Information Burden

In summary, under OMB control number 0938–1278 (expiration date March 31, 2022), we estimate that the policies proposed in this proposed rule will result in a total increase in burden of 5,513 hours through the CY 2024 EHR reporting period. The total cost increase related to this information collection is approximately $233,730 (5,513 hours × $42.40) across 4,500 eligible hospitals and CAHs. The tables summarize the total burden changes for CY 2023 and for CY 2024 EHR reporting periods compared to our currently approved information collection burden estimates (the table for the CY 2024 EHR reporting period reflects the total burden change associated with all proposals).

In the FY 2022 IPPS/LTCH PPS final rule, we estimated each eligible hospital and CAH would require 6.5 hours annually to participate in the Medicare Promoting Interoperability Program (86 FR 45517). As a result of the policies in this proposed rule, we estimate the new total annual burden to be 6.6 hours per eligible hospital and CAH as well as an additional 4 hours annually for CAHs to report eCQMs. Therefore, we estimate the adjustment in the number of eligible hospitals and CAHs from 3,300 to 4,500 results in an increase of approximately +13,290 hours ((6.6 hours × −150 eligible hospitals) + (10.6 hours × 1,350 CAHs)) at a cost of +$563,496 (+13,290 hours × $42.40).

We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1278 (expiration date March 31, 2022).

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SUMMARY OF ANNUAL MEDICARE PROMOTING INTEROPERABILITY PROGRAM INFORMATION COLLECTION BURDEN CHANGES FOR THE CY 2023 EHR REPORTING PERIOD

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1278							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of eligible hospitals/CAHs reporting**	**Average number records per eligible hospital or CAH per quarter**	**Annual burden (hours) per eligible hospital/ CAH**	**Proposed annual burden (hours) across eligible hospitals/CAHs**	**Previously finalized annual burden (hours) across eligible hospitals/CAHs**	**Net difference in annual burden hours**
Require Query of PDMP measure	0.5	1	4,500	1	0.0083	37.5	N/A	+37.5
Add Antimicrobial Use and Resistance (AUR) Surveillance measure	0.5	1	4,500	1	0.0083	37.5	N/A	+37.5
Require Active Engagement Reporting	0.5	1	4,500	1	0.0083	37.5	N/A	+37.5
	Total Change in Information Collection Burden Hours: +113							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (+113) = **+$4,770**							

SUMMARY OF ANNUAL MEDICARE PROMOTING INTEROPERABILITY PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2024 EHR REPORTING PERIOD

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1278							
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of eligible hospitals/CAHs reporting	Average number records per hospital or CAH per quarter	Annual burden (hours) per eligible hospital/CAH	Proposed annual burden (hours) across eligible hospitals/CAHs	Previously finalized annual burden (hours) across eligible hospitals/CAHs	Net difference in annual burden hours
Require Query of PDMP measure	0.5	1	4,500	1	0.0083	37.5	N/A	+37.5
Add Antimicrobial Use and Resistance (AUR) Surveillance measure	0.5	1	4,500	1	0.0083	37.5	N/A	+37.5
Require Active Engagement Reporting	0.5	1	4,500	1	0.0083	37.5	N/A	+37.5
Modify eCQM Reporting	20	4	1,350	1	1.33	5,400	N/A	+5,400
	Total Change in Information Collection Burden Hours: +5,513							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (+5,513) = **+$233,730**							

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10. ICRs for the Proposed Codification of the Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans

As discussed in section X.A. of the preamble of this proposed rule, we are proposing to codify and clarify certain policies relating to Deferred Compensation. This proposal would not change our current policies for allowable Deferred Compensation costs associated with Qualified and Non-Qualified Deferred Compensation Plans that are included in Medicare cost reports. The proposed documentation requirements would require that a provider of services must maintain and make available to its contractor and CMS, documentation to substantiate the costs incurred for the plans included in its Medicare cost report. These proposed documentation requirements are based on the recordkeeping requirements at current § 413.20, which require providers of services to maintain sufficient financial records and statistical data for proper determination of costs payable under Medicare. The OMB control number for this information collection request is 0938–0050, which expired on March 31, 2022. A reinstatement of the information collection request is currently being developed. The public will have an opportunity to review and submit comments on the reinstatement through a public notice and comment period separate from this rulemaking.

11. ICRs for Condition of Participation (CoP) Requirements for Hospitals and CAHs To Report Data Elements To Address Any Future Pandemics and Epidemics as Determined by the Secretary

a. Continued COVID–19 and Seasonal Influenza-Related Reporting

We are proposing to revise the regulations by adding provisions to the CoPs (§ 482.42 for hospitals and § 485.640 for CAHs) requiring hospitals and CAHs, after the conclusion of the current COVID–19 PHE, to continue COVID–19 and seasonal influenza-related reporting. The proposed revisions would continue to apply upon conclusion of the COVID–19 Public Health Emergency (PHE) and would continue until April 30, 2024, unless the Secretary establishes an earlier ending date. The proposed data elements align closely with those COVID–19 reporting requirements for long-term care (LTC) facilities that were finalized on November 9, 2021 (86 FR 62421) and are representative of the guidance provided to hospitals and CAHs for reporting. Therefore, we do not expect that these categories of data elements would require hospitals and CAHs to report any information beyond that which they have already been reporting. Furthermore, similar to the requirements for LTC facilities, this proposal would also allow for the scope and frequency of data collection to be reduced and limited responsive to the evolving clinical and epidemiological circumstances.

For purposes of burden estimates, we do not differentiate among hospitals and CAHs as they all would complete the same data collection.

For the estimated costs contained in the analysis below, we used data from the U.S. Bureau of Labor Statistics (BLS) to determine the mean hourly wage for

the staff member responsible for reporting the required information for a hospital (or a CAH).[1467] Based on our experience with hospitals and CAHs and the current COVID–19 and related reporting requirements, we believe that this will primarily be the responsibility of a registered nurse and we have used this position in this analysis at an average hourly salary of $39.27. For the total hourly cost, we doubled the mean hourly wage for a 100 percent increase to cover overhead and fringe benefits, according to standard HHS estimating procedures. If the total cost after doubling resulted in 0.50 or more, the cost was rounded up to the next dollar. If it was 0.49 or below, the total cost was rounded down to the next dollar. Therefore, we estimated the total hourly cost for a registered nurse to perform these duties would be $79.

According to the most recent COVID–19 hospital reporting guidance (available at *https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf*), hospitals are reporting COVID–19 and influenza-related data on a daily basis, with backdating permitted for weekends and holidays, except psychiatric and rehabilitation hospitals who report weekly. Some data element reporting fields are inactive for data collection, and therefore, hospitals can optionally report data for these fields. The inactive fields and active fields together reflect what is listed in this proposed rule for continued COVID–19 and influenza-related reporting as well as future reporting in the event of a declared PHE, which we discuss next. We do not expect, nor have we proposed, continued daily reporting for COVID–19 or influenza outside of a declared PHE. If we were to assume a weekly reporting frequency, we would anticipate that there are reduced cases and fewer data elements (with no line level patient data) being reported. Based on these assumptions, we estimate that total annual burden hours for all participating hospitals and CAHs to comply with these requirements would be 483,600 hours based on weekly reporting of the required information by approximately 6,200 hospitals and CAHs × 52 weeks per year and at an average weekly response time of 1.5 hours for a registered nurse with an average hourly salary of $79. Therefore, the estimate for total annual costs for all hospitals and CAHs to comply with the required reporting provisions weekly would be $38,204,400 or approximately $6,162 per facility annually. We acknowledge that the data elements and reporting frequency could increase or decrease over the next two years, and those changes would impact this burden estimate.

We note that this estimate is assumed to be a one-day snapshot of reporting information as opposed to a cumulative weekly report accounting for information based on each day of that week. If we assumed a cumulative weekly account, we can assume reduced burden related to the actual reporting time, but anticipate that the estimate would be slightly higher to account for the need to track closely to daily reporting. We also acknowledge that respondents may have to track and invest in infrastructure in order to timely and accurately report on the specified frequency. Thus, respondents may face ongoing burdens associated with this collection even in the case of reduced frequency of submissions. We solicit comment on this potentiality.

Furthermore, we note that this estimate likely overestimates the costs associated with reporting because it assumes that all hospitals and CAHs will report manually. Efforts are underway to automate hospital and CAH reporting that have the potential to significantly decrease reporting burden and improve reliability. Our preliminary estimates for these reporting activities (OMB control numbers 0938–0328 for hospitals and 0938–1043 for CAHs) can be found in the tables that follow.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent (low range – high range)	Average Burden per Response (in hours)	Total Burden Hours (low range – high range)
Hospitals and CAHs	CDC's NHSN or other CDC-supported surveillance systems	6,200	52	1.5	483,600
Total					483,600

ESTIMATED ANNUALIZED RESPONDENT BURDEN COSTS

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Hospital and CAH Staff—Registered Nurses	483,600	* $79	$38,204,400
Total			$38,204,000

b. Future Reporting in the Event of a PHE Declaration

In addition, we are proposing to establish reporting requirements for future PHEs related to epidemics and pandemics by requiring hospitals and CAHS to electronically report information on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection), SARS–CoV–2/COVID–19, and other viral and bacterial pathogens or infectious diseases of pandemic or epidemic potential only when the Secretary has declared a PHE directly related to such specific pathogens and

[1467] BLS. *May 2020 National Occupational Employment and Wage Estimates United States.* United States Department of Labor. Accessed at *https://www.bls.gov/oes/current/oes_nat.htm.* Accessed on August 25, 2021.

infectious diseases. Specifically, when the Secretary has declared a PHE, we propose to require hospitals and CAHs to report specific data elements to the CDC's National Health Safety Network (NHSN), or other CDC-supported surveillance systems, as determined by the Secretary. The proposed requirements of this section would apply to local, state, and national PHEs as declared by the Secretary. Relevant to the declared PHE, the categories of data elements that this report would include are as follows: Suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff; total deaths attributed to the relevant infectious disease pathogen among patients and staff; personal protective equipment and other relevant supplies in the facility; capacity and supplies in the facility relevant to the immediate and long term treatment of the relevant infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies; total hospital bed and intensive care unit bed census, capacity, and capability; staffing shortages; vaccine administration status of patients and staff for conditions monitored under this section and where a specific vaccine is applicable; relevant therapeutic inventories and/or usage; isolation capacity, including airborne isolation capacity; and key co-morbidities and/or exposure risk factors of patients being treated for the pathogen or disease of interest in this section that are captured with interoperable data standards and elements.

We are also proposing to require that, unless the Secretary specifies an alternative format by which a hospital (or a CAH) must report each applicable infection (confirmed and suspected) and the applicable vaccination data in a format that provides person-level information, to include medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients, unless the Secretary specifies an alternative format by which the hospital (or CAH) would be required report these data elements. We are also proposing in this provision to limit any person-level, directly or potentially individually identifiable, information for affected patients and staff to items outlined in this section or otherwise specified by the Secretary. We note that the provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Section 304, 306, and 308(d) of the Public Health Service Act (42 U.S.C. 242b, 242k, and 242m(d)). Lastly, we are proposing that a hospital (or a CAH) would provide the information specified on a daily basis, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) or other CDC-supported surveillance systems as determined by the Secretary.

For purposes of this burden collection, we acknowledge the unknown and the ongoing burdens that may exist even if CMS is not collecting information outside of a declared PHE. We recognize that considerations such as building and maintaining the infrastructure to support readiness are necessary to ensure compliance with this requirement. Therefore, we are soliciting comment on the burden associated with these proposed requirements given the intended flexibility provided in reducing or limiting the scope and frequency of reporting based on the state of the PHE and ongoing circumstances. We are specifically asking for comment on the potential burden associated with the proposed reporting requirements as they might relate to any differences in the public health response to one specific pathogen or infectious disease versus another that would be directly related to the declared PHE. We are also interested in public comments addressing burden estimates (and the potential differences in those estimates) for variations in the required reporting response for a local PHE versus a regional PHE versus a national PHE that might be declared by the Secretary based on the specific circumstances at the time of the declaration.

CMS will pursue an emergency collection of information in the case of a declared PHE and use such burden estimate to inform its approach at that time. CMS will also publish an accompanying **Federal Register** Notice concurrent with its submission of a request to collect information, in addition to all other actions consistent with 5 CFR 1320.13. CMS commits to ensuring that respondents are well aware in advance of the intention to collect such information and solicits comment on the appropriate timeline and notification process for such actions.

12. Summary of All Burden in This Proposed Rule

The following chart reflects the total burden and associated costs for the ICRs presented in this section of this proposed rule.

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Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Hospital Wage Index	0	0
Payment for Low-Volume Hospitals	0	0
Hospital Inpatient Quality Reporting Program	+746,300	+$23,437,906
PPS-Exempt Cancer Hospital Quality Reporting Program	0	$0
Hospital Value-Based Purchasing Program	0	$0
Hospital-Acquired Condition Reduction Program	0	$0
Hospital Readmissions Reduction Program	0	$0
Medicare Promoting Interoperability Program	+13,290	+$563,496
Long Term Care Hospital Quality Reporting Program	0	0
Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans	0	0
CoP Requirements for Hospitals and CAHs to Report Data Elements to Address Any Future Pandemics and Epidemics	+483,600	$38,204,000
TOTAL	**=1,243,190**	**=$62,205,402**

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C. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 8, 2022.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 412.24 is amended by adding paragraph (d)(3)(iii) to read as follows:

§ 412.24 Requirements under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.

* * * * *

(d) * * *

(3) * * *

(iii) *Patient safety exception.* Upon a determination by CMS that the continued requirement for PCHs to submit data on a measure raises specific patient safety concerns, CMS may elect to immediately remove the measure from the PCHQR measure set. CMS will, upon removal of the measure—

(A) Provide notice to PCHs and the public at the time CMS removes the measure, along with a statement of the specific patient safety concerns that would be raised if PCHs continued to submit data on the measure; and

(B) Provide notice of the removal in the **Federal Register**.

* * * * *

■ 3. Section 412.60 is amended by revising paragraph (b) to read as follows:

§ 412.60 DRG classification and weighting factors.

* * * * *

(b) *DRG weighting factors.* CMS assigns, for each DRG, an appropriate weighting factor that reflects the estimated relative cost of hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups, subject to a maximum ten percent reduction to the weighting factor for a DRG as compared to the weighting factor for the same DRG for the prior fiscal year.

* * * * *

■ 4. Section 412.64 is amended by adding paragraph (h)(7) to read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(h) * * *

(7) Beginning with fiscal year 2023, if CMS determines that a hospital's wage index value for a fiscal year would decrease by more than 5 percent as compared to the hospital's wage index value for the prior fiscal year, CMS limits the decrease to 5 percent for the fiscal year.

* * * * *

■ 5. Section 412.103 is amended by adding paragraph (a)(8) to read as follows:

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

(a) * * *

(8) For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at § 413.65 of this chapter as a main campus and a remote location of a hospital, approved rural reclassification status applies to the main campus and any remote location located in an urban area (as defined in § 412.64(b) and including a main campus or any remote location deemed urban under section 1886(d)(8)(B) of the Act).

* * * * *

■ 6. Section 412.106 is amended by—

■ a. Revising paragraphs (b)(4) introducotry text and (b)(4)(i) and (ii);

■ b. Redesignating paragraphs (b)(4)(iii) and (iv) as paragraphs (b)(4)(iv) and (v), respectively;

■ c. Adding a new paragraph (b)(4)(iii);

■ d. Revising paragraph (g)(1)(ii);

■ e. In paragraph (g)(1)(iii)(C)(*8*), removing the phrase ''For each subsequent fiscal year,'' and adding in its place the phrase ''For fiscal year 2022,'';

■ f. Adding paragraphs (g)(1)(iii)(C)(*10*) and (*11*);

■ g. Redesignating paragraph (h) as paragraph (i); and

■ h. Adding a new paragraph (h).

The revisions and additions read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(b) * * *

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for patients who were not entitled to Medicare Part A, but who were eligible for Medicaid on such days as described in paragraph (b)(4)(i) of this section or who were regarded as eligible for Medicaid on such days and the Secretary has determined to include such patient days in this computation as described in paragraph (b)(4)(ii)(A) or (B) of this section, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is eligible for Medicaid on a given day if the patient is eligible for inpatient hospital services under a State Medicaid plan approved under Title XIX of the Act on that day, regardless of whether particular items or services were covered or paid for on that day under the State plan.

(ii) For purposes of this computation, a patient is regarded as eligible for Medicaid on a given day if the patient

receives on that day health insurance authorized by a demonstration approved by the Secretary under section 1115(a)(2) of the Act where the cost of such health insurance may be counted as expenditures under section 1903 of the Act, or the patient has on that day health insurance purchased using premium assistance received through a demonstration approved by the Secretary under section 1115(a)(2) of the Act where the premium assistance covers all or substantially all of the cost of the health insurance and the cost of the premium assistance may be counted as expenditures under section 1903 of the Act. Of these patients regarded as eligible for Medicaid on a given day, only the days of patients meeting the following criteria on that day may be counted in this second computation:

(A) Patients who are provided by a demonstration authorized under section 1115(a)(2) of the Act health insurance that provides essential health benefits (EHB) as set forth in subpart C of part 440 of this chapter for an Alternative Benefit Plan; or

(B) Patients who have health insurance that provides EHB as set forth in subpart C of part 440 of this chapter for an Alternative Benefit Plan purchased using premium assistance provided by a demonstration authorized under section 1115(a)(2) of the Act and the premium assistance accounts for at least 90 percent of the cost of the health insurance.

(iii) Patients whose health care costs, including inpatient hospital care costs, for a given day are claimed for payment by a provider from an uncompensated, undercompensated, or other type of funding pool authorized under section 1115(a) of the Act to fund providers' uncompensated care costs are not regarded as eligible for Medicaid for purposes of paragraph (b)(4)(ii) of this section on that day and the days of such patients may not be included in this second computation.

* * * * *

(g) * * *

(1) * * *

(ii) *Factor 2.* (A) For each of fiscal years 2014, 2015, 2016, and 2017, a factor equal to 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured (and subtracting from the factor 0.1 percentage point for fiscal year 2014 and 0.2 percentage point for each of fiscal years 2015, 2016, and 2017), as determined by comparing—

(*1*) 18 percent, the percent of such individuals who are uninsured in 2013, based on the March 20, 2010, estimate of the ''Insured Share of the Nonelderly Population Including All Residents'' by the Congressional Budget Office.

(*2*) The percent of such individuals who are uninsured in the applicable fiscal year, based on the most recent estimate of the ''Insured Share of the Nonelderly Population Including All Residents'' by the Congressional Budget Office available at the time of development of the annual final rule for the hospital inpatient prospective payment system.

(B) For FY 2018 and subsequent fiscal years, a factor equal to 1 minus the percent change in the percent of individuals who are uninsured (and subtracting from the factor 0.2 percentage point for each of fiscal years 2018 and 2019), as determined by comparing the percent of individuals who are uninsured in—

(*1*) 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of the CMS); and

(*2*) The most recent period for which data is available (as so estimated and certified).

(iii) * * *

(C) * * *

(*10*) For fiscal year 2023, for all eligible hospitals, CMS will base its estimates of the amount of hospital uncompensated care on data on uncompensated care costs, defined as charity care costs plus non-Medicare and non-reimbursable Medicare bad debt costs from cost reports from the two most recent cost reporting years for which audits have been conducted. If a hospital is a new hospital (that is, a hospital that began participation in the Medicare program after the two most recent cost reporting years for which audits have been conducted) or if the hospital is treated as a new hospital for purposes of Factor 3, the Medicare Administrative Contractor (MAC) will determine Factor 3 as the ratio of the hospital's uncompensated care costs from its FY 2023 cost report to the sum of uncompensated care costs for all DSH-eligible hospitals as estimated by CMS from the most recent cost reporting year for which audits have been conducted.

(*11*) For fiscal year 2024 and subsequent fiscal years, for all eligible hospitals, CMS will base its estimates of the amount of hospital uncompensated care on data on uncompensated care costs, defined as charity care costs plus non-Medicare and non-reimbursable Medicare bad debt costs from cost reports from the three most recent cost reporting years for which audits have been conducted. If a hospital is a new hospital (that is, a hospital that began participation in the Medicare program after the three most recent cost reporting years for which audits have been conducted) or if the hospital is treated as a new hospital for purposes of Factor 3 in this paragraph (g)(1)(iii), the MAC will determine Factor 3 as the ratio of the hospital's uncompensated care costs from its cost report for the applicable fiscal year to the sum of uncompensated care costs for all disproportionate share hospital (DSH)-eligible hospitals as estimated by CMS from the most recent cost reporting year for which audits have been conducted.

(h) *Supplemental payment for Indian Health Service and Tribal hospitals and Puerto Rico hospitals.* (1) For fiscal year 2023 and each subsequent fiscal year, Indian Health Service and Tribal Hospitals and Puerto Rico hospitals that qualify for an additional payment for uncompensated care under paragraph (g) of this section for the applicable fiscal year may also qualify to receive a supplemental payment.

(2) Indian Health Service and Tribal Hospitals and Puerto Rico hospitals that do not have a Factor 3 amount for fiscal year 2022 determined under paragraph (g)(1)(iii)(C)(*9*) of this section are not eligible to receive a supplemental payment under this paragraph (h).

(3) The amount of the supplemental payment for a fiscal year is determined as the difference between the following:

(i) A base year amount defined as the FY 2022 uncompensated care payment determined for the hospital, in accordance with paragraph (g)(1) of this section, adjusted by 1 plus the percent change in the aggregate amount of uncompensated care payments as estimated by CMS in accordance with paragraphs (g)(1)(i) and (ii) of this section between fiscal year 2022 and the applicable fiscal year. If the hospital did not qualify for an additional payment for uncompensated care under paragraph (g) of this section for fiscal year 2022, CMS uses the Factor 3 determined for the hospital under paragraph (g)(1)(iii)(C)(*9*) of this section to estimate the amount of the additional payment for uncompensated care that the hospital would have received in fiscal year 2022 if the hospital had qualified for an additional payment for uncompensated care under paragraph (g)(1) of this section for that fiscal year.

(ii) The additional payment for uncompensated care determined for the hospital for the applicable fiscal year, in accordance with paragraph (g)(1) of this section.

(4) If the base year amount under paragraph (h)(3)(i) of this section is equal to or lower than the additional

payment for uncompensated care determined for the hospital for the applicable fiscal year in accordance with paragraph (g)(1) of this section, the hospital will not receive a supplemental payment under paragraph (h) of this section for that fiscal year.

* * * * *

§ 412.140 [Amended]

■ 7. Section 412.140 is amended in paragraph (d)(2)(ii) by removing the phrase ''at least 75 percent'' and adding in its place the phrase ''100 percent''.

■ 8. Section 412.168 is amended by—

■ a. Revising the section heading;

■ b. In paragraph (a), removing the phrase ''for the fiscal year 2022'' and adding in its place ''for each of fiscal years 2022 and 2023''; and

■ c. By adding paragraphs (g) through (k).

The revision and additions read as follows:

§ 412.168 Special rules for FY 2022 and FY 2023.

* * * * *

(g) CMS calculates a measure rate for all measures selected under § 412.164(a) for fiscal year 2023 but only applies § 412.165(a) to the measures included in the Clinical Outcomes Domain and the Efficiency and Cost Reduction Domain for that fiscal year, which are the following:

(1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (MORT–30–AMI).

(2) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization (MORT–30–HF).

(3) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT–30–PN (updated cohort)).

(4) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (MORT–30–COPD).

(5) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (MORT–30–CABG).

(6) Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (COMP–HIP–KNEE).

(7) Medicare Spending Per Beneficiary (MSPB)—Hospital.

(h) CMS calculates—

(1) A Clinical Outcomes Domain score for fiscal year 2023 for hospitals that report the minimum number of cases and measures with respect to the measures described in paragraphs (g)(1) through (6) of this section; and

(2) An Efficiency and Cost Reduction Domain score for fiscal year 2023 for hospitals that report the minimum number of cases with respect to the measure described in paragraph (g)(7) of this section.

(i) CMS does not award a Total Performance Score to any hospital for fiscal year 2023.

(j) The total amount available for value-based incentive payments for fiscal year 2023 is equal to the total amount of base-operating DRG payment reductions for that fiscal year, as estimated by the Secretary.

(k) CMS awards a value-based incentive payment percentage (as defined in § 412.160) for fiscal year 2023 to all hospitals to ensure that each hospital receives a value-based incentive payment amount equal to the amount of the reduction made to its base-operating DRG payment amounts.

■ 9. Section 412.273 is amended by revising paragraphs (d)(2) and (e) to read as follows:

§ 412.273 Withdrawing an application, terminating an approved 3-year reclassification, or canceling a previous withdrawal or termination.

* * * * *

(d) * * *

(2) *Timing and process of cancellation request.* Cancellation requests must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB no later than the deadline for submitting reclassification applications for the following fiscal year, as specified in § 412.256(a)(2).

* * * * *

(e) *Written request only.* (1) A request to withdraw an application must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB by all hospitals that are party to the application.

(2) A request to terminate an approved reclassification must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB by an individual hospital or by an individual hospital that is party to a group classification.

* * * * *

■ 10. Section 412.515 is revised to read as follows:

§ 412.515 LTC–DRG weighting factors.

(a) For each LTC–DRG, CMS assigns an appropriate weight that reflects the estimated relative cost of hospital resources used within that group compared to discharges classified within other groups.

(b)(1) Beginning FY 2023, each LTC–DRG weight is subject to a maximum 10 percent reduction as compared to the weight for the same LTC–DRG for the prior fiscal year, except as provided in paragraph (b)(2) of this section.

(2) The limitation described in paragraph (b)(1) of this section does not apply to no-volume LTC–DRGs.

■ 11. Section 412.525 is amended by revising paragraph (c)(1) to read as follows:

§ 412.525 Adjustments to the Federal prospective payment.

* * * * *

(c) * * *

(1) The labor portion of a long-term care hospital's Federal prospective payment is adjusted to account for geographical differences in the area wage levels using an appropriate wage index (established by CMS), which reflects the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined in accordance with the definitions set forth in § 412.503) of the hospital compared to the national average level of hospital wages and wage-related costs.

(i)(A) The appropriate wage index that is established by CMS is updated annually.

(B) Beginning in fiscal year 2023, if CMS determines that an LTCH's wage index value for a fiscal year would decrease by more than 5 percent as compared to the LTCH's wage index value for the prior fiscal year, CMS limits the decrease to 5 percent for the fiscal year.

(ii) The labor portion of a long-term care hospital's Federal prospective payment is established by CMS and is updated annually.

* * * * *

■ 12. Section 412.529 is amended by revising paragraphs (d)(4)(ii)(B) and (d)(4)(iii)(B) to read as follows:

§ 412.529 Special payment provision for short-stay outliers.

* * * * *

(d) * * *

(4) * * *

(ii) * * *

(B)(*1*) Is adjusted for different area wage levels based on the geographic classifications set forth at § 412.503 and the applicable hospital inpatient prospective payment system (IPPS) labor-related share, using the applicable hospital inpatient prospective payment system wage index value for nonreclassified hospitals (an LTCH's applicable IPPS wage index).

(*2*) Beginning in fiscal year 2023, if CMS determines that an LTCH's applicable IPPS wage index value for a fiscal year would decrease by more than

5 percent as compared to the LTCH's applicable IPPS wage index value for the prior fiscal year, CMS limits the decrease to 5 percent for the fiscal year.

(*3*) For LTCHs located in Alaska and Hawaii, the amount specified in paragraph (d)(4)(ii) of this section is also adjusted by the applicable hospital inpatient prospective payment system cost of living adjustment factors.

* * * * *

(iii) * * *

(B)(*1*) Is adjusted for the applicable geographic adjustment factors, including local cost variation based on the geographic classifications set forth at § 412.503 and the applicable full hospital inpatient prospective payment system (IPPS) wage index value for nonreclassified hospitals (an LTCH's applicable IPPS wage index) and applicable cost of living adjustment factors for LTCHs in Alaska and Hawaii.

(*2*) Beginning in fiscal year 2023, if CMS determines that an LTCH's applicable IPPS wage index value for a fiscal year would decrease by more than 5 percent as compared to the LTCH's applicable IPPS wage index value for the prior fiscal year, CMS limits the decrease to 5 percent for the fiscal year.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 13. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 14. Section 413.75 is amended in paragraph (b) by adding in alphabetical order the definitions of ''Rural track Medicare GME affiliated group'' and ''Rural track Medicare GME affiliation agreement'' to read as follows:

§ 413.75 Direct GME payments: General requirements.

* * * * *

(b) * * *

Rural track Medicare GME affiliated group means an urban hospital and a rural hospital that—

(i) Participate in a rural track program defined in this paragraph (b);

(ii) Have rural track FTE limitations in effect prior to October 1, 2022; and

(iii) Comply with the regulations at § 413.79(f)(1) through (6) for Medicare GME affiliated groups.

Rural track Medicare GME affiliation agreement means a written, signed, and dated agreement by responsible representatives of each respective hospital in a rural track Medicare GME affiliated group, as defined in this paragraph (b), that specifies all of the following:

(i) A statement attesting that each participating hospital's FTE counts and rural track FTE limitations in the agreement do not reflect FTE residents nor FTE caps associated with programs other than the rural track program.

(ii) The term of the rural track Medicare GME affiliation agreement (which, at a minimum is 1 year), beginning on July 1 of a year.

(iii) Each participating hospital's direct and indirect GME rural track FTE limitations in effect prior to the rural track Medicare GME affiliation.

(iv) The total adjustment to each hospital's rural track FTE limitations in each year that the rural track Medicare GME affiliation agreement is in effect, for both direct GME and indirect medical education (IME), that reflects a positive adjustment to one hospital's direct and indirect rural track FTE limitations that is offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect rural track FTE limitations of at least the same amount.

(v) The adjustment to each participating hospital's FTE counts resulting from the FTE resident's (or residents') participation in a shared rotational arrangement at each hospital participating in the rural track Medicare GME affiliated group for each year the Medicare GME affiliation agreement is in effect. This adjustment to each participating hospital's FTE count is also reflected in the total adjustment to each hospital's rural track FTE limitations (in accordance with paragraph (iii) of this definition).

* * * * *

■ 15. Section 413.79 is amended by revising paragraph (c)(2)(iii) to read as follows:

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

* * * * *

(c) * * *

(2) * * *

(iii) Effective for cost reporting periods beginning on or after October 1, 2001, if the hospital's unweighted number of FTE residents exceeds the limit described in this section, and the number of weighted FTE residents in accordance with paragraph (b) of this section also exceeds that limit, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the limit. If the number of FTE residents weighted in accordance with paragraph (b) of this section does not exceed that limit, then the allowable weighted FTE count is the actual weighted FTE count.

* * * * *

■ 16. Add § 413.99 to read as follows:

§ 413.99 Qualified and Non-Qualified Deferred Compensation Plans.

(a) *Statutory basis, scope, and definitions*—(1) *Basis.* All payments to providers of services must be based on the reasonable cost of services covered under Title XVIII in accordance with section 1861(v) of the Act and the regulations in this part.

(2) *Scope.* This section and § 413.100(c)(2)(vii) apply to Medicare's treatment of the costs incurred for Qualified and Non-Qualified Deferred Compensation Plans.

(3) *Definitions.* As used in this section the following definitions apply:

Deferred Compensation means remuneration currently earned by an employee that is not received until a subsequent period, usually after retirement.

Employee Retirement Income Security Act of 1974 (ERISA) is a Federal law that sets standards of protection for individuals in most voluntarily established, private-sector retirement plans. The law is set forth in Title 29, Chapter 18 of the U.S. Code.

Funded Plan means a plan in which assets have been irrevocably and unconditionally set aside with a third party for the payment of plan benefits (for example, in a trust or escrow account), and those assets are beyond the reach of the employer or its general creditors.

Non-Qualified Deferred Compensation Plan (NQDC) means an elective or non-elective plan, agreement, method, or arrangement between an employer and an employee to pay the employee compensation in the future. In comparison with qualified plans, nonqualified plans do not provide employers and employees with the tax benefits associated with qualified plans because NQDC plans do not satisfy all the requirements of 26 U.S.C. 401(a).

Non-Qualified Defined Benefit Plan (NQDB) means a type of NQDC that is established and maintained by the employer primarily to provide definitely determinable benefits to its employees usually over a period of years, or for life,

after retirement. Such benefits are generally measured by, and based on, such factors as age of employees, years of service, and compensation received by the employees.

Pension Benefit Guaranty Corporation (PBGC) is a Federal agency created by ERISA to protect benefits in private-sector QDBP plans described in section 3(35) of ERISA.

Qualified Defined Benefit Plan (QDBP) means a type of Qualified Deferred Compensation Plan that is established and maintained by the employer primarily to provide definitely determinable benefits to its employees usually over a period of years, or for life, after retirement. Such benefits are generally measured by, and based on, such factors as age of employees, years of service, and compensation received by the employees. A QDBP meets the applicable requirements of ERISA, as amended, and the requirements for a QDBP under 26 U.S.C. 401(a). Under a qualified plan, employers are entitled to deduct expenses in the year the employer makes contributions even though employees will not recognize income until the receipt of distributions.

Qualified Defined Contribution or Individual Account Plan (QDCP) means a type of Deferred Compensation Plan in which the employee, the employer, or both, contribute to an employee's individual account under the plan. The amount in the account at distribution includes the contributions and investment gains or losses, minus any investment and administrative fees. The value of the account changes based on contributions and the value and performance of the investments. A QDCP meets the applicable requirements of ERISA, as amended, and the requirements set forth in 26 U.S.C. 401(a), and, if applicable 26 U.S.C. 401(k).

Unfunded Plan means a plan in which benefits are supported by assets that have not been set aside (that is, a ''pay as you go'' plan), or by assets that have been set aside, but remain subject to the claims of the employer's general creditors.

(b) *Principle requirements*—(1) *General.* Deferred Compensation contributions or payments must be made by a provider of services, or an employee of the provider of services, to a Qualified or Non-Qualified Deferred Compensation Plan, established and maintained by the provider of services to provide retirement income to employees or to result in the deferral of income by employees for periods extending to the termination of covered employment or beyond. Contributions or payments made by a provider of services for the benefit of its employees to a Qualified or Non-Qualified Deferred Compensation Plan are allowable, when, and to the extent that, such costs are actually incurred by the provider of services and found to be reasonable and necessary under the principles of reasonable cost.

(2) *Deferred Compensation for provider-based physicians services in a hospital or SNF.* Costs incurred by a hospital or SNF to fund a Qualified or Non-Qualified Deferred Compensation Plan for a provider-based physician must meet the following requirements to be allowable under the program:

(i) The allocation of physician compensation costs required under § 415.60 does not attribute the provider-based physician's Deferred Compensation entirely to one category of service and his current compensation to another.

(ii) Contributions or payments toward the Qualified or Non-Qualified Deferred Compensation Plan do not include any cost excluded from the definition of physician compensation at § 415.60(a) of this chapter.

(iii) The amount of Deferred Compensation does not exceed the amount specified in the agreement required by § 415.60(g) of this chapter.

(iv) An arrangement between a physician and a provider of services under which the physician is reimbursed for patient charges, but the provider of services does the billing as a Deferred Compensation agreement, is not allowed.

(v) The costs incurred for physician guaranteed arrangements for hospital emergency room availability services, must meet the following additional requirements:

(A) The terms of both the guarantee arrangements and the Deferred Compensation Plan establish the amounts to be included at the beginning of the hospital's cost reporting period.

(B) The amount of Deferred Compensation is included in the guaranteed amount.

(C) The hospital contributes to the Deferred Compensation Plan from its own funds.

(D) The amount of Deferred Compensation that is allowable is limited to the amount by which the guarantee, including Deferred Compensation, exceeds the total billed by the hospital to all patients for the physician's patient care services.

(E) When the physician's charges to all patients equal or exceed the amount guaranteed by the hospital, the program does not recognize a Deferred Compensation contribution/payment.

(c) *Requirements for Non-Qualified and Qualified Deferred Compensation Plans*—(1) *NQDC requirements.* In order for contributions or payments by a provider of services to an NQDC as defined at paragraph (a)(3) of this section to be allowable under the program, the NQDC must meet the general requirements at paragraph (c)(1)(i) of this section, and it must either meet the requirements for a funded NQDC at paragraph (c)(1)(ii) of this section or the requirements for an unfunded NQDC at paragraph (c)(1)(iii) of this section, as applicable.

(i) *General requirements.* An NQDC must satisfy the requirements for document compliance and operational compliance set forth in 26 U.S.C. 409A.

(ii) *Funded NQDCs.* A funded NQDC must meet the definition of a Funded Plan in paragraph (a)(3) of this section and comply with the requirements in paragraph (c)(5) of this section.

(iii) *Unfunded NQDCs.* An NQDC that is unfunded must meet the definition of an Unfunded Plan in paragraph (a)(3) of this section, and there must be no constructive receipt of income for employees from a NQDC as a result of contributions made by a provider of services.

(2) *QDCP requirements.* A QDCP must meet the applicable requirements of ERISA, as amended, and the requirements set forth in 26 U.S.C. 401(a), and if applicable 26 U.S.C. 401(k). A QDCP must meet the definition of a Funded Plan in paragraph (a)(3) of this section and comply with the requirements in paragraph (c)(5) of this section.

(3) *QDBP requirements.* A QDBP must meet the applicable requirements of ERISA, as amended, and the requirements for a defined benefit plan under 26 U.S.C. 401(a). A QDBP must meet the definition of a Funded Plan in paragraph (a)(3) of this section and comply with the requirements in paragraph (c)(5) of this section.

(4) *NQDB requirements.* In order for contributions or payments by a provider of services to an NQDB as defined at paragraph (a)(3) of this section to be allowable under the program, the NQDB must meet the general requirements at paragraph (c)(4)(i) of this section, and it must either meet the requirements for a funded NQDB at paragraph (c)(4)(ii) of this section or the requirements for an unfunded NQDB at paragraph (c)(4)(iii) of this section, as applicable.

(i) *General requirements.* An NQDB must satisfy the requirements for document compliance set forth in 26 U.S.C. 409A and operational compliance set forth in 26 U.S.C. 409A(a).

(ii) *Funded NQDBs.* An NQDB that is funded must meet the definition of a Funded Plan in paragraph (a)(3) of this section and comply with the requirements in paragraph (c)(5) of this section.

(iii) *Unfunded NQDBs.* An NQDB that is unfunded must meet the definition of an Unfunded Plan in paragraph (a)(3) of this section, and there must be no constructive receipt of income for employees from a NQDB as a result of contributions made by a provider of services.

(5) *Funded Plan requirements*—(i) *Acceptable funding mechanism.* Both provider of services contributions and employee contributions must be used either to purchase an insured plan with a commercial insurance company, to establish a custodial bank account, or to establish a trust fund administered by a trustee.

(ii) *Life insurance contracts.* The purchase of an ordinary life insurance contract (for example, whole life, straight life, or other) is not a deferral of compensation and is not recognized as a funding mechanism, even where it is convertible at the normal retirement date specified in the policy to an annuity payable over the remaining life of the employee.

(iii) *Sole benefit of participating employees.* Regardless of the funding mechanism utilized, all provider of services and employee contributions to the fund established under the Deferred Compensation Plan and income therefrom must be used for the sole benefit of the participating employees.

(d) *Recognition of contributions or payments to Qualified and Non-Qualified Deferred Compensation Plans*—(1) *General rule.* Except as provided for in paragraph (c)(1)(iii) with respect to QDBPs and funded NQDBs, contributions to Qualified Deferred Compensation Plans or payments to plan participants from Non-Qualified Deferred Compensation Plans are recognized as allowable costs in accordance with paragraph (c)(1)(i) of this section (in the case of Unfunded Plans) and paragraph (c)(1)(ii) of this section (in the case of Funded Plans).

(i) *Unfunded Plans.* Contributions or payments made to an unfunded Deferred Compensation Plans (including unfunded NQDBs) by a provider of services on behalf of its employees are included in allowable costs only during the cost reporting period in which an actual payment is made to the participating employees (or their beneficiaries) and only to the extent considered reasonable, in accordance with § 413.100(c)(2)(vii)(A).

(ii) *Funded Plans.* Reasonable provider of services payments made under funded Deferred Compensation Plans (specifically, funded Defined Contribution Plans, but excluding QDBPs and funded NQDBs) are included in allowable costs in accordance with § 413.100(c)(2)(vii)(B).

(iii) *Exception for QDBPs and funded NQDBs.* (A) QDBP and NQDB contributions are found to have been incurred only if paid directly to participants or beneficiaries under the terms of the plan or to the QDBP or NQDB.

(B) Payments to a QDBP or funded NQDB for a cost reporting period must be measured on a cash basis. A contribution or payment is deemed to occur on the date it is credited to the fund established for the QDBP or funded NQDB, or for provider of services payments made directly to a plan participant or beneficiary, on the date the provider of services account is debited.

(C) Payments or contributions made to fully fund a terminating QDBP or funded NQDB are to be included as funding on the date they are paid. Excess assets withdrawn from a QDBP or funded NQDB are to be treated as negative contributions on the date that they are withdrawn.

(D) QDBP and funded NQDB annual allowable costs are computed as follows:

(*1*) QDBP and funded NQDB costs and limits are computed in accordance with § 413.100(c)(2)(vii)(D).

(*2*) For purposes of determining the QDBP or funded NQDB cost limit under § 413.100(c)(2)(vii)(D)(*2*), provider of services contribution payments for each applicable cost reporting period must be determined on a cash basis without regard to any limit determined for the period during which the contributions were made, and excluding any contributions deposited in a prior period and treated as carry forward contributions.

(*3*) The averaging period used to determine the QDBP or funded NQDB cost limit must be determined without regard to a provider of services period of participation in the Medicare program. Periods that are not Medicare cost reporting periods (for example, periods prior to the hospital's participation in the Medicare program) must be defined as consecutive 12-month periods ending immediately prior to the provider of services initial Medicare cost reporting period.

(*4*) The averaging period used to determine the QDBP or funded NQDB cost limit must exclude all periods ending prior to the initial effective date of the plan (or a predecessor plan in the case of a merger).

(*5*) In general, the current period defined benefit cost and limit is computed and applied separately for each QDBP or funded NQDB offered by a provider of services. In the case of a plan merger, the contributions or payments made by a provider of services to a predecessor QDBP or funded NQDB and reflected in the assets subsequently transferred to a successor plan are treated as contribution payments made to the successor plan.

(2) [Reserved]

(e) *Documentation requirements.* Documentation must be maintained by the provider of services in accordance with § 413.20 to substantiate the allowability of contributions or payments to Qualified and Non-Qualified Deferred Compensation Plan(s) that it has included in its cost reports.

(1) *Required documentation.* The provider of services must maintain and make available, upon request by the contractor or CMS, certain specified documentation, to substantiate the allowability of the contributions or payments to its Qualified or Non-Qualified Deferred Compensation Plan(s), or both:

(i) Documentation that demonstrates that the provider of services is in compliance with 26 U.S.C. 409A and 409A(a), and, if applicable, 26 U.S.C. 457.

(ii) Ledger accounts/account statements for each plan participant noting current year deferrals, distributions and loans, including any deferral election forms completed by employees, any change requests, and the approval of such requests.

(iii) Documentation that demonstrates the amount(s) and date(s) of actual contributions or payments made to the Qualified or Non-Qualified Deferred Compensation Plan during the current cost reporting period.

(iv) Schedule SB of Form 5500 (tri-agency form (Department of Labor (DOL), Internal Reveue Service (IRS), and PBGC) that plans file with the DOL's ''EFAST'' electronic filing system) for a QDBP for the current cost reporting period, or any applicable prior periods.

(v) In the case of a system-wide (multiple employer) plan, the home office shall identify the contributions attributed to each participating provider of services. If the costs included in the cost report for a period differ from the contributions made during the reporting period (that is, as a result of carry forward contributions), the provider of

services must also have data available to track and reconcile the difference.

(2) *Additional documentation.* The following additional documentation must be made available, upon request by the contractor or CMS, to substantiate the allowability of the payments/contributions by a provider of services to a Qualified or Non-Qualified Deferred Compensation Plan:

(i) The plan document, the trust document and all amendments related to the current cost reporting period.

(ii) If applicable, any Form 5330, Return of Excise Taxes Related to Employee Benefit Plans, for the cost reporting period.

(iii)(A) Supporting documents for all plan assets and liabilities, such as broker's statements, bank statements, insurance contracts, loan documents, deeds, etc.

(B) Verification of how assets are valued.

(iv)(A) Trustee or administrator reports.

(B) Ledgers.

(C) Journals.

(D) Trustee, administrator, and investment committee minutes.

(E) Certified audit report and other financial reports for the trust.

(F) Any other financial reports, including receipt and disbursement statements, a detailed income statement, and a detailed balance sheet.

(v) For each covered QDBP, documentation of the certified premium information and payments to the PBGC.

(f) *Administrative and other costs associated with Deferred Compensation Plans.* The provider of services shall file a cost report required under §§ 413.20 and 413.24(f) that is consistent with the policies set forth in this section.

(1) *Trustee and custodial fees.* Reasonable trustee or custodial fees, including PBGC premiums, paid by the provider of services are allowed as an administrative cost except where the plan provides that such fees are paid out of the corpus or earnings of the fund.

(2) *Vested benefits.* The forfeiture of an employee's benefits for cause (as defined in the plan) is recognized as an allowable cost provided that such forfeited amounts are used to reduce the provider of services contributions or payments to the plan during the cost reporting period in which the forfeiture occurs.

(3) *Benefits to be paid.* If an employee terminates participation in the Deferred Compensation Plan before their rights are vested, the applicable non-vested contributions/payments cannot be applied to increase the benefits of the surviving participants. Instead the non-vested contributions or payments should be used to reduce the provider of services contributions or payments to the Deferred Compensation Plan, in the cost reporting period in which the employee terminated participation in the Deferred Compensation Plan. Otherwise, the contributions/payments made by the provider of services must be applied to reduce the subsequent contributions or payments to the Deferred Compensation Plan in the next cost reporting period. If subsequent provider of services contributions/payments to the Deferred Compensation Plan are not made, then the provider of services costs are reduced by the contractor to the extent of such non-vested funds.

(4) *DOL, IRS, or PBGC penalties.* If the provider of services is assessed an excise tax or other remedy by the DOL, IRS, or PBGC for failure to follow DOL, IRS, or PBGC requirements under ERISA or any other penalty fee or penalty interest applicable to its Deferred Compensation Plan, the cost is unallowable in accordance with section 1861(v)(8) of the Act.

(5) *Loans made from a Deferred Compensation Plan.* A provider of services cannot make a loan to itself from a Deferred Compensation Plan where ERISA or IRS rules prohibit such a transaction, except where specifically excepted.

(6) *Termination/discontinuation of a Deferred Compensation Plan.* If the provider of services declines to vest its outstanding required contributions or payments (that is, matching or non-elective) to a Deferred Compensation Plan as a result of a termination in full or in part or a discontinuation of contributions or payments to a Deferred Compensation Plan, then the provider of services total outstanding required contributions or payments to the Deferred Compensation Plan during the cost reporting period wherein such termination is initiated cannot be included in the provider of services allowable cost for the cost reporting period in which the termination is initiated, nor any future period.

(7) *Required offset against interest expense.* Investment income earned on a Deferred Compensation Plan after its termination but prior to liquidation of the plan's assets and distribution to the provider of services must be offset against the provider of services allowable interest expense under § 413.153.

(8) *Treatment of residual assets following termination of a Funded Plan.* (i) Residual assets arising from the termination of a funded Deferred Compensation Plan must be recouped in the year of the plan termination only against the cost center(s) in which the provider of services reported its plan contributions or payments, usually the administrative and general cost center.

(ii) Residual assets exceeding the amount in the administrative and general (or other) cost center are not further offset in the current or subsequent years.

(iii) The Medicare share of the reversion is based on the Medicare utilization rate in the year the reversion occurs (or the year the actuarial surplus is determined), and not Medicare's utilization in the years the contributions to the plan were made.

(g) *Treatment of costs associated with the PBGC.* Costs associated with the requirements set forth in ERISA and by the PBGC and incurred by a provider of services who sponsors a QDBP are allowable or unallowable under the program as provided for in this paragraph (g).

(1) *Costs paid out of the plan trust.* PBGC premiums and costs paid out of the corpus or earnings of the trust are included in the contributions allowed under paragraph (d)(3)(ii) of this section, and are not allowable as separate costs.

(2) *Premium payments for single- and multi-employer plans.* The amount of PBGC premiums paid for basic benefits (flat rate or variable, excluding amounts paid out of the corpus or earnings of the trust) by a provider of services who sponsors a QDBP are allowable under the program.

(3) *Liability for missing participants or beneficiaries.* The total amount paid to the PBGC by a provider of services who sponsors a QDBP (excluding amounts paid out of the corpus or earnings of the trust) of the benefit transfer amount (as described in 29 CFR 4050.103(d)) for all missing participants or beneficiaries of the QDBP, is allowable under the program.

(4) *Plan termination due to distress.* For a defined benefit plan that terminated with insufficient assets to pay all of the plan benefits, which resulted in the PBGC making payment of vested benefits up to limits defined by law in accordance with 29 CFR part 4022, such amounts contributed to the QDBP by the provider of services who sponsors the QDBP are allowable. Benefits paid to the participants and beneficiaries of the QDBP by the PBGC are unallowable.

(5) *Restored plan payments.* If the PBGC issues or has issued a plan restoration order as described in 29 CFR part 4047, the amounts that the provider of services repays to the PBGC for guaranteed benefits and related expenses under the plan while the plan

was in terminated status, and any administrative costs assessed by the PBGC, excluding penalties, are allowable.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 17. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr, unless otherwise noted.

■ 18. Section 482.42 is amended by—
■ a. Revising paragraph (e).
■ b. Redesignating paragraph (g) as paragraph (h).
■ c. Adding a new paragraph (g).

The revision and addition read as follows:

§ 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(e) *COVID–19 and seasonal influenza reporting.* Beginning at the conclusion of the COVID–19 Public Health Emergency, as defined in § 400.200 of this chapter, and continuing until April 30, 2024, except when the Secretary specifies an earlier end date for the requirements of this paragraph (e), the hospital must electronically report information about COVID–19 and seasonal influenza in a standardized format specified by the Secretary.

(1) Related to COVID–19, to the extent as required by the Secretary, this report must include the following data elements:

(i) Suspected and confirmed COVID–19 infections among patients and staff.

(ii) Total COVID–19 deaths among patients and staff.

(iii) Personal protective equipment and testing supplies.

(iv) Ventilator use, capacity, and supplies.

(v) Total bed and intensive care unit bed census and capacity.

(vi) Staffing shortages.

(vii) COVID–19 vaccine administration data of patients and staff.

(viii) Relevant therapeutic inventories or usage, or both.

(2) Related to seasonal influenza, to the extent as required by the Secretary, this report must include the following data elements:

(i) Confirmed influenza infections among patients and staff.

(ii) Total influenza deaths among patients and staff.

(iii) Confirmed co-morbid influenza and COVID–19 infections among patients and staff.

* * * * *

(g) *Standard: Reporting of data related to viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential.* The hospital must electronically report information on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection), SARS–CoV–2/COVID–19, and other viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential only when the Secretary has declared a Public Health Emergency (PHE), as defined in § 400.200 of this chapter, directly related to such specific pathogens and infectious diseases. The requirements of this paragraph (g) will be applicable to local, state, regional, or national PHEs as declared by the Secretary.

(1) The hospital must electronically report information about the infectious disease pathogen, relevant to the declared PHE, in a standardized format specified by the Secretary. To the extent as required by the Secretary, this report must include, the following:

(i) Suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff.

(ii) Total deaths attributed to the relevant infectious disease pathogen among patients and staff.

(iii) Personal protective equipment and other relevant supplies in the hospital.

(iv) Capacity and supplies in the hospital relevant to the immediate and long term treatment of the relevant infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies.

(v) Total hospital bed and intensive care unit bed census, capacity, and capability.

(vi) Staffing shortages.

(vii) Vaccine administration data of patients and staff for conditions monitored under this section and where a specific vaccine is applicable.

(viii) Relevant therapeutic inventories or usage, or both.

(ix) Isolation capacity, including airborne isolation capacity.

(x) Key co-morbidities or exposure risk factors, or both, of patients being treated for the pathogen or disease of interest in this section that are captured with interoperable data standards and elements.

(2) Unless the Secretary specifies an alternative format by which the hospital must report these data elements, the hospital must report the applicable infection (confirmed and suspected) and vaccination data in a format that provides person-level information, which must include medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients. Facilities must not report any directly or potentially individually-identifiable information for affected patients (for example, name, social security number) that is not set out in this section or otherwise specified by the Secretary.

(3) The hospital must provide the information specified in this paragraph (g) on a daily basis, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network or other CDC-supported surveillance systems as determined by the Secretary.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 19. The authority citation for part 485 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395(hh).

■ 20. Section 485.640 is amended by—
■ a. Revising paragraph (d).
■ b. Redesignating paragraph (f) as paragraph (g).
■ c. Adding a new paragraph (f).

The revision and addition read as follows:

§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(d) *COVID–19 and seasonal influenza reporting.* Beginning at the conclusion of the COVID–19 Public Health Emergency, as defined in § 400.200 of this chapter, and continuing until April 30, 2024, except when the Secretary specifies an earlier end date for the requirements of this paragraph (d), the CAH must electronically report information about COVID–19 and seasonal influenza in a standardized format specified by the Secretary.

(1) Related to COVID–19, to the extent as required by the Secretary, this report must include the following data elements:

(i) Suspected and confirmed COVID–19 infections among patients and staff.

(ii) Total COVID–19 deaths among patients and staff.

(iii) Personal protective equipment and testing supplies.

(iv) Ventilator use, capacity, and supplies.

(v) Total bed and intensive care unit bed census and capacity.

(vi) Staffing shortages.

(vii) COVID–19 vaccine administration data of patients and staff.

(viii) Relevant therapeutic inventories or usage, or both.

(2) Related to seasonal influenza, to the extent as required by the Secretary, this report must include the following data elements:

(i) Confirmed influenza infections among patients and staff.

(ii) Total influenza deaths among patients and staff.

(iii) Confirmed co-morbid influenza and COVID–19 infections among patients and staff.

* * * * *

(f) *Standard: Reporting of data related to viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential.* The CAH must electronically report information on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection), SARS–CoV–2/COVID–19, and other viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential only when the Secretary has declared a Public Health Emergency (PHE), as defined in § 400.200 of this chapter, directly related to such specific pathogens and infectious diseases. The requirements of this paragraph (f) will be applicable to local, state, regional, or national PHEs as declared by the Secretary.

(1) The CAH must electronically report information about the relevant infectious disease pathogen in a standardized format specified by the Secretary. To the extent as required by the Secretary, this report must include the following:

(i) Suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff.

(ii) Total deaths attributed to the relevant infectious disease pathogen among patients and staff.

(iii) Personal protective equipment and other relevant supplies in the CAH.

(iv) Capacity and supplies in the CAH relevant to the immediate and long-term treatment of the relevant infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies.

(v) Total CAH bed and intensive care unit bed census, capacity, and capability.

(vi) Staffing shortages.

(vii) Vaccine administration data of patients and staff for conditions monitored under this section and where a specific vaccine is applicable.

(viii) Relevant therapeutic inventories or usage, or both.

(ix) Isolation capacity, including airborne isolation capacity.

(x) Key co-morbidities or exposure risk factors of patients being treated for the pathogen or disease of interest in this section that are captured with interoperable data standards and elements.

(2) Unless the Secretary specifies an alternative format by which the CAH must report these data elements, the CAH must report the applicable infection (confirmed and suspected) and vaccination data in a format that provides person-level information, which must include race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients. Facilities must not report any directly or personally individually-identifiable information for affected patients (for example, name, social security number) that is not set out in this section or otherwise specified by the Secretary.

(3) The CAH must provide the information specified in this paragraph (f) on a daily basis, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network or other CDC-supported surveillance systems as determined by the Secretary.

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 21. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 22. Section 495.24 is amended by—

■ a. In the introductory text:

■ i. In the last sentence, removing the phrase ''for 2019 and subsequent years'' and adding in its place ''for 2019 through 2022''; and

■ ii. Adding a sentence at the end of the paragraph;

■ b. In paragraph (e) heading, removing the phrase ''for 2019 and subsequent years'' and adding in its place the phrase ''for 2019 through 2022'';

■ c. In paragraph (e)(1)(i)(C), removing the phrase ''In 2022 and subsequent years, earn'' and adding in its place the phrase ''In 2022, earn'';

■ d. In paragraph (e)(4)(ii), removing the phrase ''In 2022 and subsequent years'' and adding in its place the phrase ''In 2022'';

■ e. In paragraph (e)(5)(ii)(B) introductory text, removing the phrase ''In 2020 and subsequent years'' and adding in its place the phrase ''In 2020 through 2022'';

■ f. In paragraph (e)(5)(iii)(A), removing the phrase ''in CY 2019 and subsequent years'' and adding in its place ''in CY 2019 through CY 2022'';

■ g. In paragraph (e)(5)(v), removing the phrase ''Beginning with the EHR reporting period in CY 2019'' and adding in its place ''For the EHR reporting periods in CY 2019 through CY 2022'';

■ h. In paragraph (e)(7)(ii) introductory text, removing the phrase ''beginning in CY 2019'' and adding in its place the phrase ''for CY 2019 through CY 2022'';

■ i. In paragraph (e)(8)(ii) introducotry text, removing the phrase ''For CY 2022 and subsequent years'' and adding in its place ''For CY 2022'';

■ j. In paragraph (e)(8)(ii)(A), removing the phrase ''For CY 2022 and subsequent years'' and adding in its place ''For CY 2022'';

■ k. In paragraphs (e)(8)(iii) introductory text, removing the phrase ''For CY 2022 and subsequent years'' and adding in its place ''For CY 2022'';

■ l. In paragraph (e)(8)(iii)(A)(*2*), removing the phrase ''For CY 2022 and subsequent years'' and adding in its place ''For CY 2022'';

■ m. In paragraph (e)(8)(iii)(D)(*2*), removing the phrase ''For CY 2022 and subsequent years'' and adding in its place ''For CY 2022'';

■ n. In paragraph (e)(8)(iii)(E)(*2*), removing the phrase ''For CY 2022 and subsequent years'' and adding in its place ''For CY 2022''; and

■ o. Adding paragraph (f).

The additions read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years.

* * * The criteria specified in paragraph (f) of this section are applicable for eligible hospitals and CAHs attesting to CMS for 2023 and subsequent years.

* * * * *

(f) *Stage 3 objectives and measures for eligible hospitals and CAHs attesting to CMS for 2023 and subsequent years*—(1) *General rule.* (i) Except as specified in paragraph (f)(2) of this section, eligible hospitals and CAHs must do all of the following as part of meeting the definition of a meaningful EHR user under § 495.4:

(A) Meet all objectives and associated measures selected by CMS under section 1886(n)(3) of the Act for an EHR reporting period.

(B) In 2023 and subsequent years, earn a total score of at least 60 points.

(ii) The numerator and denominator of the measures increment based on actions occurring during the EHR reporting period selected by the eligible hospital or CAH, unless otherwise indicated.

(2) *Exclusion for nonapplicable measures*—(i) *Exclusion of a particular measure.* An eligible hospital or CAH may exclude a particular measure that includes an option for exclusion if the eligible hospital or CAH meets the following requirements:

(A) Meets the criteria in the applicable measure that would permit the exclusion.

(B) Attests to the exclusion.

(ii) *Distribution of points for nonapplicable measures.* For eligible hospitals or CAHs that claim such exclusion, the points assigned to the excluded measure are distributed to other measures as specified by CMS for an EHR reporting period.

Dated: April 13, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

Note: The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

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Addendum—Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2022, and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2022

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the proposed prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2023 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2023. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the proposed figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this proposed rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that would be effective for cost reporting periods beginning on or after October 1, 2022.

In addition, we are setting forth a description of the methods and data we used to determine the proposed LTCH PPS standard Federal payment rate that would be applicable to Medicare LTCHs for FY 2023.

In general, except for SCHs, for FY 2023, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation. Under current law, the MDH program is effective for discharges on or before September 30, 2022. Therefore, under current law, the MDH program will expire at the end of FY 2022.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (including, as discussed in section IV.G. of the preamble of this proposed rule, uncompensated care payments under section 1886(r)(2) of the Act); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the

updated hospital-specific rate based on FY 2006 costs per discharge.

As discussed in section V.A.2. of the preamble of this proposed rule, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. In general, Puerto Rico hospitals are paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update. Accordingly, our discussion later in this section does not include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed in section II. of this Addendum, we are proposing to make changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2023. In section III. of this Addendum, we discuss our proposed policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2023. In section IV. of this Addendum, we are setting forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2023. In section V. of this Addendum, we discuss proposed policy changes for determining the LTCH PPS standard Federal rate for LTCHs paid under the LTCH PPS for FY 2023. The tables to which we refer in the preamble of this proposed rule are listed in section VI. of this Addendum and are available via the internet on the CMS website.

II. Proposed Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2023

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. In this section, we discuss the factors we are proposing to use for determining the proposed prospective payment rates for FY 2023.

In summary, the proposed standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the internet on the CMS website) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2023, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section IV.A. of the preamble of this proposed rule for a complete discussion on the proposed FY 2023 inpatient hospital update. The table that follows shows these four scenarios:

PROPOSED FY 2023 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2023	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	3.1	3.1	3.1	3.1
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.775	-0.775
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.325	0	-2.325
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.4	-0.4	-0.4	-0.4
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.7**	**0.375**	**1.925**	**-0.4**

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that is not a meaningful EHR user (as defined in section 1886(n)(3) of the Act) and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have ''three-quarters'' of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket update, reduced by 33⅓ percent. The reduction

to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users increases to 66 2/3 percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674). The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2023 and subsequent fiscal years.

- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to the standardized amount to ensure budget neutrality for our proposed permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year beginning FY 2023, as discussed in section II.E.2.d. of the preamble of this proposed rule, consistent with our current methodology for implementing DRG recalibration and reclassification budget neutrality under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to ensure the wage index and labor-related share changes (depending on the fiscal year) are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act (as discussed in the FY 2006 IPPS final rule (70 FR 47395) and the FY 2010 IPPS final rule (74 FR 44005)). We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62-percent labor-related share in certain circumstances) had not been enacted.
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2022 budget neutrality factor and applying a revised factor.
- A positive adjustment of 0.5 percent in FYs 2019 through 2023 as required under section 414 of the MACRA.
- An adjustment to the standardized amount to implement in a budget neutral manner the increase in the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals (as described in section III.N. of the preamble of this proposed rule).
- An adjustment to the standardized amount to implement in a budget neutral manner our proposal of a permanent wage index cap policy, consistent with our proposal in section III. N of the preamble of this proposed rule.
- An adjustment to ensure the effects of the Rural Community Hospital Demonstration program required under section 410A of Public Law 108–173 (as amended by sections 3123 and 10313 of Pub. L. 111–148; section 15003 of Pub. L. 114–255; and Division CC, section 128 of Pub. L. 116–260, which extended the program), are budget neutral, as required under section 410A(c)(2) of Pub. L. 108–173.
- An adjustment to remove the FY 2022 outlier offset and apply an offset for FY 2023, as provided for in section 1886(d)(3)(B) of the Act.

For FY 2023, consistent with current law, we are proposing to apply the rural floor budget neutrality adjustment to hospital wage indexes. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State-level rural floor budget neutrality adjustment to the wage index, we are proposing to apply a uniform, national budget neutrality adjustment to the FY 2023 wage index for the rural floor.

For FY 2023, we are proposing to continue to not remove the Stem Cell Acquisition Budget Neutrality Factor from the prior year's standardized amount and to not apply a new factor. If we removed the prior year's adjustment, we would not satisfy budget neutrality. We believe this approach ensures the effects of the reasonable cost based payment for allogeneic hematopoietic stem cell acquisition costs under section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) are budget neutral as required under section 108 of Public Law 116–94. For a discussion of Stem Cell Acquisition Budget Neutrality Factor, we refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 59032 and 59033). When cost report data regarding reasonable cost of acquisition become available, we intend to consider using that reasonable cost data in future rulemaking for budget neutrality.

A. Calculation of the Proposed Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. The September 1, 1983, interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2023, we are proposing to continue to use the national labor-related and nonlabor-related shares (which are based on the 2018-based IPPS market basket) that were used in FY 2022. Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2023, as discussed in section III.M. of the preamble of the proposed rule, we are proposing to use a labor-related share of 67.6 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000.

The proposed standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this proposed rule and are available via the internet on the CMS website.

2. Computing the National Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Accordingly, we are proposing to calculate the FY 2023 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, we are proposing to use the 2018-based IPPS operating and capital market baskets for FY 2023. As discussed in section IV.B. of the preamble of this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to reduce the FY 2023 applicable percentage increase (which for this proposed rule is based on IGI's fourth quarter 2021 forecast of the 2018-based IPPS market basket) by the productivity adjustment, as discussed elsewhere in this proposed rule.

Based on IGI's fourth quarter 2021 forecast (as discussed in Appendix B of this proposed rule), the forecast of the IPPS market basket increase for FY 2023 for this proposed rule is 3.1 percent. As discussed earlier, for FY 2023, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that can be applied to the standardized amount. We refer readers to section V.B. of the preamble of this proposed rule for a complete discussion on the FY 2023 inpatient hospital update to the standardized amount. We also refer readers to the previous table for the four possible applicable percentage increases that would be applied to update the national standardized amount. The proposed standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the internet on the CMS website reflect these differential amounts.

Although the update factors for FY 2023 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2023 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in Appendix B of this proposed rule.

4. Methodology for Calculation of the Average Standardized Amount

The methodology we used to calculate the proposed FY 2023 standardized amount is as follows:

- To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we applied the following inclusion and exclusion criteria: include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); exclude CAHs at the time of this proposed rule; exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS excluded- cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- As in the past, we are proposing to adjust the FY 2023 standardized amount to remove the effects of the FY 2022 geographic reclassifications and outlier payments before applying the FY 2023 updates. We then applied budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on proposed FY 2023 payment policies.
- We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- Consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- Consistent with our methodology established in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57277), in order to further ensure that we capture only FFS claims, we are excluding claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field for the budget neutrality adjustments. We are proposing to remove organ acquisition charges, except for cases that group to MS–DRG 018, from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS. Revenue centers 081X–089X are typically excluded from ratesetting, however, we are proposing to not remove revenue center 891 charges from MS–DRG 018 claims during ratesetting, because those revenue 891 charges were included in the relative weight calculation for MS–DRG 018, which is consistent with the policy finalized in FY 2021 final rule (85 FR 58600). We note that a new MedPAR variable for revenue code 891 charges was introduced in April 2020.
- For FY 2023, we are continuing to remove allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in

the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842).

• The participation of hospitals under the BPCI (Bundled Payments for Care Improvement) Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in the BPCI Advanced model in one of two capacities: As a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals would continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at *https://innovation.cms.gov/initiatives/bpci-advanced/.*

For FY 2023, consistent with how we treated hospitals that participated in the BPCI Advanced Model in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59029–59030), we are proposing to include all applicable data from subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations. We believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving IPPS payments under section 1886(d) of the Act. For the same reasons, we also are proposing to include all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

• Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations.

In order to properly determine aggregate payments on each side of the comparison, consistent with the approach we have taken in prior years, for FY 2023, we are proposing to continue to apply a proposed proxy based on the prior fiscal year hospital readmissions payment adjustment (for FY 2023 this would be FY 2022 final adjustment factors from Table 15 of the FY 2022 IPPS/LTCH PPS final rule) and a proposed proxy based on the prior fiscal year hospital VBP payment adjustment (for FY 2023, this proposed proxy would be an adjustment factor of 1 to reflect our policy for the FY 2022 program year to suppress measures and award each hospital a value-based payment amount that matches the reduction to the base operating DRG payment amount) on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). That is, we are proposing to apply a proxy readmissions payment adjustment factor from the prior final rule and a proxy hospital VBP payment adjustment factor from the prior final rule on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

• The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, would be available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

To do this for FY 2023 (as we did for the last 9 fiscal years), we are proposing to include estimated empirically justified Medicare DSH payments that would be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we are proposing to consider estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

• When calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section IV.G. of the preamble to this proposed rule and later in this section, we are proposing to continue to use the FY 2014 finalized methodology under which we take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we are proposing to include estimated uncompensated care payments in this comparison.

• We are proposing to include an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2023. Similar to FY 2022, we are including this adjustment based on data on the prior year's performance. Payments for hospitals would be estimated based on the proposed applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2023.

• In our determination of all budget neutrality factors described in section

II.A.4. of this Addendum, we used transfer-adjusted discharges. Specifically, we calculated the transfer-adjusted discharges using the statutory expansion of the postacute care transfer policy to include discharges to hospice care by a hospice program as discussed in section IV.A.2. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 45239 through 42342).

We note that prior to FY 2020, the Rural Community Hospital (RCH) Demonstration budget neutrality factor was typically applied to the standardized amount after all wage index and other budget neutrality factors were applied. In the past we completed all the wage index budget neutrality factors and then applied the RCH Demonstration budget neutrality factor. Beginning with FY 2020, we finalized and implemented additional policies in a budget neutral manner such as the increase in the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals and the transitional wage indexes. When these new policies were implemented beginning with FY 2020, the associated budget neutrality adjustments were applied to the standardized amount after the RCH Demonstration budget neutrality factor was applied. Taking into consideration that we are proposing to place a permanent cap on wage index decreases beginning FY 2023, we believe the RCH Demonstration budget neutrality factor should revert to the order prior to FY 2020 and be applied after all wage index and other budget neutrality adjustments. Therefore, beginning in FY 2023, we are proposing to change the ordering of budget neutrality factors with the proposed RCH Demonstration budget neutrality factor applied after all wage index and other budget neutrality factors. We believe this re-ordering of applying the RCH Demonstration budget neutrality factor after all wage index and other budget neutrality factors will have a minimal impact and minor interactive affects.

a. Proposed Reclassification and Recalibration of MS–DRG Relative Weights Before Proposed Cap

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.E of this proposed rule, we are proposing to determine the MS DRG relative weights for FY 2023 by averaging the relative weights as calculated with and without COVID–19 cases in the FY 2021 data. We refer the reader to section II.E.2.c for complete details. As discussed in section II.E. of the preamble of this proposed rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

For this FY 2023 proposed rule, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2021 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2022 labor-related share percentages, the FY 2022 relative weights, and the FY 2022 pre-reclassified wage data, and applied the estimated FY 2023 hospital readmissions payment adjustments and estimated FY 2023 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2022 labor-related share percentages, the proposed FY 2023 relative weights before applying the proposed 10-percent cap, and the FY 2022 pre-reclassified wage data, and applied the estimated FY 2023 hospital readmissions payment adjustments and estimated FY 2023 hospital VBP payment adjustments applied previously.

Because this payment simulation uses the proposed FY 2023 relative weights (before application of the proposed 10-percent cap), consistent with our proposal in section IV.I. of the preamble to this proposed rule, we applied the proposed adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments. We note that because the simulations of payments for all of the budget neutrality factors discussed in this section also use the FY 2023 relative weights, we are proposing to apply the adjustor for certain MS–DRG 18 cases in all simulations of payments for the budget neutrality factors discussed later in this section. We refer the reader to section IV.I. of the preamble of this proposed rule for a complete discussion on the proposed adjustor for certain cases that group to MS–DRG 018 and to section II.E.2.b. of the preamble of this proposed rule, for a complete discussion of the proposed adjustment to the FY 2023 relative weights to account for certain cases that group to MS–DRG 018.

Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we are proposing to apply the MS–DRG reclassification and recalibration budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2022. Please see the table later in this section setting forth each of the proposed FY 2023 budget neutrality factors.

b. Proposed Budget Neutrality Adjustment for Reclassification and Recalibration of MS–DRG Relative Weights With Proposed Cap

As discussed in section II.E.2.d of this proposed rule, we are proposing a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. As discussed in section II.E.2.d of this proposed rule, and consistent with our current methodology for implementing budget neutrality for MS–DRG reclassification and recalibration of the relative weights under section 1886(d)(4)(C)(iii) of the Act, we are proposing to apply a budget neutrality adjustment to the standardized amount for all hospitals so that this proposed 10-percent cap on relative weight reductions does not increase estimated aggregate Medicare payments beyond the payments that would be made had we never applied this cap. We refer the reader to section II.E.2.d of this proposed rule for further discussion on our proposed permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, including the proposed budget neutrality adjustment to the standardized amount.

To calculate this proposed budget neutrality adjustment factor for FY 2023, we used FY 2021 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2022 labor-related share percentages, the FY 2023 relative weights before applying the proposed 10-percent cap, and the FY 2022 pre-reclassified wage data, and applied the estimated FY 2023 hospital readmissions payment adjustments and estimated FY 2023 hospital VBP payment adjustments; and

• Aggregate payments using the FY 2022 labor-related share percentages, the proposed FY 2023 relative weights with the proposed 10-percent cap, and the FY 2022 pre-reclassified wage data, and applied the estimated FY 2023 hospital readmissions payment adjustments and estimated FY 2023 hospital VBP payment adjustments applied previously.

Because this payment simulation uses the FY 2023 relative weights, consistent with our proposal in section IV.I. of the preamble to this proposed rule, we applied the proposed adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments. We note that because the simulations of payments for all of the budget neutrality factors discussed in this section also use the FY 2023 relative weights, we are proposing to apply the adjustor for certain MS–DRG 18 cases in all simulations of payments for the budget neutrality factors discussed later in this section. We refer the reader to section IV.I. of the preamble of this proposed rule for a complete discussion on the proposed adjustor for certain cases that group to MS–DRG 018 and to section II.E.2.b. of the preamble of this proposed rule, for a complete discussion of the proposed adjustment to the FY 2023 relative weights to account for certain cases that group to MS–DRG 018.

In addition, we applied the proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor before the proposed cap (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2022 to FY 2023. Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we are proposing to apply this budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2022. Please see the table later in this section setting forth each of the proposed FY 2023 budget neutrality factors.

c. Updated Wage Index—Proposed Budget Neutrality Adjustment

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2023, we are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.E. of the preamble of this proposed rule.

To compute a proposed budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2021 discharge data to simulate payments and compared the following:

• Aggregate payments using the proposed FY 2023 relative weights and the FY 2022 pre-reclassified wage indexes, applied the FY 2022 labor-related share of 67.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the proposed FY 2023 hospital readmissions payment adjustment and the estimated FY 2023 hospital VBP payment adjustment; and

• Aggregate payments using the proposed FY 2023 relative weights and the proposed FY 2023 pre-reclassified wage indexes, applied the proposed labor-related share for FY 2023 of 67.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same proposed FY 2023 hospital readmissions payment adjustments and estimated FY 2023 hospital VBP payment adjustments applied previously.

In addition, we applied the proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor before the proposed cap (derived in the first step) and the proposed 10-percent cap on relative weight reductions adjustment factor (derived from the second step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2022 to FY 2023. Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount for changes to the wage index. Please see the table later in this section for a summary of the FY 2023 proposed budget neutrality factors.

d. Reclassified Hospitals—Proposed Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note, with regard to the requirement under section 1886(d)(8)(C)(iii) of the Act, as finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42333 through 42336), we excluded the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in § 412.103) from the calculation of the wage index for rural areas in the State in which the county is located. We refer the reader to the FY 2015 IPPS final rule (79 FR 50371 and 50372) for a complete discussion regarding the requirement of section 1886(d)(8)(C)(iii) of the Act. We further note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) of the Act shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the proposed budget neutrality adjustment factor for FY 2023, we used FY 2021 discharge data to simulate payments and compared the following:

• Aggregate payments using the proposed FY 2023 labor-related share percentage, the proposed FY 2023 relative weights, and the proposed FY 2023 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the estimated FY 2023 hospital readmissions payment adjustments and the estimated FY 2023 hospital VBP payment adjustments; and

• Aggregate payments using the proposed FY 2023 labor-related share percentage, the proposed FY 2023 relative weights, and the proposed FY 2023 wage data after such reclassifications, and applied the same estimated FY 2023 hospital readmissions payment adjustments and the estimated FY 2023 hospital VBP payment adjustments applied previously.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this proposed rule, which is available via the internet on the CMS website. This table reflects reclassification crosswalks proposed for FY 2023, and applies the proposed policies explained in section III. of the preamble of this proposed rule. Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount to ensure that the effects of these provisions are budget neutral, consistent with the statute. Please see the table later in this section for a summary of the proposed FY 2023 budget neutrality factors.

The proposed FY 2023 budget neutrality adjustment factor was applied to the proposed standardized amount after removing the effects of the FY 2022 budget neutrality adjustment factor. We note that the proposed FY 2023 budget neutrality adjustment reflects FY 2023 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of this proposed rule.

e. Proposed Rural Floor Proposed Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) is equal to the aggregate prospective payments that would have been made in the absence of this provision. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of the preamble of this proposed rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor is a national adjustment to the wage index. We note, as finalized in the FY 2020 IPPS/LTCH final rule (84 FR 42332 through 42336), for FY 2023 we are calculating the rural floor without including the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in § 412.103).

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2023, we are proposing to calculate a national rural Puerto Rico wage index. Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the FY 2023 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we use the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous (share a border with) to the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the proposed FY 2023 rural Puerto Rico wage index is calculated based on the average of the proposed FY 2023 wage indexes for the following urban areas: Aguadilla-Isabela, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660); San German, PR (CBSA 41900); and San Juan-Carolina-Caguas, PR (CBSA 41980).

To calculate the national rural floor budget neutrality adjustment factor, we used FY 2021 discharge data to simulate payments, and the post-reclassified national wage indexes and compared the following:

• National simulated payments without the rural floor; and

• National simulated payments with the rural floor.

Based on this comparison, we determined a proposed national rural floor budget neutrality adjustment factor. The national adjustment was applied to the national wage indexes to produce proposed rural floor budget neutral wage indexes. Please see the table later in this section for a summary of the proposed FY 2023 budget neutrality factors.

As further discussed in section III.G.2. of this proposed rule, we note that section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2), enacted on March 11, 2021 amended section 1886(d)(3)(E)(i) of the Act (42 U.S.C. 1395ww(d)(3)(E)(i)) and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index (or imputed floor) for hospitals in all-urban States for discharges occurring on or after October 1, 2021. Unlike the imputed floor that was in effect from FY 2005 through FY 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner Specifically, section 9831(b) of Public Law 117–2 amends section 1886(d)(3)(E)(i) of the Act to exclude the imputed floor from the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act. In the past, we budget neutralized the estimated increase in payments each year resulting from the imputed floor that was in effect from FY 2005 through FY 2018. For FY 2022 and subsequent years, in applying the imputed floor required under section 1886(d)(3)(E)(iv) of the Act, we are applying the imputed floor after the application of the rural floor and applying no reductions to the standardized amount or to the wage index to fund the increase in payments to hospitals in all-urban States resulting from the application of the imputed floor. We refer the reader to section III.G.2. of the preamble of this proposed rule for a complete discussion regarding the imputed floor.

f. Proposed Continuation of the Low Wage Index Hospital Policy—Proposed Budget Neutrality Adjustment

As discussed in section III.G.3. of the preamble of this proposed rule, we are proposing to continue for FY 2023 the wage index policy finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities by increasing the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals (the low wage index hospital policy). As discussed in section III.G.3. of this proposed rule, consistent with our current methodology for implementing wage index budget neutrality under section 1886(d)(3)(E) of the Act, we are proposing to make a budget neutrality adjustment to the national standardized amount for all hospitals so that the increase in the wage index for hospitals with a wage index below the 25th percentile wage index, is implemented in a budget neutral manner.

To calculate this proposed budget neutrality adjustment factor for FY 2023, we used FY 2021 discharge data to simulate payments and compared the following:

• Aggregate payments using the proposed FY 2023 labor-related share percentage, the proposed FY 2023 relative weights, and the proposed FY 2023 wage index for each hospital before adjusting the wage indexes under

the low wage index hospital policy, and applied the estimated FY 2023 hospital readmissions payment adjustments and the estimated FY 2023 hospital VBP payment adjustments, and the operating outlier reconciliation adjusted outlier percentage discussed later in this section; and

- Aggregate payments using the proposed FY 2023 labor-related share percentage, the proposed FY 2023 relative weights, and the proposed FY 2023 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy, and applied the same estimated FY 2023 hospital readmissions payment adjustments and the estimated FY 2023 hospital VBP payment adjustments applied previously, and the operating outlier reconciliation adjusted outlier percentage discussed later in this section.

This proposed FY 2023 budget neutrality adjustment factor was applied to the standardized amount.

g. Proposed Permanent Cap Policy for the Wage Index—Proposed Budget Neutrality Adjustment

As noted previously, in section III.N. of the preamble to this proposed rule, for FY 2023 and subsequent years, we are proposing to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, we are proposing that a hospital's wage index for FY 2023 would not be less than 95 percent of its final wage index for FY 2022, and that for subsequent years, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. In section III.N.2. of this proposed rule, we are also proposing to apply this proposed wage index cap policy in a budget neutral manner through an adjustment to the standardized amount to ensure that estimated aggregate payments under our proposed wage index cap policy for hospitals that would have a decrease in their wage indexes for the upcoming fiscal year of more than 5 percent would equal what estimated aggregate payments would have been without the proposed wage index cap policy. We refer readers to sections III.N.1 and III.N.2 of the preamble of this proposed rule for a complete discussion regarding this proposed policy.

To calculate a proposed wage index cap budget neutrality adjustment factor for FY 2023, we used FY 2021 discharge data to simulate payments and compared the following:

- Aggregate payments without the proposed 5-percent cap using the proposed FY 2023 labor-related share percentages, the proposed FY 2023 relative weights, the proposed FY 2023 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy with the associated budget neutrality adjustment to the standardized amount, and applied the estimated FY 2023 hospital readmissions payment adjustments and the estimated FY 2023 hospital VBP payment adjustments, and the operating outlier reconciliation adjusted outlier percentage discussed later in this section; and
- Aggregate payments with the proposed 5-percent cap using the proposed FY 2023 labor-related share percentages, the proposed FY 2023 relative weights, the proposed FY 2023 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy with the associated budget neutrality adjustment to the standardized amount, and applied the same estimated FY 2023 hospital readmissions payment adjustments and the estimated FY 2023 hospital VBP payment adjustments applied previously, and the operating outlier reconciliation adjusted outlier percentage discussed later in this section.

We note, Table 2 associated with this proposed rule contains the wage index by provider before and after applying the low wage index hospital policy and the proposed cap.

h. Proposed Rural Community Hospital Demonstration Program Adjustment

In section V.K. of the preamble of this proposed rule, we discuss the Rural Community Hospital (RCH) Demonstration program, which was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Subsequently, section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act, as further discussed later in this section). Finally, Division CC, section 128(a) of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260) again amended section 410A to require a 15-year extension period in place of the 10-year period. We make an adjustment to the standardized amount to ensure the effects of the RCH Demonstration program are budget neutral as required under section 410A(c)(2) of Public Law 108–173. We refer readers to section V.K. of the preamble of this proposed rule for complete details regarding the Rural Community Hospital Demonstration.

With regard to budget neutrality, as mentioned earlier, we make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration are budget neutral, as required under section 410A(c)(2) of Public Law 108–173. For FY 2023, based on the latest data for this proposed rule, the total amount that we would apply to make an adjustment to the standardized amounts to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral is $107,945,638. Accordingly, using the most recent data available to account for the estimated costs of the demonstration program, for FY 2023, we computed a factor for the Rural Community Hospital Demonstration budget neutrality adjustment that would be applied to the standardized amount. Please see the table later in this section for a summary of the FY 2023 budget neutrality factors. We refer readers to section V.K. of the preamble of this proposed rule on complete details regarding the calculation of the amount we would apply to make an adjustment to the standardized amounts.

The following table is a summary of the proposed FY 2023 budget neutrality factors, as discussed in the previous sections.

Summary of Proposed FY 2023 Budget Neutrality Factors	
MS-DRG Reclassification and Recalibration Budget Neutrality Factor	1.000491
Cap Policy MS-DRG Weights Budget Neutrality Factor	0.999765
Wage Index Budget Neutrality Factor	1.001303
Reclassification Budget Neutrality Factor	0.985346
*Rural Floor Budget Neutrality Factor	0.993656
Low Wage Index Hospital Policy Budget Neutrality Factor	0.998205
Cap Policy Wage Index Budget Neutrality Factor	0.999563
Rural Demonstration Budget Neutrality Factor	0.998925

*The rural floor budget neutrality factor is applied to the national wage indexes while the rest of the budget neutrality adjustments are applied to the standardized amounts.

As discussed in section II.A. of this proposed rule, we are proposing to use the FY 2021 data for FY 2023 ratesetting, with certain proposed modifications to our relative weight and outlier methodologies. As discussed elsewhere in this proposed rule and in this Addendum, we are soliciting comments on, as an alternative to our proposed approach, the use of the FY 2021 MedPAR claims for purposes of FY 2023 ratesetting without these proposed modifications to our usual methodologies. In order to facilitate comments on this alternative approach, we are making available budget neutrality and other ratesetting adjustments calculated under this alternative approach, which can be found on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. We refer the reader to section I.O. of Appendix A of this proposed rule for further discussion of the files that we are making available with regard to our alternative approach.

i. Proposed Adjustment for FY 2023 Required Under Section 414 of Public Law 114–10 (MACRA)

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment for each of FYs 2018 through 2023. (As noted in the FY 2018 IPPS/LTCH PPS proposed and final rules, section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted December 13, 2016, reduced the adjustment for FY 2018 from 0.5 percentage points to 0.4588 percentage points.) Therefore, for FY 2023, we are proposing to implement the required +0.5 percent adjustment to the standardized amount. This is a permanent adjustment to the payment rates.

j. Proposed Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' (As discussed later in this section, we are also proposing to include the proposed supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals in the computation of the proposed outlier fixed-loss cost threshold beginning in FY 2023.) To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2023 is 80 percent, or 90 percent for burn MS–DRGs 927, 928, 929, 933, 934 and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost factor of 80 percent for all other DRGs since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the percent target by dividing the total operating outlier payments by the total operating DRG payments plus outlier payments. As discussed in the next section, for FY 2023, we are proposing to incorporate an estimate of outlier reconciliation when setting the outlier threshold. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier payments may be found on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.html.*

(1) Proposed Methodology To Incorporate an Estimate of Outlier Reconciliation in the FY 2023 Outlier Fixed-Loss Cost Threshold

The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement will be based on operating and capital cost-to-charge ratios (CCRs) calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. We have instructed MACs to identify for CMS any instances where: (1) A

hospital's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate outlier payments when a bill is processed; and (2) the total outlier payments for the hospital exceeded $500,000.00 for that cost reporting period. If we determine that a hospital's outlier payments should be reconciled, we reconcile both operating and capital outlier payments. We refer readers to section 20.1.2.5 of Chapter 3 of the Medicare Claims Processing Manual (available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) for complete details regarding outlier reconciliation. The regulation at § 412.84(m) further states that at the time of any outlier reconciliation under § 412.84(i)(4), outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Section 20.1.2.6 of Chapter 3 of the Medicare Claims Processing Manual contains instructions on how to assess the time value of money for reconciled outlier amounts.

If the operating CCR of a hospital subject to outlier reconciliation is lower at cost report settlement compared to the operating CCR used for payment, the hospital would owe CMS money because it received an outlier overpayment at the time of claim payment. Conversely, if the operating CCR increases at cost report settlement compared to the operating CCR used for payment, CMS would owe the hospital money because the hospital outlier payments were underpaid.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42635), we finalized a methodology to incorporate outlier reconciliation in the FY 2020 outlier fixed loss cost threshold. As discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19592), we stated that rather than trying to predict which claims and/or hospitals may be subject to outlier reconciliation, we believe a methodology that incorporates an estimate of outlier reconciliation dollars based on actual outlier reconciliation amounts reported in historical cost reports would be a more feasible approach and provide a better estimate and predictor of outlier reconciliation for the upcoming fiscal year. We also stated that we believe the methodology addresses stakeholder's concerns on the impact of outlier reconciliation on the modeling of the outlier threshold. For a detailed discussion of additional background regarding outlier reconciliation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule.

(a) Incorporating a Proposed Projection of Outlier Payment Reconciliations for the FY 2023 Outlier Threshold Calculation

Based on the methodology finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625), for FY 2023, we are proposing to continue to incorporate outlier reconciliation in the FY 2023 outlier fixed loss cost threshold.

As discussed in the FY 2020 IPPS/LTCH PPS final rule, for FY 2020, we used the historical outlier reconciliation amounts from the FY 2014 cost reports (cost reports with a begin date on or after October 1, 2013, and on or before September 30, 2014), which we believed would provide the most recent and complete available data to project the estimate of outlier reconciliation. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625) for a discussion on the use of the FY 2014 cost report data for purposes of projecting outlier payment reconciliations for the FY 2020 outlier threshold calculation. For FYs 2021 and 2022, we applied the same methodology finalized in FY 2020, using the historical outlier reconciliation amounts from the FY 2015 cost reports (cost reports with a begin date on or after October 1, 2014, and on or before September 30, 2015) and the FY 2016 cost reports (cost reports with a begin date on or after October 1, 2015, and on or before September 30, 2016), respectively.

Similar to the FY 2022 methodology, in this proposed rule, we are proposing to determine a projection of outlier payment reconciliations for the FY 2023 outlier threshold calculation, by advancing the methodology by 1 year. Specifically, we are proposing to use FY 2017 cost reports (cost reports with a begin date on or after October 1, 2016, and on or before September 30, 2017).

For FY 2023, we are proposing to use the same methodology from FY 2020 to incorporate a projection of operating outlier payment reconciliations for the FY 2023 outlier threshold calculation. The following steps are the same as those finalized in the FY 2020 final rule but with updated data for FY 2023:

Step 1.—Use the Federal FY 2017 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules, and exclude sole community hospitals (SCHs) that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We note that when there are multiple columns available for the lines of the cost report described in the following steps and the provider was paid under the IPPS for that period(s) of the cost report, then we believe it is appropriate to use multiple columns to fully represent the relevant IPPS payment amounts, consistent with our methodology for the FY 2020 final rule.

Step 2.—Calculate the aggregate amount of historical total of operating outlier reconciliation dollars (Worksheet E, Part A, Line 2.01) using the Federal FY 2017 cost reports from Step 1.

Step 3.—Calculate the aggregate amount of total Federal operating payments using the Federal FY 2017 cost reports from Step 1. The total Federal operating payments consist of the Federal payments (Worksheet E, Part A, Line 1.01 and Line 1.02, plus Line 1.03 and Line 1.04), outlier payments (Worksheet E, Part A, Line 2 and Line 2.02), and the outlier reconciliation payments (Worksheet E, Part A, Line 2.01). We note that a negative amount on Worksheet E, Part A, Line 2.01 for outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital.

Step 4.—Divide the amount from Step 2 by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total operating outlier reconciliation dollars to total Federal operating payments for FY 2017. This percentage amount would be used to adjust the outlier target for FY 2023 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the Medicare claims data in the MedPAR file used to model the outlier threshold, we are proposing to target 5.1 percent minus the percentage determined in Step 4 in determining the outlier threshold. Using the FY 2017 cost reports based on the December 2021 HCRIS extract, because the aggregate outlier reconciliation dollars from Step 2 are negative, we are targeting an amount higher than 5.1 percent for outlier payments for FY 2023 under our proposed methodology.

For this FY 2023 proposed rule, we used the December 2021 HCRIS extract of the cost report data to calculate the proposed percentage adjustment for outlier reconciliation. For the FY 2023 final rule, we propose to use the latest quarterly HCRIS extract that is publicly available at the time of the development of that rule which, for FY 2023, would be the March 2022 extract. Similar to the FY 2022 final rule, we may also

consider the use of more recent data that may become available for purposes of projecting the estimate of operating outlier reconciliation used in the calculation of the final FY 2023 outlier threshold.

For this FY 2023 proposed rule, based on the December 2021 HCRIS, 10 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 2.01 for total operating outlier reconciliation dollars of negative $11,939,505 (Step 2). The total Federal operating payments based on the December 2021 HCRIS was $88,388,722,611 (Step 3). The ratio (Step 4) is a negative −0.013508 percent, which, when rounded to the second digit, is −0.01 percent. Therefore, for FY 2023, we are proposing to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.11 percent [5.1 percent-(−.01 percent)].

When the percentage of operating outlier reconciliation dollars to total Federal operating payments rounds to a negative value (that is, when the aggregate amount of outlier reconciliation as a percent of total operating payments rounds to a negative percent), the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. In section II.A.4.i.(2). of the Addendum to this proposed rule, we provide the FY 2023 outlier threshold as calculated for this proposed rule both with and without including this proposed percentage estimate of operating outlier reconciliation.

As explained in the FY 2020 IPPS/LTCH PPS final rule, we would continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount. In the past, the outlier offset was six decimals because we targeted and set the threshold at 5.1 percent by adjusting the standardized amount by the outlier offset until operating outlier payments divided by total operating Federal payments plus operating outlier payments equaled approximately 5.1 percent (this approximation resulted in an offset beyond three decimals). However, under our methodology, we believe a three decimal offset of 0.949 reflecting 5.1 percent is appropriate rather than the unrounded six decimal offset that we have calculated for prior fiscal years. Specifically, as discussed in section II.A.5. of this Addendum, we are proposing to determine an outlier adjustment by applying a factor to the standardized amount that accounts for the projected proportion of total estimated FY 2023 operating Federal payments paid as outliers. Our proposed modification to the outlier threshold methodology is designed to adjust the total estimated outlier payments for FY 2023 by incorporating the projection of negative outlier reconciliation. That is, under this proposal, total estimated outlier payments for FY 2023 would be the sum of the estimated FY 2023 outlier payments based on the claims data from the outlier model and the estimated FY 2023 total operating outlier reconciliation dollars. We believe the proposed methodology would more accurately estimate the outlier adjustment to the standardized amount by increasing the accuracy of the calculation of the total estimated FY 2023 operating Federal payments paid as outliers. In other words, the net effect of our outlier proposal to incorporate a projection for outlier reconciliation dollars into the threshold methodology would be that FY 2023 outlier payments (which include the proposed estimated recoupment percentage for FY 2023 of 0.01 percent) would be 5.1 percent of total operating Federal payments plus total outlier payments. Therefore, the proposed operating outlier offset to the standardized amount is 0.949 (1 − 0.051).

We are inviting public comment on our proposed methodology for projecting an estimate of outlier reconciliation and incorporating that estimate into the modeling for the fixed-loss cost outlier threshold for FY 2023.

(b) Proposed Reduction to the FY 2023 Capital Standard Federal Rate by an Adjustment Factor To Account for the Projected Proportion of Capital IPPS Payments Paid as Outliers

We establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital related costs (58 FR 46348). Similar to the calculation of the adjustment to the standardized amount to account for the projected proportion of operating payments paid as outlier payments, as discussed in greater detail in section III.A.2. of this Addendum, we are proposing to reduce the FY 2023 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement would be based on operating and capital CCRs calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. As such, any reconciliation also applies to capital outlier payments.

For FY 2023, we are proposing to use the same methodology from FY 2020 to adjust the FY 2023 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. Similar to FY 2020, as part of our proposal for FY 2023 to incorporate into the outlier model the total outlier reconciliation dollars from the most recent and most complete fiscal year cost report data, we also are proposing to adjust our estimate of FY 2023 capital outlier payments to incorporate a projection of capital outlier reconciliation payments when determining the adjustment factor to be applied to the capital standard Federal rate to account for the projected proportion of capital IPPS payments paid as outliers. To do so, we are proposing to use the following methodology, which generally parallels the proposed methodology to incorporate a projection of operating outlier reconciliation payments for the FY 2023 outlier threshold calculation.

Step 1.—Use the Federal FY 2017 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules, and exclude SCHs that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We note that when there are multiple columns available for the lines of the cost report described in the following steps and the provider was paid under the IPPS for that period(s) of the cost report, then we believe it is appropriate to use multiple columns to fully represent the relevant IPPS payment amounts, consistent with our methodology for the FY 2020 final rule. We used the December 2021 HCRIS extract for this proposed rule and expect to use the March 2022 HCRIS extract for the FY 2023 final rule. Similar to the FY 2022 final rule, we may also consider the use of more recent data that may become available for purposes of projecting the estimate of capital outlier reconciliation used in the calculation of the final FY 2023 adjustment to the FY 2023 capital standard Federal rate.

Step 2.—Calculate the aggregate amount of the historical total of capital outlier reconciliation dollars (Worksheet E, Part A, Line 93, Column 1) using the Federal FY 2017 cost reports from Step 1.

Step 3.—Calculate the aggregate amount of total capital Federal payments using the Federal FY 2017

cost reports from Step 1. The total capital Federal payments consist of the capital DRG payments, including capital indirect medical education (IME) and capital disproportionate share hospital (DSH) payments (Worksheet E, Part A, Line 50, Column 1) and the capital outlier reconciliation payments (Worksheet E, Part A, Line 93, Column 1). We note that a negative amount on Worksheet E, Part A, Line 93 for capital outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital.

Step 4.—Divide the amount from Step 2 by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total capital outlier reconciliation dollars to total capital Federal payments for FY 2017. This percentage amount would be used to adjust the estimate of capital outlier payments for FY 2023 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the specific Medicare claims data in the MedPAR file used to estimate outlier payments, we are proposing that the estimate of capital outlier payments for FY 2023 would be determined by adding the percentage in Step 4 to the estimated percentage of capital outlier payments otherwise determined using the shared outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. (We note that this percentage is added for capital outlier payments but subtracted in the analogous step for operating outlier payments. We have a unified outlier payment methodology that uses a shared threshold to identify outlier cases for both operating and capital payments. The difference stems from the fact that operating outlier payments are determined by first setting a ''target'' percentage of operating outlier payments relative to aggregate operating payments which produces the outlier threshold. Once the shared threshold is set, it is used to estimate the percentage of capital outlier payments to total capital payments based on that threshold. Because the threshold is already set based on the operating target, rather than adjusting the threshold (or operating target), we adjust the percentage of capital outlier to total capital payments to account for the estimated effect of capital outlier reconciliation payments. This percentage is adjusted by adding the capital outlier reconciliation percentage from Step 4 to the estimate of the percentage of capital outlier payments to total capital payments based on the shared threshold.) Because the aggregate capital outlier reconciliation dollars from Step 2 are negative, the estimate of capital outlier payments for FY 2023 under our proposed methodology would be lower than the percentage of capital outlier payments otherwise determined using the shared outlier threshold.

Similarly, for this FY 2023 proposed rule, we used the December 2021 HCRIS extract of the cost report data to calculate the proposed percentage adjustment for outlier reconciliation. For the FY 2023 final rule, we are proposing to use the latest quarterly HCRIS extract that is publicly available at the time of the development of that rule which, for FY 2023, would be the March 2022 extract. As previously noted, we may also consider the use of more recent data that may become available for purposes of projecting the estimate of capital outlier reconciliation used in the calculation of the final FY 2023 adjustment to the FY 2023 capital standard Federal rate.

For this FY 2023 proposed rule, the estimated percentage of FY 2023 capital outlier payments otherwise determined using the shared outlier threshold is 5.56 percent (estimated capital outlier payments of $394,593,407 divided by (estimated capital outlier payments of $394,593,407 plus the estimated total capital Federal payment of $6,707,033,365)). Based on the December 2021 HCRIS, # hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 93 for total capital outlier reconciliation dollars of negative $759,945 (Step 2). The total Federal capital payments based on the December 2021 HCRIS was $7,992,953,494 (Step 3) which results in a ratio (Step 4) of −0.01 percent. Therefore, for FY 2023, taking into account projected capital outlier reconciliation payments under our proposed methodology would decrease the estimated percentage of FY 2023 aggregate capital outlier payments by 0.01 percent.

As discussed in section III.A.2. of this Addendum, we are proposing to incorporate the capital outlier reconciliation dollars from Step 5 when applying the outlier adjustment factor in determining the capital Federal rate based on the estimated percentage of capital outlier payments to total capital Federal rate payments for FY 2023.

We are inviting public comment on our proposed methodology for projecting an estimate of capital outlier reconciliation and incorporating that estimate into the modeling of the estimate of FY 2023 capital outlier payments for purposes of determining the capital outlier adjustment factor.

(2) Proposed FY 2023 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for a detailed discussion of the changes.

As we have done in the past, to calculate the proposed FY 2023 outlier threshold, we simulated payments by applying proposed FY 2023 payment rates and policies using cases from the FY 2021 MedPAR file. As noted in section II.C. of this Addendum, we specify the formula used for actual claim payment which is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described later in this section) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

In order to determine the proposed FY 2023 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2021 to FY 2023. Consistent with the FY 2020 IPPS/LTCH PPS final rule (84 FR 42626 and 42627), we are proposing to use the following methodology to calculate the charge inflation factor for FY 2023:

- Include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); include CAHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor; include hospitals in Maryland; and remove PPS-excluded cancer hospitals who have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- Include providers that are in both periods of charge data that are used to calculate the 1-year average annual rate of-change in charges per case. We note this is consistent with the methodology used since FY 2014.

• We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

• In order to ensure that we capture only FFS claims, we included claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).

• In order to further ensure that we capture only FFS claims, we excluded claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).

• We examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS. As noted previously, we are proposing to remove allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835–58842).

• Because this payment simulation uses the proposed FY 2023 relative weights, consistent with our proposal discussed in section IV.I. of the preamble to this proposed rule, we applied the proposed adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments. As discussed in section II.E.2.b. of the preamble of this proposed rule, we are applying a proposed adjustment to account for certain cases that group to MS–DRG 018 in calculating the FY 2023 relative weights and for purposes of budget neutrality and outlier simulations.

Our general methodology to inflate the charges computes the 1-year average annual rate-of-change in charges per case which is then applied twice to inflate the charges on the MedPAR claims by 2 years since we typically use claims data for the fiscal year that is 2 years prior to the upcoming fiscal year.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42627), we modified our charge inflation methodology. We stated that we believe balancing our preference to use the latest available data from the MedPAR files and stakeholders' concerns about being able to use publicly available MedPAR files to review the charge inflation factor can be achieved by modifying our methodology to use the publicly available Federal fiscal year period (that is, for FY 2020, we used the charge data from Federal fiscal years 2017 and 2018), rather than the most recent data available to CMS which, under our prior methodology, was based on calendar year data. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for a complete discussion regarding this change.

For FY 2023, under our policy of computing the charge inflation factor using the publicly available Federal fiscal year period, we would ordinarily use charge data from the MedPAR files for Federal fiscal years 2020 and 2021 to compute the 1-year average annual rate-of-change in charges per case. Specifically, for this proposed rule, we would ordinarily use the December 2020 MedPAR file of FY 2020 (October 1, 2019, through September 30, 2020) charge data and the December 2021 MedPAR file of FY 2021 (October 1, 2021, through September 30, 2021) charge data to compute the proposed charge inflation factor. However, based on our analysis, the charge inflation factors calculated using these two most recently available years of MedPAR claims data (FY 2020 and FY 2021) are abnormally high as compared to recent historical levels prior to the COVID–19 PHE period. Specifically, we calculated a 1-year average annual rate-of-change in charges per case of approximately 10 percent based on the FY 2020 and FY 2021 MedPAR claims data, as compared to approximately 6 percent based on the FY 2018 and 2019 MedPAR claims data for the two most recent Federal fiscal year time periods prior to the PHE. We believe this abnormally high charge inflation as compared to historical levels was partially due to the high number of COVID–19 cases with higher charges that were treated in IPPS hospitals in FY 2021. As discussed in section I.F of the preamble of this proposed rule, we believe there will be fewer COVID–19 cases in FY 2023 than in FY 2021. Therefore, we do not believe it is reasonable to assume charges will continue to increase at these abnormally high rates.

Therefore, for FY 2023, we are proposing to use the same methodology as FY 2020, with a proposed modification to use the most recent 1-year average annual rate-of-change in charges per case for the period prior to the COVID–19 PHE, and based on the same data used in the FY 2021 IPPS/LTCH PPS final rule to determine the charge inflation factor for this proposed rule. We further note that this is the same data used to determine the charge inflation factor for the FY 2022 IPPS/LTCH PPS rulemaking. Specifically, for FY 2023, we are proposing to use the MedPAR files for the two most recent available Federal fiscal year time periods prior to the COVID–19 PHE to calculate the charge inflation factor. Specifically, for this proposed rule we are proposing to use the March 2019 MedPAR file of FY 2018 (October 1, 2017, to September 30, 2018) charge data (released for the FY 2020 IPPS/LTCH PPS final rule) and the March 2020 MedPAR file of FY 2019 (October 1, 2018, to September 30, 2019) charge data (released for the FY 2021 IPPS/LTCH PPS final rule) to compute the proposed charge inflation factor. We propose that for the FY 2023 IPPS/LTCH PPS final rule, we would continue to use the charge inflation estimate from the FY 2021 IPPS/LTCH PPS final rule. Under this proposed methodology, to compute the 1-year average annual rate-of-change in charges per case for FY 2023, we compared the average covered charge per case of $61,578.82 ($584,618,863,834/9,493,830 cases) from October 1, 2017, through September 31, 2018, to the average covered charge per case of $65,522.10 ($604,209,834,327/9,221,466 cases) from October 1, 2018, through September 31, 2019. This rate-of-change was 6.4 percent (1.06404) or 13.2 percent over two years (1.13218). Because we are proposing to use the FY 2021 MedPAR for the FY 2023 ratesetting, we applied a factor of 13.2 percent over 2 years. The billed charges are obtained from the claim from the MedPAR file and inflated by the inflation factor specified previously.

We are also soliciting comments on the alternative approach of using the data we would ordinarily use to determine the charge inflation factor for purposes of this FY 2023 rule (that is, charge data from FYs 2020 and 2021 to compute the 1-year average annual rate of change in charges per case), and note that under this alternative approach, if finalized, we would anticipate using more recently updated data from FYs 2020 and 2021 for purposes of the FY 2023 IPPS/LTCH PPS final rule. As previously noted, in order to facilitate comments on our alternative approach of using the FY 2021 MedPAR claims for purposes of FY 2023 ratesetting but without the proposed modifications to our usual methodologies, including use of the same data that we would

ordinarily use for purposes of determining the charge inflation factor for this FY 2023 rulemaking, and which we may consider finalizing for FY 2023 based on consideration of comments received, we are making available budget neutrality and other ratesetting adjustments, including the charge inflation factor, calculated under this alternative approach, which can be found on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.* We include in a supplemental data file the following: Budget neutrality factors, charge inflation factor, the CCR adjustment factors, an impact file and outlier threshold based on this alternative approach. Consistent with historical practice, if we were to finalize this alternative approach, we would use the most recent available data for the final rule, as appropriate.

In this proposed rule, we are proposing to establish the FY 2023 outlier threshold using hospital CCRs from the December 2021 update to the Provider-Specific File (PSF), the most recent available data at the time of developing this proposed rule. We are proposing to apply the following edits to providers' CCRs in the PSF. We believe these edits are appropriate in order to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replace these CCRs with the statewide average CCR for the upcoming fiscal year. We also assign the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We do not apply the adjustment factors described later in this section to hospitals assigned the statewide average CCR. For FY 2023, we are also proposing to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained further in this section).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

Ordinarily, for the proposed rule, we would apply a proposed adjustment factor to adjust the CCRs from the December 2021 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2020 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2021 update of the PSF. However, the operating and capital CCR adjustment factors based on the data we ordinarily would use are above 1.0. Since the implementation of our new methodology to adjust the CCRs in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), the operating and capital CCR adjustment factors have typically been below 1.0 (for example, operating and capital CCR adjustment factors of approximately 1.03 and 1.03, respectively, based on the December 2020 and December 2021 updates to the PSF as compared to operating and capital CCR adjustment factors of approximately 0.97 and 0.96, respectively, based on the March 2019 and March 2020 updates to the PSF). As stated in section I.F. of the preamble to this proposed rule, we believe this abnormally high CCR adjustment factor as compared to historical levels is partially due to the high number of COVID–19 cases with higher charges that were treated in IPPS hospitals in FY 2021. As we previously stated, we believe there will be fewer COVID–19 cases in FY 2023 than in FY 2021. Therefore, we do not believe it is reasonable to assume CCRs will continue to increase at these abnormally high rates. Therefore, we are proposing to adjust the CCRs from the December 2021 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the March 2019 update of the PSF to the national average case-weighted operating CCR and capital CCR from the March 2020 update of the PSF, which is the last update of the PSF prior to the PHE. We note that this is the same data used to adjust the CCRs for the FY 2022 IPPS/LTCH PPS rulemaking. We believe using these data for the latest available period prior to the PHE, for which the percentage change in the national average case weighted operating CCR and capital CCR is below 1.0, is appropriate in light of our expectation that the CCRs will not continue to increase at these abnormally high rates for FY 2023. We note that we used total transfer-adjusted cases from FY 2019 to determine the national average case-weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison, because this would produce the true percentage change in the average case-weighted operating and capital CCR from 1 year to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology, for this proposed rule, we calculated a March 2019 operating national average case-weighted CCR of 0.254027 and a March 2020 operating national average case-weighted CCR of 0.247548. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the March 2019 operating national average case-weighted CCR from the March 2020 operating national average case-weighted CCR and then dividing the result by the March 2019 national operating average case-weighted CCR. This resulted in a proposed one-year national operating CCR adjustment factor of 0.974495. Because we are proposing to use CCRs from the December 2021 update of the PSF for FY 2023, we are applying a one-year proposed national operating CCR adjustment.

We used this same proposed methodology to adjust the capital CCRs. Specifically, we calculated a March 2019 capital national average case-weighted CCR of 0.02073 and a March 2020 capital national average case-weighted CCR of 0.019935. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the March 2019 capital national average case-weighted CCR from the March 2020 capital national average case-weighted CCR and then dividing the result by the March 2019 capital national average case-weighted CCR. This resulted in a proposed one-year national capital CCR adjustment factor of 0.96165. Because we are proposing to use CCRs from the December 2021 update of the PSF for FY 2023, we are applying a one-year proposed national capital CCR adjustment.

As discussed in section I.F. of this proposed rule and in section I.O. of Appendix A of this proposed rule, we are soliciting comments on an alternative approach of using the data that we would ordinarily use for purposes of adjusting the CCRs for this FY 2023 rulemaking, which we may consider finalizing for FY 2023 based on consideration of comments received. As previously noted, in order to facilitate comments on our alternative approach of using the FY 2021 MedPAR claims for purposes of FY 2023 ratesetting but

without the proposed modifications to our usual methodologies, we are making available supplemental data files, including the following: Budget neutrality factors, charge inflation factor, the CCR adjustment factors, and outlier threshold based on this alternative approach. Consistent with historical practice, if we were to finalize this alternative approach, we would use the most recent available data for the final rule, as appropriate.

For purposes of estimating the proposed outlier threshold for FY 2023, we used a wage index that reflects the policies discussed in the proposed rule. This includes all of the following:

- The proposed frontier State floor adjustments in accordance with section 10324(a) of the Affordable Care Act.
- The proposed out-migration adjustment as added by section 505 of Public Law 108–173.
- Incorporating the proposed FY 2023 low wage index hospital policy (described in section III. G. 4 of the preamble of this proposed rule) for hospitals with a wage index value below the 25th percentile, where the increase in the wage index value for these hospitals would be equal to half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals.
- Incorporating our proposed policy (described in section III. N of the preamble of this proposed rule) to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline.

If we did not take the aforementioned into account, our estimate of total FY 2023 payments would be too low, and, as a result, our proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments (which includes outlier reconciliation).

As described in sections V.K. and V.L., respectively, of the preamble of this proposed rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the proposed hospital VBP payment adjustments and the hospital readmissions payment adjustments in the proposed outlier threshold calculation or the proposed outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we are proposing to exclude the estimated hospital VBP payment adjustments and the estimated hospital readmissions payment adjustments from the calculation of the proposed outlier fixed-loss cost threshold.

We note that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) of the Act, the uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, for FY 2023, we are proposing to allocate an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally. Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2023, we are proposing to include estimated FY 2023 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we are proposing to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

In addition, as discussed in section IV.E. of the preamble of the proposed rule, we are proposing to establish a supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, beginning in FY 2023. We are proposing to make interim payments of this proposed new supplement payment on a per-discharge basis. Consistent with the policy of including estimated uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold, as previously summarized, we are proposing to use our authority under section 1886(d)(5)(I) of the Act to include the estimated supplemental payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we are proposing to use the estimated per-discharge supplemental payments to hospitals eligible for the supplemental payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1. of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, we are proposing to incorporate an estimate of FY 2023 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, for this FY 2023 proposed rule, the ratio of outlier reconciliation dollars to total Federal Payments (Step 4) is a negative 0.013508 percent, which, when rounded to the second digit, is −0.01 percent. Therefore, for FY 2023, we are proposing to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.11 percent [5.1 percent − (−.01 percent)]. Under this proposed approach, we determined a threshold of $43,214 and calculated total outlier payments of $4,709,906,314 and total operating Federal payments of $88,837,735,468. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.11 percent target, which reflects our proposal to incorporate an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum). We

note that, if calculated without applying our proposed methodology for incorporating an estimate of outlier reconciliation in the determination of the outlier threshold, the proposed threshold would be $43,292. We are proposing an outlier fixed-loss cost threshold for FY 2023 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, proposed estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and any add-on payments for new technology, plus $43,214.

As previously noted, and as discussed further in section I.O of the Appendix A of this proposed rule, we are also considering an alternative approach of using the FY 2021 MedPAR claims for purposes of FY 2023 ratesetting but without the proposed modifications to our usual methodologies, including use of the same data we would ordinarily use for purposes of this FY 2023 rulemaking to compute the charge inflation factors and CCR adjustment factors in determining the FY 2023 outlier fixed-loss amount for IPPS cases. Under this alternative approach, we estimate an outlier threshold of $58,798 rather than the proposed threshold of $43,214 above.

(3) Other Proposed Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a higher percentage of outlier payments for capital-related costs than for operating costs. We project that the threshold for FY 2023 (which reflects our methodology to incorporate an estimate of operating outlier reconciliation) would result in outlier payments that would equal 5.1 percent of operating DRG payments and we estimate that capital outlier payments would equal 5.55 percent of capital payments based on the Federal rate (which reflects our methodology discussed previously to incorporate an estimate of capital outlier reconciliation).

In accordance with section 1886(d)(3)(B) of the Act and as discussed previously, we are proposing to reduce the FY 2023 standardized amount by 5.1 percent to account for the projected proportion of payments paid as outliers.

The proposed outlier adjustment factors that would be applied to the operating standardized amount and capital Federal rate based on the proposed FY 2023 outlier threshold are as follows:

	Operating Standardized Amounts	Capital Federal Rate*
National	0.949	0.944536

*The adjustment factor for the capital Federal rate includes an adjustment to the estimated percentage of FY 2023 capital outlier payments for capital outlier reconciliation, as discussed previously and in section III. A. 2 in the Addendum of this proposed rule.

We are proposing to apply the outlier adjustment factors to the FY 2023 payment rates after removing the effects of the FY 2022 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we currently apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the MAC computes operating CCRs greater than 1.222 or capital CCRs greater than 0.141 or hospitals for which the MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the proposed statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the range previously specified. These statewide average ratios would be effective for discharges occurring on or after October 1, 2022, and would replace the statewide average ratios from the prior fiscal year. Table 8B listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the comparable proposed statewide average capital CCRs. As previously stated, the proposed CCRs in Tables 8A and 8B would be used during FY 2023 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted previously. Table 8C listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the proposed statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that section 20.1.2 of chapter three of the Medicare Claims Processing Manual (on the internet at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) covers an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their MAC on a possible alternative operating and/or capital CCR as explained in the manual. Use of an alternative CCR developed by the hospital in conjunction with the MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR at any time as long as the guidelines of the manual are followed. In addition, the manual outlines the outlier reconciliation process for hospitals and Medicare contractors. We refer hospitals to the manual instructions for complete details on outlier reconciliation.

(4) FY 2021 Outlier Payments

Our current estimate, using available FY 2021 claims data, is that actual outlier payments for FY 2021 were approximately 5.62 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2021, the percentage of actual outlier payments relative to actual total payments is

higher than we projected for FY 2021. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2021 are equal to 5.1 percent of total MS–DRG payments. As explained in the FY 2003 Outlier final rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS–DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the statutory language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section states that outlier payments be equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS–DRG payments. We believe that an important goal of a PPS is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that, because the MedPAR claims data for the entire FY 2022 period would not be available until after September 30, 2022, we are unable to provide an estimate of actual outlier payments for FY 2022 based on FY 2022 claims data in this proposed rule. We will provide an estimate of actual FY 2022 outlier payments in the FY 2024 IPPS/LTCH PPS proposed rule.

5. Proposed FY 2023 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the internet on the CMS website) contain the national standardized amounts that we are proposing to apply to all hospitals, except hospitals located in Puerto Rico, for FY 2023. The proposed standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). The proposed amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 67.6 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are proposing to apply a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we would apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the proposed standardized amounts reflecting the proposed applicable percentage increases for FY 2023.

The proposed labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2023 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). Similarly, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2022 national standardized amounts to the proposed FY 2023 national standardized amounts. The second through fifth columns display the changes from the FY 2022 standardized amounts for each proposed applicable FY 2023 standardized amount. The first row of the table shows the updated (through FY 2022) average standardized amount after restoring the FY 2022 offsets for outlier payments, geographic reclassification, rural demonstration, lowest quartile, and transition budget neutrality. The MS–DRG reclassification and recalibration, wage index, and stem cell acquisition budget neutrality factors are cumulative (that is, we have not restored the offsets). Accordingly, those FY 2022 adjustment factors have not been removed from the base rate in the following table. Additionally, for FY 2023 we have applied the budget neutrality factors for the lowest quartile hospital policy, described previously.

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CHANGES FROM FY 2022 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2023 STANDARDIZED AMOUNTS

	Hospital Submitted Quality Data and is a Meaningful EHR User	**Hospital Submitted Quality Data and is NOT a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User**
FY 2023 Base Rate after removing: 1. FY 2022 Geographic Reclassification Budget Neutrality (0.986741) 2. FY 2022 Operating Outlier Offset (0.949) 3. FY 2022 Rural Demonstration Budget Neutrality Factor (0.999361) 4. FY 2022 Lowest Quartile Budget Neutrality Factor (0.998029) 5. FY 2022 Transition Budget Neutrality Factor (0.999859)	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,431.41 Nonlabor (32.4%): $ 2,123.93	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,431.41 Nonlabor (32.4%): $ 2,123.93	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,431.41 Nonlabor (32.4%): $ 2,123.93	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,431.41 Nonlabor (32.4%): $ 2,123.93
	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 4,064.31 Nonlabor (38%): $ 2,491.03	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 4,064.31 Nonlabor (38%): $ 2,491.03	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 4,064.31 Nonlabor (38%): $ 2,491.03	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 4,064.31 Nonlabor (38%): $ 2,491.03
Proposed FY 2023 Update Factor	1.027	1.00375	1.01925	0.996
Proposed FY 2023 MS-DRG Reclassification and Recalibration Budget Neutrality Factor Before Cap	1.000491	1.000491	1.000491	1.000491
Proposed FY 2023 Cap Policy MS-DRG Weight Budget Neutrality Factor	0.999765	0.999765	0.999765	0.999765
Proposed FY 2023 Wage Index Budget Neutrality Factor	1.001303	1.001303	1.001303	1.001303
Proposed FY 2023 Reclassification Budget Neutrality Factor	0.985346	0.985346	0.985346	0.985346
Proposed FY 2023 Lowest Quartile Budget Neutrality Factor	0.998205	0.998205	0.998205	0.998205
Proposed FY 2023 Cap Policy Wage Index Budget Neutrality Factor	0.999563	0.999563	0.999563	0.999563
Proposed FY 2023 RCH Demonstration Budget Neutrality Factor	0.998925	0.998925	0.998925	0.998925
Proposed FY 2023 Operating Outlier Factor	0.949	0.949	0.949	0.949
Adjustment for FY 2023 Required under Section 414 of Pub. L. 114-10 (MACRA)	1.005	1.005	1.005	1.005
Proposed National Standardized Amount for FY 2023 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (67.6/32.4)	**Labor: $4,269.46 Nonlabor $2,046.31**	**Labor: $4,172.80 Nonlabor: $1,999.98**	**Labor: $4,237.24 Nonlabor: $2,030.87**	**Labor: $4,140.59 Nonlabor: $1,984.54**
Proposed National Standardized Amount for FY 2023 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38)	**Labor: $3,915.78 Nonlabor: $2,399.99**	**Labor: $3,827.12 Nonlabor: $2,345.66**	**Labor: $3,886.23 Nonlabor: $2,381.88**	**Labor: $3,797.58 Nonlabor: $2,327.55**

B. Proposed Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the internet on the CMS website), contain the proposed labor-related and nonlabor-related shares that we are proposing to use to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2023. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Proposed Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national prospective payment rate to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. For FY 2023, as discussed in section IV.B.3. of the preamble of this proposed rule, we are proposing to apply a labor-related share of 67.6 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000. In section III. of the preamble of this proposed rule, we discuss the data and methodology for the FY 2023 wage index.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described previously. To account for higher non-labor related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii by an adjustment factor.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the U.S. Office of Personnel Management (OPM) every 4 years (at the same time as the update to the labor related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively). For FY 2022, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45546 through 45547), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule. Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we are continuing to use the same COLA factors in FY 2023 that were used in FY 2022 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. The following table lists the COLA factors for FY 2023.

FY 2023 Cost-of-Living Adjustment Factors (COLA): Alaska and Hawaii Hospitals

Area	FY 2022 - FY 2025
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.22
Rest of Alaska	1.24
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.22
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

Lastly, as we finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701), we intend to update the COLA factors based on our methodology every 4 years, at the same time as the update to the labor-related share of the IPPS market basket.

C. Calculation of the Proposed Prospective Payment Rates

1. General Formula for Calculation of the Prospective Payment Rates for FY 2023

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs, for FY 2023 equals the Federal rate (which includes uncompensated care payments). Under current law, the MDH program is effective for discharges on or before September 30, 2022. Therefore, under current law, the MDH program will expire at the end of FY 2022.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (which, as discussed in section VI.G. of the preamble of this proposed rule, includes uncompensated care payments); the updated hospital-

specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2022 equals the higher of the applicable Federal rate, or the hospital-specific rate as described later in this section.

2. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula specified in this section is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described previously) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier). We note that the formula specified below reflects our proposal to include the proposed estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals in the computation of the outlier fixed-loss cost threshold.

Step 1—Determine the MS–DRG and MS–DRG relative weight (from Table 5) for each claim based on the ICD–10–CM diagnosis and ICD–10–PCS procedure codes on the claim.

Step 2—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described previously.

Step 3—Compute the operating and capital Federal payment rate:

—Federal Payment Rate for Operating Costs = MS–DRG Relative Weight × [(Labor-Related Applicable Standardized Amount × Applicable CBSA Wage Index) + (Nonlabor-Related Applicable Standardized Amount × Cost-of-Living Adjustment)] × (1 + IME + (DSH * 0.25))

—Federal Payment for Capital Costs = MS–DRG Relative Weight × Federal Capital Rate × Geographic Adjustment Fact × (l + IME + DSH)

Step 4—Determine operating and capital costs:

—Operating Costs = (Billed Charges × Operating CCR)

—Capital Costs = (Billed Charges × Capital CCR).

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital outlier threshold to account for local cost variation):

—Operating CCR to Total CCR = (Operating CCR)/(Operating CCR + Capital CCR)

—Operating Outlier Threshold = [Fixed Loss Threshold × ((Labor-Related Portion × CBSA Wage Index) + Nonlabor-Related portion)] × Operating CCR to Total CCR + Federal Payment with IME, DSH + Uncompensated Care Payment + Proposed Supplemental Payment for IHS/Tribal hospitals and Puerto Rico hospitals + New Technology Add-On Payment Amount

—Capital CCR to Total CCR = (Capital CCR)/(Operating CCR + Capital CCR)

—Capital Outlier Threshold = (Fixed Loss Threshold × Geographic Adjustment Factor × Capital CCR to Total CCR) + Federal Payment with IME and DSH

Step 6—Compute operating and capital outlier payments:

—Marginal Cost Factor = 0.80 or 0.90 (depending on the MS–DRG)

—Operating Outlier Payment = (Operating Costs − Operating Outlier Threshold) × Marginal Cost Factor

—Capital Outlier Payment = (Capital Costs − Capital Outlier Threshold) × Marginal Cost Factor

The payment rate may then be further adjusted for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b). The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Payments also may be reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments in accordance with section 1886(d)(5)(K) and (L) of the Act. In addition, we add the uncompensated care payment to the total claim payment amount. As noted in the previous formula, we take uncompensated care payments and new technology add-on payments into consideration when calculating outlier payments. Finally, as previously discussed, we are also proposing, beginning in FY 2023, to take into consideration the proposed supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals when calculating outlier payments.

3. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment. (We note, under current law, the MDH program is effective for discharges on or before September 30, 2022. Therefore, under current law, the MDH program will expire at the end of FY 2022.)

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2023

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the proposed applicable percentage increases to the hospital-specific rates applicable to SCHs are the following:

FY 2023	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	3.1	3.1	3.1	3.1
Proposed Adjustment for Failure to Submit Quality Data under section 1886(b)(3)(B)(viii) of the Act	0	0	-0.775	-0.775
Proposed Adjustment for Failure to be a Meaningful EHR User under section 1886(b)(3)(B)(ix) of the Act	0	-2.325	0	-2.325
Proposed Productivity Adjustment under section 1886(b)(3)(B)(xi) of the Act	-0.4	-0.4	-0.4	-0.4
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.7**	**0.375**	**1.925**	**-0.4**

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs, we refer readers to section V.B. of the preamble of this proposed rule.

In addition, because SCHs use the same MS–DRGs as other hospitals when they are paid based on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital specific-rate for an SCH is adjusted by the proposed MS–DRG reclassification and recalibration budget neutrality factor, as discussed in section III. of this Addendum and listed in the table in section II. of this Addendum. In addition, as discussed in section II.E.2.d of this proposed rule and above, we are proposing a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. As discussed in section II.E.2.d of this proposed rule, and consistent with our current methodology for implementing budget neutrality for DRG reclassification and recalibration of the relative weights, we are proposing to apply a budget neutrality adjustment to the standardized amount for all hospitals so that this proposed 10-percent cap on relative weight reductions does not increase estimated aggregate Medicare payments beyond the payments that would be made had we never applied this cap. As mentioned previously, SCHs use the same MS–DRGs as other hospitals when they are paid based on the hospital-specific rate. Therefore, we are proposing that the hospital specific-rate for an SCH would be adjusted by the proposed MS–DRG 10-percent cap budget neutrality factor. The resulting rate is used in determining the payment rate that an SCH would receive for its discharges beginning on or after October 1, 2022. We note that, in this proposed rule, for FY 2023, we are not proposing to make a documentation and coding adjustment to the hospital specific-rate. We refer readers to section II.D. of the preamble of this proposed rule for a complete discussion regarding our proposed policies and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case mix.

We note, as mentioned previously, under current law, the MDH program is effective for discharges on or before September 30, 2022. Therefore, under current law, the MDH program will expire at the end of FY 2022. However, if the MDH program were to be extended by Congress for FY 2023, we would propose to apply the MS–DRG reclassification and recalibration budget neutrality factor and the proposed cap policy MS–DRG budget neutrality factor to the hospital specific rate for MDHs.

III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2023

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. In this section of this Addendum, we discuss the factors that we are proposing to use to determine the capital Federal rate for FY 2023, which would be effective for discharges occurring on or after October 1, 2022.

All hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. We annually update the capital standard Federal rate, as provided in § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs, which currently specifies capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the Federal rate.

A. Determination of the Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update for FY 2023

In the discussion that follows, we explain the factors that we are proposing to use to determine the capital Federal rate for FY 2023. In particular, we explain why the proposed FY 2023 capital Federal rate would increase approximately 1.63 percent, compared to the FY 2022 capital Federal rate. As discussed in the impact analysis in Appendix A to this proposed rule, we

estimate that capital payments per discharge would decrease approximately 0.4 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a 1-percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

In section I.F. of the preamble to this proposed rule, we discuss our proposal to use FY 2021 data for purposes of FY 2023 IPPS ratesetting. Consistent with this proposal, for this proposed rule we are proposing to use claims from the December 2021 update of the FY 2021 MedPAR file for purposes of calculating the budget neutrality adjustment factors for changes resulting from the annual DRG reclassification and recalibration and changes in the GAF. However, we also discuss in section I.F of the preamble to this proposed rule certain modifications we propose to make to our usual methodologies to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries at IPPS hospitals in FY 2023 as compared to FY 2021. First, we are proposing to modify the calculation of the FY 2023 MS–DRG relative weights by first calculating two sets of weights, one including and one excluding COVID–19 claims in the FY 2021 data, and then averaging the two sets of relative weights to determine the proposed FY 2023 MS–DRG relative weight values (as described in greater detail in section II.E. of the preamble to this proposed rule). Second, we are proposing to modify our methodologies for determining the FY 2023 outlier fixed-loss amount for IPPS cases by using charge inflation factors and CCR adjustment factors based on the last 1-year period prior to the COVID–19 PHE (as discussed in greater detail in section II.A.4. of the Addendum to this proposed rule). In section I.O. of Appendix A of this proposed rule, we are also considering as an alternative to this proposal, to use the FY 2021 data for purposes of FY 2023 IPPS ratesetting without these proposed modifications to our usual methodologies for the calculation of the FY 2023 MS–DRG relative weights or the usual methodologies used to determine the FY 2023 outlier fixed-loss amount for IPPS cases. We refer the reader to section I.O. of Appendix A of this proposed rule for a discussion of the files that we are making available with regard to our alternative approach.

1. Projected Capital Standard Federal Rate Update

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate of change, as appropriate, each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The proposed update factor for FY 2023 under that framework is 1.7 percent based on a projected 1.7 percent increase in the 2018-based CIPI, a proposed 0.0 percentage point adjustment for intensity, a proposed 0.0 percentage point adjustment for case-mix, a proposed 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a proposed forecast error correction of 0.0 percentage point. As discussed in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2023 CIPI projection in that same section of this Addendum. In this proposed rule, we describe the policy adjustments that we are proposing to apply in the update framework for FY 2023.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons—

- The average resource use of Medicare patient changes (''real'' case-mix change);
- Changes in hospital documentation and coding of patient records result in higher-weighted DRG assignments (''coding effects''); or
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients, as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts, as discussed in section II. of Appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2023, we are projecting a 1.0 percent total increase in the case-mix index. We estimated that the real case-mix increase would equal 1.0 percent for FY 2023. The net adjustment for change in case-mix is the difference between the projected real increases in case mix and the projected total increase in case mix. Therefore, the proposed net adjustment for case-mix change in FY 2023 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, for this proposed rule, we have the FY 2021 MedPAR claims data available to evaluate the effects of the FY 2021 DRG reclassification and recalibration as part of our update for FY 2023. We assume for purposes of this adjustment, that the estimate of FY 2021 DRG reclassification and recalibration would result in no change in the case-mix when compared with the case mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, we are proposing to make a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2023.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is greater than 0.25 percentage point in absolute terms. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended

under this framework. A forecast error of −0.1 percentage point was calculated for the FY 2021 update, for which there are historical data. That is, current historical data indicated that the forecasted FY 2021 CIPI (1.1 percent) used in calculating the FY 2021 update factor is 0.1 percentage point higher than actual realized price increases (1.0 percent). As this does not exceed the 0.25 percentage point threshold, we are not proposing an adjustment for forecast error in the update for FY 2023.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculate this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflects how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the CPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity changes that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual change is due to each of these factors. Thus, the capital update framework provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this proposed rule, we are proposing to continue to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2023 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 0436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2023, we are proposing to use an intensity measure that is based on an average of cost-per-discharge data from the 5-year period beginning with FY 2016 and extending through FY 2020. Based on these data, we estimated that case-mix constant intensity declined during FYs 2016 through 2020. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimated that intensity would decline during that 5-year period, we believe it is appropriate to continue to apply a zero-intensity adjustment for FY 2023. Therefore, we are proposing to make a 0.0 percentage point adjustment for intensity in the update for FY 2023.

Earlier, we described the basis of the components we used to develop the proposed 1.7 percent capital update factor under the capital update framework for FY 2023, as shown in the following table.

PROPOSED FY 2023 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.7
Intensity:	0.0
Case-Mix Adjustment Factors:	
Projected Case-Mix Change	-1.0
Real Across DRG Change	1.0
Subtotal	0.0
Effect of FY 2021 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Proposed Update	1.7

*The capital input price index represents the 2018-based CIPI.

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A shared threshold is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier threshold is set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments. For FY 2023, we are proposing to incorporate the estimated outlier reconciliation payment amounts into the outlier threshold model, as we did for FY 2022. (For more details on our proposal to incorporate outlier reconciliation payment amounts into the outlier threshold model, please see section II.A. of this Addendum to this proposed rule.)

For FY 2022, we estimated that outlier payments for capital-related PPS payments would equal 5.29 percent of inpatient capital-related payments based on the capital Federal rate in FY 2022. Based on the threshold discussed in section II.A. of this Addendum, we estimate that prior to taking into account projected capital outlier reconciliation payments, outlier payments for capital-related costs would equal 5.56 percent for inpatient capital-related payments based on the proposed capital Federal rate in FY 2023. However, using the methodology outlined in section II.A. of this Addendum, we estimate that taking into account projected capital outlier reconciliation payments would decrease FY 2023 aggregate estimated capital outlier payments by 0.01 percent. Therefore, accounting for estimated capital outlier reconciliation, the estimated outlier payments for capital-related PPS payments would equal 5.55 percent (5.56 percent − 0.01 percent) of inpatient capital-related payments based on the capital Federal rate in FY 2023. Accordingly, we are proposing to apply an outlier adjustment factor of 0.9445 in determining the capital Federal rate for FY 2023. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for

FY 2023 would be higher than the percentage for FY 2022.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The proposed FY 2023 outlier adjustment of 0.9445 is a −0.27 percent change from the FY 2022 outlier adjustment of 0.9471. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2023 is 0.9973 (0.9445/0.9471) so that the proposed outlier adjustment would decrease the FY 2023 capital Federal rate by approximately −0.27 percent compared to the FY 2022 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate, after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF, are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes.

As discussed in section III.G.3. of the preamble of this proposed rule, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized a policy to help reduce wage index disparities between high and low wage index hospitals by increasing the wage index values for hospitals with a wage index value below the 25th percentile wage index. We stated that this policy will be effective for at least 4 years, beginning in FY 2020. Therefore, as discussed in section III.G.3 of the preamble of this proposed rule, this policy was applied in FYs 2020, 2021 and 2022, and will continue to apply in FY 2023. In addition, in FYs 2020 and 2021, we placed a 5 percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year (see (84 FR 42336 through 42338) and (85 FR 58753 through 58755)). In FY 2022, we finalized a policy that for hospitals that received the transition in FY 2021 (that is hospitals that received a 5 percent cap on their FY 2021 wage index), we continued a wage index transition for FY 2022 under which we applied a 5 percent cap on any decrease in the hospital's wage index compared to its wage index for FY 2021 (86 FR 45164 through 45165). Beginning in FY 2023, as discussed in section III.N. of the preamble to this proposed rule, we are proposing a permanent cap on wage index decreases, limiting the overall reductions in a hospital's wage index value for the upcoming FY to be no greater than 5 percent of its wage index value for the current FY. That is, under this proposed policy a hospital's wage index value would not be less than 95 percent of its prior year value.

As we discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42638 through 42639), we augmented our historical methodology for computing the budget neutrality factor for changes in the GAFs in light of the effect of those wage index changes on the GAFs. Specifically, we established a 2-step methodology, under which we first calculate a factor to ensure budget neutrality for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy, consistent with our historical GAF budget neutrality factor methodology. In the second step, we calculate a factor to ensure budget neutrality for changes to the GAFs due to our policy to increase the wage index for hospitals with a wage index value below the 25th percentile wage index and our policy to place a 5 percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year. In this section, we refer to these two policies as the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases. We further note that in this section, we refer to the proposed permanent cap on wage index decreases beginning in FY 2023 as the proposed 5 percent cap on wage index decreases policy.

The budget neutrality factors applied for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are built permanently into the capital Federal rate; that is, they are applied cumulatively in determining the capital Federal rate. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45552), we finalized our proposal to not permanently apply the budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases such that they would not be applied cumulatively in determining the capital Federal rate. We believe this is more technically appropriate because the GAFs with the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases policies applied from the previous year are not used in the budget neutrality factor calculations for the current year. Accordingly and consistent with this approach, prior to calculating the proposed GAF budget neutrality factors for FY 2023, we removed from the capital Federal rate the budget neutrality factor applied in FY 2022 for the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases. Specifically, we divided the capital Federal rate by the FY 2022 budget neutrality factor of 0.9974 (86 FR 45552). We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45552) for additional discussion on our policy of removing the prior year budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases from the capital Federal rate.

In light of the proposed changes to the wage index and other proposed wage index policies for FY 2023 discussed previously, which directly affect the GAF, we are proposing to continue to compute a budget neutrality adjustment for changes in the GAFs in two steps. We discuss our proposed 2-step calculation of the proposed GAF budget neutrality factors for FY 2023 as follows.

To determine the GAF budget neutrality factors for FY 2023, we first compared estimated aggregate capital Federal rate payments based on the FY 2022 MS–DRG classifications and relative weights and the FY 2022 GAFs to estimated aggregate capital Federal rate payments based on the FY 2022 MS–DRG classifications and relative weights and the proposed FY 2023 GAFs without incorporating the lowest quartile hospital wage index adjustment and the proposed 5 percent cap on wage index decreases policy. To achieve budget neutrality for these proposed changes in the GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 1.0019 for FY 2023. Next, we compared estimated aggregate capital Federal rate payments based on the proposed FY 2023 GAFs with and without the lowest quartile hospital wage index adjustment and the proposed 5 percent cap on wage index decreases policy. For this calculation, estimated aggregate capital Federal rate payments were calculated using the proposed FY 2023 MS–DRG classifications and relative weights (after application of the proposed 10 percent cap discussed later in this section) and the proposed FY 2023 GAFs (both with and without the lowest quartile hospital wage index adjustment and the proposed 5 percent cap on wage index decreases policy). (We note, for this calculation the proposed GAFs included the imputed floor, out-migration and Frontier state adjustments.) To achieve budget

neutrality for the effects of the lowest quartile hospital wage index adjustment and the proposed 5 percent cap on wage index decreases policy on the proposed FY 2023 GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9971. As discussed earlier in this section, the budget neutrality factor for the lowest quartile hospital wage index adjustment factor and the 5 percent cap on wage index decreases is not permanently built into the capital Federal rate. Consistent with this, we present the proposed budget neutrality factor for the lowest quartile hospital wage index adjustment and the proposed 5 percent cap on wage index decreases calculated under the second step of this 2-step methodology separately from the other proposed budget neutrality factors in the discussion that follows, and this proposed factor is not included in the calculation of the proposed combined GAF/DRG adjustment factor described later in this section.

In section II.E.2. of the preamble to this proposed rule, we discuss our proposal to apply a permanent 10 percent cap on the reduction in a MS–DRG's relative weight in a given year. Consistent with our current methodology for adjusting the capital standard Federal rate to ensure that the effects of the annual DRG reclassification and the recalibration of DRG weights are budget neutral under § 412.308(c)(4)(ii), we are proposing to apply an additional budget neutrality factor to the capital standard Federal rate so that the proposed 10 percent cap on decreases in an MS–DRG's relative weight is implemented in a budget neutral manner. Specifically, in light of this proposal, we are proposing to augment our historical methodology for computing the budget neutrality factor for the annual DRG reclassification and recalibration by computing a budget neutrality adjustment for the annual DRG reclassification and recalibration in two steps. We are proposing to first calculate a budget neutrality factor to account for the annual DRG reclassification and recalibration prior to the application of the 10 percent cap on MS–DRG relative weight decreases. We then are proposing to calculate an additional budget neutrality factor to account for the application of the 10 percent cap on MS–DRG relative weight decreases.

To determine the proposed DRG budget neutrality factors for FY 2023, we first compared estimated aggregate capital Federal rate payments based on the FY 2022 MS–DRG classifications and relative weights to estimated aggregate capital Federal rate payments based on the proposed FY 2023 MS–DRG classifications and relative weights prior to the application of the proposed 10 percent cap. For these calculations, estimated aggregate capital Federal rate payments were calculated using the proposed FY 2023 GAFs without the lowest quartile hospital wage index adjustment and the proposed 5 percent cap on wage index decreases. The proposed incremental adjustment factor for DRG classifications and changes in relative weights prior to the application of the proposed 10 percent cap is 1.0006. Next, we compared estimated aggregate capital Federal rate payments based on the proposed FY 2023 MS–DRG classifications and relative weights prior to the application of the 10 percent cap to estimated aggregate capital Federal rate payments based on the proposed FY 2023 MS–DRG classifications and relative weights after the application of the proposed 10 percent cap. For these calculations, estimated aggregate capital Federal rate payments were also calculated using the proposed FY 2023 GAFs without the lowest quartile hospital wage index adjustment and the proposed 5 percent cap on wage index decreases. The proposed incremental adjustment factor for the proposed application of the proposed 10 percent cap on relative weight decreases is 0.9998. Therefore, to achieve budget neutrality for the proposed FY 2023 MS–DRG reclassification and recalibration (including the proposed 10 percent cap), based on the proposed calculations described previously, we are proposing to apply an incremental budget neutrality adjustment factor of 1.0003 (1.0006×0.9998) for FY 2023 to the capital Federal rate. We note that all the values are calculated with unrounded numbers.

The proposed incremental adjustment factor for the proposed FY 2023 MS–DRG reclassification and recalibration (1.0003) and for proposed changes in the FY 2023 GAFs due to the proposed update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy (1.0019) is 1.0023 (1.0003×1.0019). This incremental adjustment factor is built permanently into the capital Federal rates. To achieve budget neutrality for the effects of the lowest quartile hospital wage index adjustment and the proposed 5 percent cap on wage index decreases policy on the FY 2023 GAFs, as described previously, we calculated a proposed budget neutrality adjustment factor of 0.9971 for FY 2023. We refer to this budget neutrality factor for the remainder of this section as the lowest quartile/cap adjustment factor.

We applied the budget neutrality adjustment factors described previously to the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are determined separately. Under the capital IPPS, there is a single budget neutrality adjustment factor for changes in the GAF that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy. In addition, there is no adjustment for the effects that geographic reclassification, the lowest quartile hospital wage index adjustment, or the proposed 5 percent cap on wage index decreases policy described previously have on the other payment parameters, such as the payments for DSH or IME.

The proposed incremental GAF/DRG adjustment factor of 1.0023 accounts for the proposed MS–DRG reclassifications and recalibration (including application of the proposed 10 percent cap on relative weight decreases) and for proposed changes in the GAFs that result from proposed updates to the wage data, the effects on the GAFs of FY 2023 geographic reclassification decisions made by the MGCRB compared to FY 2022 decisions, and the application of the rural floor policy. The proposed lowest quartile/cap adjustment factor of 0.9971 accounts for changes in the GAFs that result from our policy to increase the wage index values for hospitals with a wage index value below the 25th percentile wage index and the proposed 5 percent cap on wage index decreases policy. However, these factors do not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Proposed Capital Federal Rate for FY 2023

For FY 2022, we established a capital Federal rate of $472.59 (86 FR 45553, as corrected in 86 FR 58026). We are

proposing to establish an update of 1.7 percent in determining the FY 2023 capital Federal rate for all hospitals. As a result of this proposed update and the proposed budget neutrality factors discussed earlier, we are proposing to establish a national capital Federal rate of $480.29 for FY 2023. The proposed national capital Federal rate for FY 2023 was calculated as follows:

- The proposed FY 2023 update factor is 1.017; that is, the proposed update is 1.7 percent.
- The proposed FY 2023 GAF/DRG budget neutrality adjustment factor that is applied to the capital Federal rate for proposed changes in the MS–DRG classifications and relative weights (including application of the proposed 10 percent cap on relative weight decreases) and proposed changes in the GAFs that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy is 1.0023.
- The proposed FY 2023 lowest quartile/cap budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the GAFs that result from our policy to increase the wage index values for hospitals with a wage index value below the 25th percentile wage index and the proposed 5 percent cap on wage index decreases policy is 0.9971.
- The proposed FY 2023 outlier adjustment factor is 0.9445.

We are providing the following chart that shows how each of the proposed factors and adjustments for FY 2023 affects the computation of the proposed FY 2023 national capital Federal rate in comparison to the FY 2022 national capital Federal rate. The proposed FY 2023 update factor has the effect of increasing the capital Federal rate by 1.7 percent compared to the FY 2022 capital Federal rate. The proposed GAF/DRG budget neutrality adjustment factor has the effect of increasing the capital Federal rate by 0.23 percent. The proposed FY 2023 lowest quartile/cap budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.03 percent compared to the FY 2022 capital Federal rate. The proposed FY 2023 outlier adjustment factor has the effect of decreasing the capital Federal rate by 0.27 percent compared to the FY 2022 capital Federal rate. The combined effect of all the proposed changes would increase the national capital Federal rate by approximately 1.63 percent, compared to the FY 2022 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2022 CAPITAL FEDERAL RATE AND THE PROPOSED FY 2023 CAPITAL FEDERAL RATE

	FY 2022	FY 2023	Change	Percent Change
Update Factor[1]	1.0080	1.0170	1.0070	1.70
GAF/DRG Adjustment Factor[1]	1.0004	1.0023	1.0023	0.23
Quartile/Cap Adjustment Factor[2]	0.9974	0.9971	0.9997	-0.03
Outlier Adjustment Factor[3]	0.9471	0.9445	0.9973	-0.27
Capital Federal Rate	$472.59	$480.29	1.0122	1.63[4]

[1] The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rate. Thus, for example, the incremental change from FY 2022 to FY 2023 resulting from the application of the proposed 1.0023 GAF/DRG budget neutrality adjustment factor for FY 2023 is a net change of 0.0023 (or 0.23 percent).

[2] The lowest quartile/cap budget neutrality adjustment factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the proposed FY 2023 lowest quartile/cap budget neutrality adjustment factor is 0.9971/0.9974 or 0.9997 (or -0.03 percent).

[3] The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the proposed FY 2023 outlier adjustment factor is 0.9445/0.9471 or 0.9973 (or -0.27 percent).

[4] Percent change may not sum due to rounding.

B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2023

For purposes of calculating payments for each discharge during FY 2023, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. Section 412.312(c) provides for a shared threshold to identify outlier cases for both inpatient operating and inpatient capital-related payments. The proposed outlier threshold for FY 2023 is in section II.A. of this Addendum. For FY 2023, a case will qualify as a cost outlier if the cost for the case is greater than the prospective payment rates for the MS–DRG plus IME and DSH payments (including the empirically justified Medicare DSH payment and the estimated uncompensated care payment), any add-on payments for new technology, and, as we are proposing beginning in FY 2023, the proposed estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals (as discussed in section IV.E. of the preamble of this proposed rule), plus the proposed fixed-loss amount of $43,214.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation, unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the

stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. For this proposed rule, we are proposing to use the IPPS operating and capital market baskets that reflect a 2018 base year. For a complete discussion of this rebasing, we refer readers to section IV. of the preamble of the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45213).

2. Forecast of the CIPI for FY 2023

Based on IHS Global Inc.'s fourth quarter 2021 forecast, for this proposed rule, we are forecasting the 2018-based CIPI to increase 1.7 percent in FY 2023. This reflects a projected 2.3 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 4.3 percent increase in other capital expense prices in FY 2023, partially offset by a projected 2.7 percent decline in vintage-weighted interest expense prices in FY 2023. The weighted average of these three factors produces the forecasted 1.7 percent increase for the 2018-based CIPI in FY 2023. We are also proposing that if more recent data becomes available (for example, a more recent estimate of the increase in the 2018-based CIPI), we would use such data, if appropriate, to determine the FY 2023 increase in the 2018-based CIPI for the final rule.

IV. Proposed Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2023

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are made on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital, based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage specified in § 413.40(c)(3). In addition, as specified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38536), effective for cost reporting periods beginning during FY 2018, the annual update to the target amount for extended neoplastic disease care hospitals (hospitals described in § 412.22(i) of the regulations) also is the rate-of-increase percentage specified in § 413.40(c)(3). (We note that, in accordance with § 403.752(a), religious nonmedical health care institutions (RNHCIs) are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

For this FY 2023 IPPS/LTCH PPS proposed rule, based on IGI's 2021 fourth quarter forecast, we estimated that the 2018-based IPPS operating market basket update for FY 2023 is 3.1 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, the FY 2023 rate-of-increase percentage that will be applied to the FY 2022 target amounts in order to calculate the FY 2023 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals will be 3.1 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket update), we would use such data, if appropriate, to calculate the IPPS operating market basket update for FY 2023.

IRFs and rehabilitation distinct part units, IPFs and psychiatric units, and LTCHs are excluded from the IPPS and paid under their respective PPSs. The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VIII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule for the changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2023. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Proposed Changes to the Payment Rates for the LTCH PPS for FY 2023

A. Proposed LTCH PPS Standard Federal Payment Rate for FY 2023

1. Overview

In section VIII. of the preamble of this proposed rule, we discuss our annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2023.

Under § 412.523(c)(3) of the regulations, for FY 2012 and subsequent years, we updated the standard Federal payment rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by sections 1886(m)(3) (citing sections 1886(b)(3)(B)(xi)(II) and 1886(m)(4) of the Act as set forth in the regulations at § 412.523(c)(3)(viii) through (xvii)). (For a summary of the payment rate development prior to FY 2012, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38310 through 38312) and references therein.)

Section 1886(m)(3)(A) of the Act specifies that, for rate year 2012 and each subsequent rate year, any annual update to the standard Federal payment rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act as discussed in section VIII.C.2 of the preamble of this proposed rule. This section of the Act further provides that the application of section 1886(m)(3)(B) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VIII.C.2. of the preamble of this proposed rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For LTCHs that fail to submit the required quality reporting data in accordance with the LTCH QRP, the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

2. Development of the Proposed FY 2023 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice and § 412.523(c)(3)(xvii), for FY 2023 we are proposing to apply the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the proposed LTCH PPS standard Federal payment rate for FY 2023, we also are proposing to make certain regulatory adjustments, consistent with past practices. Specifically, in determining the proposed FY 2023 LTCH PPS

standard Federal payment rate, we are proposing to apply a budget neutrality adjustment factor for the changes related to the area wage level adjustment (that is, changes to the wage data and labor-related share) as discussed in section V.B.5.of this Addendum to this proposed rule.

In this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 2.7 percent (that is, the most recent estimate of the LTCH PPS market basket increase of 3.1 percent less the proposed productivity adjustment of 0.4 percentage point). Therefore, in accordance with § 412.523(c)(3)(xvii), we are proposing to apply an update factor of 1.027 to the FY 2022 LTCH PPS standard Federal payment rate of $44,713.67 to determine the proposed FY 2023 LTCH PPS standard Federal payment rate. Also, in accordance with § 412.523(c)(3)(xvii) and (c)(4), we are required to reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points for LTCHs that fail to submit the required quality reporting data for FY 2023 as required under the LTCH QRP. Therefore, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 0.7 percent (that is, an update factor of 1.007) for FY 2023 for LTCHs that fail to submit the required quality reporting data for FY 2023 as required under the LTCH QRP. Consistent with § 412.523(d)(4), we are proposing to apply an area wage level budget neutrality factor to the FY 2023 LTCH PPS standard Federal payment rate of 1.000691, based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment (that is, the proposed annual update of the wage index (including application of the proposed 5-percent cap on wage index decreases, discussed later in this section), and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we are proposing to establish an LTCH PPS standard Federal payment rate of $45,952.67 (calculated as $44,713.67 × 1.027 × 1.000691) for FY 2023. For LTCHs that fail to submit quality reporting data for FY 2023, in accordance with the requirements of the LTCH QRP under section 1866(m)(5) of the Act, we are proposing to establish an LTCH PPS standard Federal payment rate of $45,057.78 (calculated as $44,713.67 × 1.007 × 1.000691) for FY 2023.

B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2023

1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

The proposed FY 2023 LTCH PPS standard Federal payment rate wage index values that would be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2022, through September 30, 2023, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website.

2. Proposed Geographic Classifications (Labor Market Areas) for the LTCH PPS Standard Federal Payment Rate

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB, and a ''rural area'' is defined as any area outside of an urban area (75 FR 37246).

The geographic classifications (labor market area definitions) currently used under the LTCH PPS, effective for discharges occurring on or after October 1, 2014, are based on the Core Based Statistical Areas (CBSAs) established by OMB, which are based on the 2010 decennial census data. In general, the current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. (We note we have adopted minor revisions and updates in the years between the decennial censuses.) We adopted these labor market area delineations because they were at that time based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas. We also believed that these OMB delineations would ensure that the LTCH PPS area wage level adjustment most appropriately accounted for and reflected the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We noted that this policy was consistent with the IPPS policy adopted in FY 2015 under § 412.64(b)(1)(ii)(D) (79 FR 49951 through 49963). (For additional information on the CBSA-based labor market area (geographic classification) delineations currently used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).)

In general, it is our historical practice to update the CBSA-based labor market area delineations annually based on the most recent updates issued by OMB. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. OMB Bulletin No. 17–01, issued August 15, 2017, established the delineations for the Nation's statistical areas, and the corresponding changes to the CBSA-based labor market areas were adopted in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41731). A copy of this bulletin may be obtained on the website at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/bulletins/2017/b-17-01.pdf.*

On April 10, 2018, OMB issued OMB Bulletin No. 18–03, which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04, which superseded the April 10, 2018 OMB Bulletin No. 18–03. Historically OMB bulletins issued between decennial censuses have only contained minor modifications to CBSA delineations based on changes in population counts. However, OMB's 2010 Standards for Delineating Metropolitan and Micropolitan Standards created a larger mid-decade redelineation that takes into account commuting data from the American Commuting Survey. As a

result, the September 14, 2018 OMB Bulletin No. 18–04 included more modifications to the CBSAs than are typical for OMB bulletins issued between decennial censuses. We adopted the updates set forth in OMB Bulletin No. 18–04 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59050 through 59051). A copy of the September 14, 2018 OMB Bulletin No. 18–04, may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.*

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04, which was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the update to statistical areas since September 14, 2018. (For a copy of this bulletin, we refer readers to the following website: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf.*) In OMB Bulletin No. 20–01, OMB announced one new Micropolitan Statistical Area and one new component of an existing Combined Statistical Area. After reviewing OMB Bulletin No. 20–01, we determined that the changes in Bulletin 20–01 encompassed delineation changes that would not affect the CBSA-based labor market area delineations used under the LTCH PPS. Therefore, we adopted the updates set forth in OMB Bulletin No. 20–01 in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45556 through 45557) consistent with our general policy of adopting OMB delineation updates; however, the LTCH PPS area wage level adjustment was not altered as a result of adopting the updates because the CBSA-based labor market area delineations were the same as the CBSA-based labor market area delineations adopted in the FY 2021 IPPS/LTCH PPS final rule based on OMB Bulletin No. 18–04 (85 FR59050 through 59051).

We believe the CBSA-based labor market area delineations, as established in OMB Bulletin 20–01, ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (81 FR 57298). Therefore, for FY 2023, we are not proposing any changes to the CBSA-based labor market area delineations as established in OMB Bulletin 20–01 and adopted in the FY 2022 IPPS/LTCH final rule.

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on their website at *https://www.census.gov/programs-surveys/geography/technical-documentation/county-changes.html.* We believe that it is important to use the latest counties or county equivalent entities to properly crosswalk LTCHs from a county to a CBSA for purposes of the wage indexes used under the LTCH PPS. Based on the latest information included in the Census Bureau's website at *https://www.census.gov/programs-surveys/geography/technical-documentation/county-changes.2010.html,* the Census Bureau has made the following updates to the Federal Information Processing Series (FIPS) codes for counties or county equivalent entities:

- Chugach Census Area, AK (FIPS State County Code 02–063) and Copper River Census Area, AK (FIPS State County Code 02–066) were created from former Valdez-Cordova Census Area (02–261) which was located in CBSA 02. The CBSA code for these two new county equivalents remains 02.

We believe using the latest FIPS codes allows us to maintain a more accurate and up-to-date payment system that reflects population shifts and labor market conditions. Therefore, we are proposing to implement these FIPS code updates listed previously, effective October 1, 2022. We note that while the county update changes listed previously changed the county names, the CBSAs to which these counties map did not change from the prior counties. We also note that there are currently no LTCHs located in these counties. However, if an LTCH were to open in one of these counties, there would be no impact or change to the LTCH for purposes of the LTCH PPS wage indexes as a result of our implementation of these FIPS code updates. We are publishing as a supplemental file to this proposed rule an updated county-to-CBSA crosswalk that reflects this proposal.

3. Proposed Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's standard Federal payment rate is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs and a labor-related portion of capital costs using the applicable LTCH market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

For FY 2013, we rebased and revised the market basket used under the LTCH PPS by adopting a 2009-based LTCH market basket. In addition, for FY 2013 through FY 2016, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2009-based LTCH market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479).) For FY 2017, we rebased and revised the 2009-based LTCH market basket to reflect a 2013 base year. In addition, for FY 2017 through FY 2020, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2013-based LTCH market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57085 through 57096).) Then, effective for FY 2021, we rebased and revised the 2013-based LTCH market basket to reflect a 2017 base year and determined the labor-related share annually as the sum of the relative importance of each labor-related cost category in the 2017-based LTCH market basket using the most recent available data. (For more details, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926).)

In this proposed rule, consistent with our historical practice, we are proposing that the LTCH PPS labor-related share for FY 2023 is the sum of the FY 2023 relative importance of each labor-related cost category in the LTCH market basket using the most recent available data. Specifically, we are proposing that the labor-related share for FY 2023 would continue to include the sum of the labor-related portion of operating costs from the 2017-based LTCH market basket (that is, the sum of the FY 2023 relative importance shares of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services) and a portion of the relative importance of Capital-Related cost weight from the 2017-based LTCH

market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2017) and FY 2023. Based on IHS Global Inc.'s fourth quarter 2021 forecast of the 2017-based LTCH market basket, the sum of the FY 2023 relative importance for Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, & Repair Services; and All Other: Labor-Related Services is 64.0 percent. The portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent (that is, the same percentage applied to the 2009-based and 2013-based LTCH market baskets). Since the FY 2023 relative importance for capital-related costs is 9.2 percent based on IHS Global Inc.'s fourth quarter 2021 forecast of the 2017-based LTCH market basket, we took 46 percent of 9.2 percent to determine the labor-related share of capital-related costs for FY 2023 of 4.2 percent. Therefore, we are proposing a total labor-related share for FY 2023 of 68.2 percent (the sum of 64.0 percent for the operating costs and 4.2 percent for the labor-related share of capital-related costs). We are also proposing that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the relative importance of each labor-related cost category of the 2017-based LTCH market basket), we would use such data, if appropriate, to determine the FY 2023 LTCH PPS labor-related share.

4. Proposed Wage Index for FY 2023 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the ''urban'' or ''rural'' designation of any related or affiliated provider. As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also employ a policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable area wage index values for the FY 2023 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to continue to employ our historical practice of using the same data we are proposing to use to compute the proposed FY 2023 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this proposed rule (that is, wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2019) because these data are the most recent complete data available.

In addition, we are proposing to compute the FY 2023 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, the proposed labor market area delineations as previously discussed in section V.B. of this Addendum) and our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. We are also proposing to continue to apportion the wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values, for FY 2023 we are proposing to continue to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data is determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2019 IPPS wage data that we are proposing to use to determine the proposed FY 2023 LTCH PPS area wage index values in this final rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with our existing methodology, we calculated the proposed FY 2023 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this proposed rule.

Based on the FY 2019 IPPS wage data that we are proposing to use to determine the proposed FY 2023 LTCH PPS standard Federal payment rate area wage index values in this proposed rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a proposed LTCH PPS wage index value for rural areas with no IPPS wage data for FY 2023. We note that, as IPPS wage data are dynamic, it is possible that the number of rural areas without IPPS wage data will vary in the future.

5. Proposed Permanent Cap on Wage Index Decreases

a. Proposed Permanent Cap on LTCH PPS Wage Index Decreases

In the past, we have proposed and finalized temporary transition policies to mitigate significant changes to payments due to changes to the LTCH PPS wage index, particularly when adopting changes that have large negative impacts on an LTCH's payments. In the FY 2021 IPPS/LTCH final rule (85 FR 59052), we implemented a 5 percent cap on any decrease in an LTCH's wage index from the LTCH's final wage index in FY 2020, so that the hospital's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020. We implemented this policy to mitigate potential negative consequences of finalizing the adoption of revised CBSA delineations announced in OMB Bulletin 18–04 for FY 2021. In particular, we acknowledged that a significant portion of Medicare LTCH PPS payments are adjusted by the wage index and that some changes in OMB delineations destabilized payments to LTCHs. We stated our belief that applying the 5 percent cap to all wage index decreases for FY 2021 provided an adequate safeguard against significant payment reductions related to the adoption of the revised CBSAs and that it would improve stability and predictability in payment levels to LTCHs. We applied a budget neutrality adjustment to the FY 2021 standard Federal payment rate to achieve budget neutrality for this policy (85 FR 59053).

Although we did not propose or implement a cap on wage index decreases for LTCH's in FY 2022, we acknowledged that some commenters requested that we extend the FY 2021 transition policy, citing the continuing impact of changes related to the OMB updates and the unprecedented nature

of the ongoing COVID–19 PHE. In response to those comments, we reiterated that our policy principles with regard to the wage index include generally using the most current data and information available and providing that data and information, as well as addressing significant effects on Medicare payments resulting from potential scenarios in notice and comment rulemaking.

For FY 2023, we have further considered comments received during the FY 2022 rulemaking, including requests for a broader, permanent wage index policy to mitigate unpredictable changes in payments to LTCHs resulting from large wage index decreases. We recognize that changes to the wage index have the potential to create instability and significant negative impacts on certain providers even when we have not adopted specific changes to wage index policy. That is, year to year fluctuations in an area's wage index can occur due to external factors that can be difficult for an LTCH to predict and are often outside an LTCH's ability to directly control, such as the COVID–19 PHE. We recognize that predictability in Medicare payments is important to enable hospitals to budget and plan their operations. For LTCHs, in particular, we further recognize that a significant portion of Medicare LTCH PPS payments are adjusted by the wage index and that a large decrease from one year to the next can have significant implications for LTCH payments.

For these reasons, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing, beginning with FY 2023, to apply a permanent 5 percent cap on any decrease to an LTCH's wage index from its wage index in the prior year. We believe that a 5 percent reduction is an appropriate threshold to mitigate large negative financial impacts on hospitals and limit the magnitude of the associated proposed budget neutrality adjustment (discussed later in this section). Typical year-to-year variations in the LTCH wage index has historically been within 5 percent, and we expect this will continue to be the case in future years. Because providers typically experience some level of wage index fluctuation, we believe applying a 5 percent cap on all wage index decreases each year, regardless of the reason for the decrease, would effectively mitigate instability and increase predictability in LTCH PPS payments due to any significant wage index decreases.

We believe this proposed policy to provide a permanent cap to wage index decreases would provide greater predictability to LTCHs. That is, the policy would smooth year-to-year changes in LTCHs' wage indexes and provide for increased predictability in their wage index and thus their LTCH PPS payments. We also believe our proposed permanent policy would mitigate significant payment reductions due to changes in wage index policy, such as the adoption of the revised CBSAs in FY 2021, thereby eliminating the need for one-off temporary transition adjustments to wage index levels in the future. Because applying a 5 percent cap on all wage index decreases would generally represent a small overall impact on the adjustment for area wage levels, we believe the 5 percent cap would not distort the integrity of the wage index as a relative measure of the value of labor in a labor market area. We also note that this proposal is similar to our proposal to establish a permanent 5 percent cap on annual wage index decreases for IPPS hospitals, as discussed in section III.N. of the preamble to this proposed rule.

Furthermore, consistent with the requirement at § 412.525(c)(2) that changes to area wage level adjustments are made in a budget neutral manner, we propose that the 5 percent cap on the decrease on an LTCH's wage index should not result in any change in estimated aggregate LTCH PPS payments by including the application of this policy in the determination of the area wage level budget neutrality factor that is applied to the standard Federal payment rate, as is discussed later in section V.B.6. of the addendum to the proposed rule.

We are proposing that an LTCH's wage index cap adjustment would be determined based on the wage index value applicable to the LTCH on the last day of the prior Federal fiscal year. We are proposing that new LTCHs that became operational during the prior Federal fiscal year would be subject to the LTCH PPS wage index cap. For example, if an LTCH begins operations on July 1, 2022 and is paid its area wage index of 0.9000 for the remainder of FY 2022, its FY 2023 wage index would be capped at 95 percent of that value and could not be lower than 0.8550 (0.95 × 0.9000). However, for newly opened LTCHs that become operational on or after the first day of the fiscal year to which this proposed rule would apply, we propose that these LTCHs would not be subject to the LTCH PPS wage index cap since they were not paid under the LTCH PPS in the prior year. These LTCHs would receive the calculated wage index for the area in which they are geographically located, even if other LTCHs in the same geographic area are receiving a wage cap. For example, a hospital that opens on December 1, 2022 would not be eligible for a capped wage index in FY 2023, as it was not paid a wage index during FY 2022.

For each LTCH we identify in our rulemaking data, we are including in a supplemental data file the wage index values from both fiscal years used in determining its capped wage index. This will include the LTCH's final prior year wage index value, the LTCH's uncapped current year wage index value, and the LTCH's capped current year wage index value. Due to the lag in rulemaking data, a new LTCH may not be listed in this supplemental file for a few years. For this reason, a newly opened LTCH could contact their MAC to ensure that its wage index value is not less than 95 percent of the value paid to it for the prior Federal fiscal year. This supplemental data file for public use will be posted on the CMS website for this proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

In summary, we are proposing a permanent wage index cap policy that limits the reductions in an LTCH's LTCH PPS wage index value for the upcoming FY to 5 percent of the LTCH's wage index value for the current FY. We are also proposing that this wage index cap policy would be implemented in a budget neutral manner by including the application of this policy in the area wage level budget neutrality factor that is applied to the standard Federal payment rate. We believe that this proposed policy appropriately mitigates instability and significant negative impacts to LTCHS resulting from significant changes to the wage index and increases predictability of LTCH payments. We are proposing to reflect the proposed permanent cap on wage index decreases at § 412.525(c)(1) by adding paragraphs (c)(1)(i) and (ii) to specify that CMS updates the wage index for LTCHs annually and that, beginning in FY 2023, if CMS determines that an LTCH's wage index value for a fiscal year would decrease by more than 5 percent as compared to the LTCH's wage index value for the prior year, we would limit the decrease to 5 percent for the fiscal year.

b. Proposed Permanent Cap on IPPS Comparable Wage Index Decreases

Determining LTCH PPS payments for short-stay-outlier cases (reflected in § 412.529) and site neutral payment rate cases (reflected in § 412.522(c)) requires calculating an ''IPPS comparable amount.'' For information on this ''IPPS comparable amount'' calculation, we

refer the reader to the FY 2016 IPPS/LTCH PPS final rule (FR 80 49608 through 49610). Determining LTCH PPS payments for LTCHs that do not meet the applicable discharge payment percentage (reflected in § 412.522(d)) requires calculating an ''IPPS equivalent amount.'' For information this ''IPPS equivalent amount'' calculation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule (FR 84 49608 through 49610).

Calculating both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' requires adjusting the IPPS operating and capital standardized amounts by the applicable IPPS wage index for nonreclassified IPPS hospitals. That is, the standardized amounts are adjusted by the IPPS wage index for nonreclassified IPPS hospitals located in the same geographic area as the LTCH. Consistent with our proposed policy to apply a 5 percent cap on decreases in the LTCH PPS wage index and under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing, beginning with FY 2023 to apply a permanent 5 percent cap on decreases in an LTCH's applicable IPPS comparable wage index from its applicable IPPS comparable wage index in the prior year. As with our proposed policy to apply a cap on decreases in the LTCH PPS wage index each year, we believe a permanent cap on applicable IPPS comparable wage index decreases would provide greater predictability to LTCHs by mitigating instability and significant negative impacts to LTCHs resulting from significant changes to the wage index and increase predictability of LTCH payments. Historically, we have not budget neutralized changes to LTCH PPS payments that result from the annual update of the IPPS wage index for nonreclassified IPPS hospitals. Consistent with this approach, we are proposing that the cap on decreases in an LTCH's applicable IPPS comparable wage index not be applied in a budget neutral manner.

We are proposing that an LTCH's applicable IPPS comparable wage index cap adjustment would be determined based on the wage index value assigned to the LTCH on the last day of the prior Federal fiscal year. We are proposing that new LTCHs that became operational during the prior Federal fiscal year be subject to the applicable IPPS comparable wage index cap. However, for newly opened LTCHs that become operational on or after the first day of the fiscal year to which this proposed rule applies, we propose that these LTCHs would not be subject to the applicable IPPS comparable wage index cap since they were not paid under the LTCH PPS in the prior year. Similar to the information we are making available for the proposed cap on the LTCH PPS wage index values (described previously), for each LTCH we identify in our rulemaking data, we are including in a supplemental data file the wage index values from both fiscal years used in determining its capped applicable IPPS comparable wage index. Due to the lag in rulemaking data, a new LTCH may not be listed in this supplemental file for a few years. For this reason, a newly opened LTCH could contact its MAC to ensure that its applicable IPPS comparable wage index value is not less than 95 percent of the value paid to them for the prior Federal fiscal year. This supplemental data file for public use will be posted on the CMS website for this proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. We propose to reflect the proposed permanent cap on IPPS comparable wage index decreases at § 412.529(d)(4)(ii)(B) to state that, beginning in FY 2023, an LTCH's applicable IPPS wage index used to adjust the IPPS operating standardized amount is subject to a 5 percent cap on decreases to an LTCH's applicable IPPS wage index value from the prior fiscal year. We also propose to reflect the proposed permanent cap on IPPS comparable wage index decreases at § 412.529(d)(4)(iii)(B) to state that, beginning in FY 2023, an LTCH's applicable IPPS wage index used to adjust the IPPS capital Federal rate is subject to a 5 percent cap on decreases to an LTCH's applicable IPPS wage index value from the prior fiscal year. In addition, we are taking this opportunity to propose to remove the reference in § 412.529(d)(4)(iii)(B) related to the applicable large urban location adjustment because this policy is no longer applicable under the IPPS effective with discharges occurring on or after October 1, 2007 (72 FR 47400).

6. Proposed Budget Neutrality Adjustments for Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage level adjustment budget neutrality factor that is applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we have applied an area wage level adjustment budget neutrality factor in determining the standard Federal payment rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

For FY 2023, in accordance with § 412.523(d)(4), we are proposing to apply an area wage level budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments, consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). As discussed in section V.B.5. of the Addendum to this proposed rule, we are proposing, for each year, beginning with FY 2023, to limit a hospital's LTCH PPS wage index value for the coming year by capping it at 95 percent of its prior year value. As also discussed previously, we are proposing to apply the proposed 5 percent cap on wage index decreases, consistent with § 412.525(c)(2), in a budget neutral manner.

Specifically, we are proposing to determine an area wage level adjustment budget neutrality factor that is applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2023 using the following methodology, which would incorporate our proposed 5 percent cap on decreases in a hospital's wage index:

Step 1—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2022 wage index values and the FY 2022 labor-related share of 67.9 percent.

Step 2—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the proposed FY 2023 wage index values (including application of the proposed 5 percent

cap on wage index decreases) and the proposed FY 2023 labor-related share of 68.2 percent. (As noted previously, the changes to the wage index values based on updated hospital wage data are discussed in section V.B.4. of this Addendum to this proposed rule and the labor-related share is discussed in section V.B.3. of this Addendum to this proposed rule.)

Step 3—Calculate the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2022 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the proposed FY 2023 updates to the area wage level adjustment (calculated in Step 2) to determine the proposed budget neutrality factor for updates to the area wage level adjustment for FY 2023 LTCH PPS standard Federal payment rate payments.

Step 4—Apply the proposed FY 2023 updates to the area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2023 LTCH PPS standard Federal payment rate after the application of the proposed FY 2023 annual update.

In section I.F. of the preamble to this proposed rule, we discuss our proposal to use FY 2021 claims data for the FY 2023 LTCH PPS ratesetting. We also state our belief that it is reasonable to assume that there will be fewer COVID–19 hospitalizations among Medicare beneficiaries at LTCHs in FY 2023 than there were in FY 2021. For this reason, we are proposing modifications in our determination of the FY 2023 MS–LTC–DRG relative weights and outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases. We believe that these modifications will account for an anticipated decline in, but not elimination of, COVID–19 hospitalizations at LTCHs in FY 2023. However, when modeling payments for determining the area wage level adjustment budget neutrality factor, we are proposing to use the full set of LTCH PPS standard Federal payment rate cases (including all COVID–19 cases) identified in the FY 2021 claims data. In the absence of a set of MedPAR claims that reflect our expectation that there will be fewer (but not zero) COVID–19 cases in FY 2023 as compared to the COVID–19 cases in the FY 2021 claims data, we believe this is the best data available for determining the budget neutrality factors. We note this is consistent with the proposed calculation of the budget neutrality factors for proposed changes to the MS–LTC–DRG classifications and relative weights (including the proposed 10 percent cap) discussed in section VIII.B.4.b. (Step 11) of the preamble of this proposed rule. We also note this is consistent with the approach being proposed under the IPPS as discussed in section II.A.4. of the Addendum of this proposed rule. We are also soliciting feedback from commenters on alternative ways to use the FY 2021 claims data for purposes of calculating the FY 2023 budget neutrality factors.

We note that, because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, consistent with historical practice, we only used data from claims that qualified for payment at the LTCH PPS standard Federal payment rate under the dual rate LTCH PPS to calculate the proposed FY 2023 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor. For this proposed rule, using the steps in the methodology previously described, we determined a proposed FY 2023 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.000691. Accordingly, in section V.A. of the Addendum to this proposed rule, we applied the proposed area wage level adjustment budget neutrality factor of 1.000691 to determine the proposed FY 2023 LTCH PPS standard Federal payment rate, in accordance with § 412.523(d)(4).

C. Proposed Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels previously described. The methodology used to determine the COLA factors for Alaska and Hawaii is based on a comparison of the growth in the Consumer Price Indexes (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). It also includes a 25-percent cap on the CPI-updated COLA factors. Under our current policy, we update the COLA factors using the methodology as previously described every 4 years (at the same time as the update to the labor-related share of the IPPS market basket) and we last updated the COLA factors for Alaska and Hawaii published by OPM for 2009 in FY 2022 (86 FR 45559 through 45560).

We continue to believe that determining updated COLA factors using this methodology would appropriately adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii. Therefore, in this proposed rule, for FY 2023, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, we are proposing to continue to use the COLA factors based on the 2009 OPM COLA factors updated through 2020 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as established in the FY 2022 IPPS/LTCH PPS final rule. (For additional details on our current methodology for updating the COLA factors for Alaska and Hawaii and for a discussion on the FY 2022 COLA factors, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45559 through 45560).)

PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS (COLA): ALASKA AND HAWAII UNDER THE LTCH PPS FOR FY2023

Area	FY 2023
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.22
Rest of Alaska	1.24
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.22
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

D. Proposed Adjustment for LTCH PPS High Cost Outlier (HCO) Cases

1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Public Law 113–67. LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the FY 2016 IPPS/LTCH PPS final rule, we established separate fixed-loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8-percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases that would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case.

To maintain budget neutrality, consistent with the budget neutrality requirement at § 412.523(d)(1) for HCO payments to LTCH PPS standard Federal rate payment cases, we also adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulations for further details.) We note that, during the 4-year transitional period, the site neutral payment rate HCO budget neutrality factor did not apply to the LTCH PPS standard Federal payment rate portion of the blended payment rate at § 412.522(c)(3) payable to site neutral payment rate cases. (For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).)

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

As noted previously, CCRs are used to determine payments for HCO adjustments for both payment rates under the LTCH PPS and also are used to determine payments for site neutral payment rate cases. As noted earlier, in determining HCO and the site neutral payment rate payments (regardless of whether the case is also an HCO), we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding CCRs and HCO adjustments for either LTCH PPS payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate.)

The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs, previously the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases.

b. Proposed LTCH Total CCR Ceiling

Consistent with our historical practice, we are proposing to use the best available data to determine the LTCH total CCR ceiling for FY 2023 in this proposed rule. Specifically, in this proposed rule, we are proposing to use our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the December 2021 update of the Provider Specific File (PSF), which is the most recent data available. Accordingly, we are proposing an LTCH total CCR ceiling of 1.321 under the LTCH PPS for FY 2023 in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCO cases under either payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate. Consistent with our historical practice, we are proposing to use the best available data, if applicable, to determine the LTCH total CCR ceiling for FY 2023 in the final rule. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48117 through 48119).)

c. Proposed LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on ''total'' IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(C), the SSO policy at § 412.529(f)(4)(iii), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this proposed rule, we are proposing to use our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the December 2021 update of the PSF. We are proposing LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for discharges occurring on or after October 1, 2022, through September 30, 2023, in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the internet on the CMS website). Consistent with our historical practice, we also are proposing to use the best available data, if applicable, to determine the LTCH PPS statewide average total CCRs for FY 2023 in the final rule.

Under the current LTCH PPS labor market areas, all areas in Delaware, the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut has areas that are designated as rural, in our calculation of the LTCH statewide average CCRs, there were no short-term, acute care IPPS hospitals classified as rural or LTCHs located in these rural areas as of December 2021. Therefore, consistent with our existing methodology, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Connecticut in Table 8C. While Massachusetts also has rural areas, the statewide average CCR for rural areas in Massachusetts is based on one IPPS provider whose CCR is an atypical 1.205. Because this is much higher than the statewide urban average (0.480) and furthermore implies costs greater than charges, as with Connecticut, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Massachusetts in Table 8C. Furthermore, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, we are proposing to continue to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are proposing to use this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

d. Reconciliation of HCO Payments

Under the HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(D), the payments for HCO cases are subject to reconciliation. Specifically, any such payments are reconciled at settlement based on the CCR that was calculated based on the cost report coinciding with the discharge. For additional information on the reconciliation policy, we refer readers to sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4), as added by Change Request 7192 (Transmittal 2111; December 3, 2010), and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

3. Proposed High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

a. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

Under the regulations at § 412.525(a)(2)(ii) and as required by section 1886(m)(7) of the Act, the fixed-loss amount for HCO payments is set each year so that the estimated aggregate HCO payments for LTCH PPS standard Federal payment rate cases are 99.6875 percent of 8 percent (that is, 7.975 percent) of estimated aggregate LTCH PPS payments for LTCH PPS standard Federal payment rate cases. (For more details on the requirements for high-cost outlier payments in FY 2018 and subsequent years under section 1886(m)(7) of the Act and additional information regarding high-cost outlier payments prior to FY 2018, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38542 through 38544).)

b. Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2023

When we implemented the LTCH PPS, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments (that is, the target percentage) under the LTCH PPS (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY

2016, we established that, in general, the historical LTCH PPS HCO policy would continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount for LTCH PPS standard Federal payment rate cases would be determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

To determine the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been an LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. In accordance with § 412.525(a)(2)(ii), the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45562–45566), we finalized a number of technical changes to the methodology for determining the charge inflation factor and the CCR used when calculating the fixed-loss amount, while maintaining estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases. First, we finalized a technical change to the methodology for determining the charge inflation factor applied to the charges on the MedPAR claims when calculating the fixed-loss amount for each FY. Second, we finalized a technical change to the methodology for determining the CCRs used when calculating the fixed-loss amount for each FY. These methodologies are described in greater detail later in this section.

(1) Proposed Charge Inflation Factor for Use in Determining the Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2023

Under the LTCH PPS, the cost of each claim is estimated by multiplying the charges on the claim by the provider's CCR. Due to the lag time in the availability of claims data, when estimating costs for the upcoming payment year we typically inflate the charges from the claims data by a uniform factor.

For greater accuracy in calculating the fixed-loss amount, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45562–45566), we finalized a technical change to our methodology for determining the charge inflation factor. Similar to the method used under the IPPS hospital payment methodology (as discussed in section II.A.4.h.(2) of the Addendum to this proposed rule), our methodology determines the LTCH charge inflation factor based on the historical growth in charges for LTCH PPS standard Federal payment rate cases, calculated using historical MedPAR claims data. In this section we describe our charge inflation factor methodology using the most recently available data. However, as discussed in further detail later in this section, we are proposing to not use the charge inflation factor derived from the most recently available data. Rather, we are proposing to use the charge inflation factor used in the FY 2022 IPPS/LTCH PPS final rule that was based on the growth in charges that occurred between FY 2018 and FY 2019.

Step 1—Identify LTCH PPS Standard Federal Payment Rate Cases

The first step in our methodology is to identify LTCH PPS standard Federal payment rate cases from the MedPAR claim files for the two most recently available Federal fiscal year time periods. For both fiscal years, consistent with our historical methodology for determining payment rates for the LTCH PPS, we remove any claims submitted by LTCHs that were all-inclusive rate providers as well as any Medicare Advantage claims. For both fiscal years, we also remove claims from providers that only had claims in one of the fiscal years.

Step 2—Remove Statistical Outliers

The next step in our methodology is to remove all claims from providers whose growth in average charges was a statistical outlier. We remove these statistical outliers prior to calculating the charge inflation factor because we believe they may represent aberrations in the data that would distort the measure of average charge growth. To perform this statistical trim, we first calculate each provider's average charge in both fiscal years. Then, we calculate a charge growth factor for each provider by dividing its average charge in the most recent fiscal year by its average charge in the prior fiscal year. We then remove all claims for providers whose calculated charge growth factor was outside 3 standard deviations from the mean provider charge growth factor.

Step 3—Calculate the Charge Inflation Factor

The final step in our methodology is to use the remaining claims to calculate a national charge inflation factor. We first calculate the average charge for those remaining claims in both fiscal years. We then calculate the national charge inflation factor by dividing the average charge in the more recent fiscal year by the average charge in the prior fiscal year.

Following the methodology described previously, we computed a charge inflation factor based on the most recently available data. Specifically, we used the December 2021 update of the FY 2021 MedPAR file and the December 2020 update of the FY 2020 MedPAR as the basis of the LTCH PPS standard Federal payment rate cases for the two most recently available Federal fiscal year time periods, as described previously in our methodology. Therefore, we trimmed the December 2021 update of the FY 2021 MedPAR file and the December 2020 update of the FY 2020 MedPAR file as described in steps 1 and 2 of our methodology. To compute the 1-year average annual rate-of-change in charges per case, we compared the average covered charge per case of $239,245 ($14,013,531,722/58,574 cases) from FY 2020 to the average covered charge per case of $266,358 ($13,426,298,925/50,407 cases) from FY 2021. This rate-of-change was 11.3327 percent, which results in a 1-year charge inflation factor of 1.113327, and a 2-year charge inflation factor of 1.239497 (calculated by squaring the 1-year factor).

We recognize that the LTCH charge inflation factor calculated previously is abnormally high compared to recent historical levels prior to the COVID–19 PHE. As discussed in section I.F. of the preamble to this proposed rule, we believe this abnormally high charge inflation factor is partially due to the high number of COVID–19 cases that were treated in LTCHs in FY 2021. We also believe there will be fewer COVID–19 cases in FY 2023 than in FY 2021 and therefore do not believe it is reasonable to assume charges will continue to increase at this abnormally high rate. Consequently, when determining the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2023, we are not proposing to use this charge inflation factor, which was based on the growth in charges that occurred between FY 2020 and FY 2021. Rather, as discussed in section I.F. of the preamble to this proposed rule, we are proposing to use the charge inflation factor

determined in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45565), which was based on the growth in charges that occurred between FY 2018 and FY 2019 (the last 1-year period prior to the COVID–19 PHE).

The rate of LTCH charge growth determined in the FY 2022 IPPS/LTCH PPS final rule, based on the growth in charges that occurred between FY 2018 and FY 2019, was 6.0723 percent. This results in a 1-year charge inflation factor of 1.060723, and a 2-year charge inflation factor of 1.125133 (calculated by squaring the 1-year factor). Therefore, we propose to inflate the billed charges obtained from the FY 2021 MedPAR file by this 2-year charge inflation factor of 1.125133 when determining the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2023.

(2) Proposed CCRs for Use in Determining the Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2023

For greater accuracy in calculating the fixed-loss amount, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45562–45566), we finalized a technical change to our methodology for determining the CCRs used to calculate the fixed-loss amount. Similar to the methodology used for IPPS hospitals (as discussed in section II.A.4.h.(2). of the Addendum to this proposed rule), our methodology adjusts CCRs obtained from the best available PSF data by an adjustment factor that is calculated based on historical changes in the average case-weighted CCR for LTCHs. We believe these adjusted CCRs more accurately reflect CCR levels in the upcoming payment year because they account for historical changes in the relationship between costs and charges for LTCHs. In this section, we describe our CCR adjustment factor methodology using the most recently available data. However, as discussed in further detail later in this section, we are not proposing to use the CCR adjustment factor derived from the most recently available data. Rather, we are proposing to use the CCR adjustment factor that was derived in the FY 2022 IPPS/LTCH PPS final rule, which is based on the change in CCRs that occurred between the March 2019 PSF and the March 2020 PSF.

Step 1—Assign Providers Their Historical CCRs

The first step in our methodology is to identify providers with LTCH PPS standard Federal payment rate cases in the most recent MedPAR claims file (excluding all-inclusive rate providers and providers with only Medicare Advantage claims). For each of these providers, we then identify the CCR from the most recently available PSF. For each of these providers we also identify the CCR from the PSF that was made available one year prior to the most recently available PSF.

Step 2—Trim Providers With Insufficient CCR Data

The next step in our methodology is to remove from the CCR adjustment factor calculation any providers for which we cannot accurately measure changes to their CCR using the PSF data. We first remove any provider whose CCR was missing in the most recent PSF or prior year PSF. We next remove any provider assigned the statewide average CCR for their State in either the most recent PSF or prior year PSF. We lastly remove any provider whose CCR was not updated between the most recent PSF and prior year PSF (determined by comparing the effective date of the records).

Step 3—Remove Statistical Outliers

The next step in our methodology is to remove providers whose change in their CCR is a statistical outlier. To perform this statistical trim, for those providers remaining after application of Step 2, we calculate a provider-level CCR growth factor by dividing the provider's CCR from the most recent PSF by its CCR in the prior year's PSF. We then remove any provider whose CCR growth factor was outside 3 standard deviations from the mean provider CCR growth factor. These statistical outliers are removed prior to calculating the CCR adjustment factor because we believe that they may represent aberrations in the data that would distort the measure of average annual CCR change.

Step 4—Calculate a CCR Adjustment Factor

The final step in our methodology is to calculate, across all remaining providers after application of Step 3, an average case-weighted CCR from both the most recent PSF and prior year PSF. The provider case counts that we use to calculate the case-weighted average are determined from claims for LTCH standard Federal rate cases from the most recent MedPAR claims file. We note when determining these case counts, consistent with our historical methodology for determining the MS–LTC–DRG relative weights, we do not count short-stay outlier claims as full cases but instead as a fraction of a case based on the ratio of covered days to the geometric mean length of stay for the MS–LTC–DRG grouped to the case. We calculate the national CCR adjustment factor by dividing the case-weighted CCR from the most recent PSF by the case-weighted CCR from the prior year PSF.

Following the methodology described previously, we computed a CCR adjustment factor based on the most recently available data. Specifically, we used the December 2021 PSF as the most recently available PSF and the December 2020 PSF as the PSF that was made available one year prior to the most recently available PSF, as described in our methodology. In addition, we used claims from the December 2021 update of the FY 2021 MedPAR file in our calculation of average case-weighted CCRs described in Step 4 of our methodology. Specifically, following the methodology described previously and, for providers with LTCH PPS standard Federal payment rate cases in the December 2021 update of the FY 2021 MedPAR file, we identified their CCRs from both the December 2020 PSF and December 2021 PSF. After performing the trims outlined in our methodology, we used the LTCH PPS standard Federal payment rate case counts from the FY 2021 MedPAR file (classified using proposed Version 40 of the GROUPER) to calculate case-weighted average CCRs. Based on this data, we calculated a December 2020 national average case-weighted CCR of 0.244856 and a December 2021 national average case-weighted CCR of 0.234409. We then calculated a national CCR adjustment factor by dividing the December 2021 national average case-weighted CCR by the December 2020 national average case-weighted CCR. This results in a 1-year national CCR adjustment factor of 0.957334.

Unlike the charge inflation factor calculated using the most recently available data, the CCR adjustment factor calculated previously is not significantly different from historical levels. However, consistent with our proposal to derive our proposed charge inflation factor for FY 2023 based on data from the last 1-year period prior to the COVID–19 PHE, we are proposing to use the CCR adjustment factor determined in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45565), which was based on the change in CCRs that occurred between the March 2019 PSF and the March 2020 PSF (the last 1-year period prior to the COVID–19 PHE).

We note that the CCR adjustment factor of 0.961554 determined in the FY 2022 IPPS/LTCH PPS final rule is close to the CCR adjustment factor we calculated previously using the most recently available data. We note this

proposal is consistent with the approach being proposed under the IPPS as discussed in section II.A.4.h.(2). of the Addendum of this proposed rule.

When calculating the proposed fixed-loss amount for FY 2023, we assigned the statewide average CCR for the upcoming fiscal year to all providers who were assigned the statewide average in the December 2021 PSF or whose CCR was missing in the December 2021 PSF. For all other providers, we multiplied their CCR from the December 2021 PSF by the proposed 1-year national CCR adjustment factor of 0.961554.

(3) Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2023

In section in of the preamble to this proposed rule, we discuss our proposal to use FY 2021 claims data for the FY 2023 LTCH PPS ratesetting. We also state our belief that it is reasonable to assume that there will be fewer COVID–19 hospitalizations among Medicare beneficiaries at LTCHs in FY 2023 than there were in FY 2021. For this reason, as discussed previously, we are proposing modifications to the charge inflation and CCR adjustment factors used in determining the outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases. However, when modeling payments for the outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases, we are proposing to use the full set of LTCH PPS standard Federal payment rate cases (including all COVID–19 cases) identified in the FY 2021 claims data. In the absence of a set of MedPAR claims that reflect our expectation that there will be fewer (but not zero) COVID–19 cases in FY 2023 as compared to the COVID–19 cases in the FY 2021 claims data, we believe this is the best data available for determining the outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases. We note that this is consistent with the approach being proposed for determining the budget neutrality adjustments for the annual update to the MS–LTC–DRG classifications and relative weights (as discussed in section B.4.b. of the preamble to this proposed rule) and changes to the area wage level adjustment (as discussed in section V.B.6. of the addendum to this proposed rule.) We also note this is consistent with the approach being proposed under the IPPS as discussed in section II.A.4.h.(2). of the Addendum of this proposed rule. We are also soliciting feedback from commenters on alternative ways to use the FY 2021 claims data for purposes of calculating the FY 2023 outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases.

In this proposed rule, for FY 2023, using the best available data, we calculated a proposed fixed-loss amount that would maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the payment rates and policies for these cases presented in the proposed rule). Therefore, based on LTCH claims data from the December 2021 update of the FY 2021 MedPAR file adjusted for charge inflation and adjusted CCRs from the December 2021 update of the PSF, under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are proposing a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2023 of $44,182 that would result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2023 payments for such cases. We also are proposing to continue to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed adjusted LTCH PPS standard Federal payment rate payment and the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases of $44,182).

Consistent with our historical practice, we are proposing to use the best available LTCH claims data and CCR data, if applicable, when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2023 in the final rule. In section I.O. of Appendix A of this proposed rule, we are also considering as an alternative to this proposal, to use the FY 2021 data without any of our proposed methodological changes that account for an anticipated decline in COVID–19 cases in FY 2023. We note, under this alternative, the fixed-loss amount for LTCH PPS standard Federal payment rate cases would be $61,842.

4. Proposed High-Cost Outlier Payments for Site Neutral Payment Rate Cases

When we implemented the application of the site neutral payment rate in FY 2016, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the Actuary projections regarding how LTCHs will likely respond to our implementation of policies resulting from the statutory payment changes. We again relied on these considerations and actuarial projections in FY 2017 and FY 2018 because the historical claims data available in each of these years were not all subject to the LTCH PPS dual rate payment system. Similarly, for FYs 2019 through 2022, we continued to rely on these considerations and actuarial projections because, due to the transitional blended payment policy for site neutral payment rate cases, FY 2018 and FY 2019 claims for these cases were not subject to the full effect of the site neutral payment rate.

For FYs 2016 through 2022, our actuaries projected that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. In light of these projections and expectations, we discussed that we believed that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49617 through 49619 and 81 FR 57305 through

57307). For those reasons, we stated that we believed that the most appropriate fixed-loss amount for site neutral payment rate cases for FYs 2016 through 2022 would be equal to the IPPS fixed-loss amount for that particular fiscal year. Therefore, we established the fixed-loss amount for site neutral payment rate cases as the corresponding IPPS fixed-loss amounts for FYs 2016 through 2022. In particular, in FY 2022, we established the fixed-loss amount for site neutral payment rate cases as the FY 2021 IPPS fixed-loss amount of $30,988 (86 FR 45567).

As discussed in section I.F. of the preamble of this proposed rule, we are proposing to use FY 2021 data in the FY 2023 LTCH PPS ratesetting. Section 3711(b)(2) of the CARES Act, which provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID–19 PHE period, was in effect for the entirety of FY 2021. Therefore, all LTCH PPS cases in FY 2021 were paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria. Because not all FY 2021 claims in the data used for this proposed rule were subject to the site neutral payment rate, we continue to rely on the same considerations and actuarial projections used in FYs 2016 through 2022 when developing a fixed-loss amount for site neutral payment rate cases for FY 2023. Our actuaries continue to project that the costs and resource use for FY 2023 cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what was found based on the historical data. (Based on the FY 2021 LTCH claims data used in the development of this proposed rule, if the provisions of the CARES Act had not been in effect, approximately 72 percent of LTCH cases would have been paid the LTCH PPS standard Federal payment rate and approximately 28 percent of LTCH cases would have been paid the site neutral payment rate for discharges occurring in FY 2021.)

For these reasons, we continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2023 is the IPPS fixed-loss amount for FY 2023. Therefore, consistent with past practice, we are proposing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the proposed IPPS fixed-loss amount. That is, we are proposing a fixed-loss amount for site neutral payment rate cases of $43,214, which is the same proposed FY 2023 IPPS fixed-loss amount discussed in section II.A.4.j.(1). of the Addendum to this proposed rule. Accordingly, for FY 2023, we are proposing to calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the site neutral payment rate payment and the proposed fixed-loss amount for site neutral payment rate cases of $43,214).

In establishing a HCO policy for site neutral payment rate cases, we established a budget neutrality adjustment under § 412.522(c)(2)(i). We established this requirement because we believed, and continue to believe, that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases is budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments.

To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2023 would not result in any increase in estimated aggregate FY 2023 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce site neutral payment rate payments by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2023. Consistent with our historical practice, we are proposing to continue this policy.

As discussed earlier, consistent with the IPPS HCO payment threshold, we estimate the proposed fixed-loss threshold would result in FY 2023 HCO payments for site neutral payment rate cases to equal 5.1 percent of the site neutral payment rate payments that are based on the IPPS comparable per diem amount. As such, to ensure estimated HCO payments payable for site neutral payment rate cases in FY 2023 would not result in any increase in estimated aggregate FY 2023 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate amount paid under § 412.522(c)(1)(i) by 5.1 percent to account for the estimated additional HCO payments payable for site neutral payment rate cases in FY 2023. To achieve this, for FY 2023, we are proposing to apply a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as 1.0 − 5.1/100 = 0.949) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We note that, consistent with our current policy, this proposed HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount (81 FR 57309).

E. Proposed Update to the IPPS Comparable Amount To Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), we established a policy to reflect the changes to the Medicare IPPS DSH payment adjustment methodology made by section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' under the SSO policy at § 412.529 and the ''IPPS equivalent amount'' under the site neutral payment rate at § 412.522. Historically, the determination of both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' includes an amount for inpatient operating costs ''for the costs of serving a disproportionate share of low-income patients.'' Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all IPPS hospitals that receive Medicare DSH payments.

To reflect the statutory changes to the Medicare DSH payment adjustment methodology in the calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated that we will

include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating Medicare DSH payment amount that has historically been reflected in the LTCH PPS payments that are based on IPPS rates). We also stated that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

For FY 2023, as discussed in greater detail in section V.E.4.b. of the preamble of this proposed rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 65.71 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount is then used to determine the amount available to make uncompensated care payments to eligible IPPS hospitals in FY 2023. In other words, the amount of the Medicare DSH payments that would have been made prior to the amendments made by the Affordable Care Act is adjusted to 49.28 percent (the product of 75 percent and 65.71 percent) and the resulting amount is used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2023, we project that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, will result in overall Medicare DSH payments of 74.28 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of the amendments made by the Affordable Care Act (that is, 25 percent + 49.28 percent = 74.28 percent).

Therefore, for FY 2023, we are proposing to establish that the calculation of the ''IPPS comparable amount'' under § 412.529 would include an applicable operating Medicare DSH payment amount that is equal to 74.28 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, we are proposing that, if more recent data became available, we would use that data to determine this factor in the final rule.

F. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2023

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal payment rate. Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages by multiplying the labor-related share of the LTCH PPS standard Federal payment rate for a case by the applicable LTCH PPS wage index (the proposed FY 2023 values are shown in Tables 12A through 12B listed in section VI. of the Addendum to this proposed rule and are available via the internet on the CMS website). The LTCH PPS standard Federal payment rate is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the proposed FY 2023 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this proposed rule, we are proposing to establish an LTCH PPS standard Federal payment rate for FY 2023 of $45,952.67, as discussed in section V.A. of the Addendum to this proposed rule. We illustrate the methodology to adjust the proposed LTCH PPS standard Federal payment rate for FY 2023 in the following example:

Example:

During FY 2023, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is, an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in CBSA 16984, which has a proposed FY 2023 LTCH PPS wage index value of 1.0505 (as shown in Table 12A listed in section VI. of the Addendum to this proposed rule). The Medicare patient case is classified into proposed MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a proposed relative weight for FY 2023 of 0.9562 (as shown in Table 11 listed in section VI. of the Addendum to this proposed rule). The LTCH submitted quality reporting data for FY 2023 in accordance with the LTCH QRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted proposed Federal prospective payment for this Medicare patient case in FY 2023, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted proposed FY 2023 LTCH PPS standard Federal payment rate ($45,952.67) by the proposed labor-related share (0.682 percent) and the proposed wage index value (1.0505). This wage-adjusted amount was then added to the proposed nonlabor-related portion of the unadjusted proposed LTCH PPS standard Federal payment rate (0.318 percent; adjusted for cost of living, if applicable) to determine the adjusted proposed LTCH PPS standard Federal payment rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (0.9562) to calculate the total adjusted proposed LTCH PPS standard Federal prospective payment for FY 2023 ($45,453.28). The table illustrates the components of the calculations in this example.

Unadjusted Proposed LTCH PPS Standard Federal Prospective Payment Rate	$45,952.67
Proposed Labor-Related Share	x 0.682
Proposed Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $31,339.72
Proposed Wage Index (CBSA 16984)	x 1.0505
Proposed Wage-Adjusted Labor Share of the LTCH PPS Standard Federal Payment Rate	= $32,922.38
Proposed Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($45,952.67 x 0.318)	+ $14,612.95
Adjusted Proposed LTCH PPS Standard Federal Payment Amount	= $47,535.33
Proposed MS-LTC-DRG 189 Relative Weight	x 0.9562
Total Adjusted Proposed LTCH PPS Standard Federal Prospective Payment	= $45,453.28

VI. Tables Referenced in This Proposed Rule Generally Available Through the Internet on the CMS Website

This section lists the tables referred to throughout the preamble of this proposed rule and in the Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2022, for the FY 2023 rulemaking cycle, the IPPS and LTCH PPS tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be available through the internet. Specifically, all IPPS tables listed in the proposed rule, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E, will generally be available through the internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules. For additional discussion of the information included in the IPPS and LTCH PPS tables associated with the IPPS/LTCH PPS proposed and final rules, as well as prior changes to the information included in these tables, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45569 through 45571).

In addition, under the HAC Reduction Program, established by section 3008 of the Affordable Care Act, a hospital's total payment may be reduced by 1 percent if it is in the lowest HAC performance quartile. The hospital-level data for the FY 2023 HAC Reduction Program will be made publicly available once it has undergone the review and corrections process.

We note, Tables 7A and 7B historically contained the Medicare prospective payment system selected percentile lengths of stay for the MS–DRGs for the prior year and upcoming fiscal year. As discussed in section II.E of this proposed rule, we are proposing to determine the MS DRG relative weights for FY 2023 by averaging the relative weights as calculated with and without COVID–19 cases in the FY 2021 data. Because we are using MS–DRG weights based on an average of the relative weights, the percentile lengths of stay, which are based on separate sets of MS–DRG relative weights prior to averaging are not applicable to the proposed averaged MS–DRG relative weights for FY 2023. The separate percentile lengths of stay statistics are only applicable to the relative weights as calculated with and without COVID–19 cases. Additionally, we note that unlike the other files listed as tables in this section that typically contain information/variables relating to a hospital's IPPS claim for payment, Tables 7A and 7B are informational files containing percentile lengths of stay that are not used for claim payment. Therefore, beginning with this FY 2023 IPPS/LTCH PPS proposed rule, we are proposing to instead provide the percentile length of stay information previously included in Tables 7A and 7B in the supplemental AOR/BOR data file, as described in section XII.A. of this proposed rule, which contains additional data relevant to the MS–DRG relative weights. For FY 2023, because we are proposing to average the relative weights, we are providing an AOR/BOR file for the relative weights calculated with COVID–19 cases in the December 2021 update of the FY 2021 MedPAR file and an AOR/BOR file for the relative weights calculated without COVID–19 cases in the December 2021 update of the FY 2021 MedPAR file. Therefore, instead of including the percentile lengths of stay that are typically in Tables 7A and 7B (that is, for this proposed rule, the selected percentile lengths of stay based on the MedPAR data and MS–DRGs for the prior year and upcoming fiscal year (for FY 2023, this would be the proposed version 40 GROUPER and version 39 GROUPER)) we are including this statistical information in the AOR/BOR File for the relative weights as calculated with and without COVID–19 cases. The AOR/BOR files can be found on the FY 2023 IPPS proposed rule home page on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

As was the case for the FY 2022 IPPS/LTCH PPS proposed and final rules, we are no longer including Table 15, which had typically included the fiscal year readmissions payment adjustment factors because hospitals have not yet had the opportunity to review and correct the data before the data are made public under our policy regarding the reporting of hospital1specific data. After hospitals have been given an opportunity to review and correct their calculations for FY 2023, we will post Table 15 (which will be available via the internet on the CMS website) to display the final FY 2023 readmissions payment adjustment factors that will be applicable to discharges occurring on or after October 1, 2022. We expect Table 15 will be posted on the CMS website in the fall of 2022.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified in this proposed rule should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this proposed rule are generally available through the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Click on the link on the left side of the screen titled ''FY 2023 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files—for Download.'' We refer readers to section I.O. of the Appendix A of this proposed rule for a discussion of the supplemental data files we are making available based on the use of the FY 2021 data without the proposed modifications to our usual methodologies for the calculation of the FY 2023 MS–DRG and MS–LTC–DRG relative weights or our usual methodologies for the determination of the FY 2023 outlier fixed-loss amount for IPPS cases and LTCH PPS standard Federal payment rate cases for this FY 2023 ratesetting, which we are also making available on the CMS website.

Table 2.—Proposed Case-Mix Index and Wage Index Table by CCN—FY 2023 Proposed Rule

Table 3.—Proposed Wage Index Table by CBSA—FY 2023 Proposed Rule

Table 4A.—Proposed List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2023 Proposed Rule

Table 4B.—Counties Redesignated under Section 1886(d)(8)(B) of the Act (LUGAR Counties)—FY 2023 Proposed Rule

Table 5.—Proposed List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2023

Table 6A.—New Diagnosis Codes—FY 2023

Table 6B.—New Procedure Codes—FY 2023

Table 6C.—Invalid Diagnosis Codes—FY 2023

Table 6E.—Revised Diagnosis Code Titles—FY 2023

Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2023

Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2023

Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2023

Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2023

Table 6I.1.—Proposed Additions to the MCC List—FY 2023

Table 6I.2.—Proposed Deletions to the MCC List—FY 2023

Table 6J.1.—Proposed Additions to the CC List—FY 2023

Table 6J.2.—Proposed Deletions to the CC List—FY 2023

Table 6P.—ICD–10–CM and ICD–10–PCS Codes for Proposed MS–DRG and Medicare Code Editor (MCE) Changes—FY 2023 (Table 6P contains multiple tables, 6P.1a. through 6P.6c that include the ICD–10–CM and ICD–10–PCS code lists relating to specific proposed MS–DRG and MCE changes. These tables are referred to throughout section II.D. of the preamble of this proposed rule.)

Table 8A.—Proposed FY 2023 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)

Table 8B.—Proposed FY 2023 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 16.—Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors That Would Apply for FY 2023 If Our Proposals to Revise the Scoring and Payment Methodology For That Program Year Are Not Finalized

Table 18.—Proposed FY 2023 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2023 proposed rule are available through the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1771–P:

Table 8C.—Proposed FY 2023 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)

Table 11.—Proposed MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges Occurring from October 1, 2022, through September 30, 2023

Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2022, through September 30, 2023

Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2022, through September 30, 2023

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TABLE 1A.— PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (67.6 PERCENT LABOR SHARE/32.4 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)--FY 2023

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.7 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.375 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.925 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.4 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,269.46	$2,046.31	$4,172.80	$1,999.98	$4,237.24	$2,030.87	$4,140.59	$1,984.54

TABLE 1B.— PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2023

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.7 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.375 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.925 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.4 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,915.78	$2,399.99	$3,827.12	$2,345.66	$3,886.23	$2,381.88	$3,797.58	$2,327.55

TABLE 1C.— PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1);—FY 2023

	Rates if Wage Index Greater Than 1		Hospital is a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = 2.7)		Hospital is NOT a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = 1.115)	
	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
National[1]	Not Applicable	Not Applicable	$3,915.78	$2,399.99	$3,856.68	$2,363.77

[1] For FY 2023, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D.— PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2023

	Rate
National	$480.29

TABLE 1E.— LTCH PPS STANDARD FEDERAL PAYMENT RATE--FY 2023

	Full Update (2.7 Percent)	Reduced Update* (0.7 Percent)
Standard Federal Rate	$45,952.67	$45,057.78

* For LTCHs that fail to submit quality reporting data for FY 2023 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

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Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary in order to make payment and policy changes under the IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS. Also, as we note later in this Appendix, the primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the proposed changes in this proposed rule, such as the proposed updates to the IPPS and LTCH PPS rates, and the proposals and discussions relating to applications for new technology add-on payments, are needed to further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries.

We expect that these proposed changes would ensure that the outcomes of the prospective payment systems are reasonable and provide equitable payments, while avoiding or minimizing unintended adverse consequences.

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

a. Proposed Update to the IPPS Payment Rates

In accordance with section 1886(b)(3)(B) of the Act and as described in section V.A. of the preamble to this proposed rule, we are proposing to update the national standardized amount for inpatient hospital operating costs by the proposed applicable percentage increase of 2.7 percent (that is, a 3.1 percent market basket update with a proposed reduction of 0.4 percentage point for the productivity adjustment) and by a proposed 0.5 percentage point adjustment required under section 414 of the MACRA. We are also proposing to apply the proposed applicable percentage increase (including the market basket update and the proposed productivity adjustment) to the hospital-specific rates.

Subsection (d) hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act would receive an applicable percentage increase of 1.925 percent. Hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act would receive an applicable percentage increase of 0.375 percent.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act would receive a proposed applicable percentage increase of −0.4 percent, which reflects a one-quarter percent reduction of the market basket update for failure to submit quality data and a three-quarter percent reduction of the market basket update for being identified as not a meaningful EHR user.

b. Proposed Use of FY 2021 Data in the FY 2023 IPPS and LTCH PPS Ratesetting

As discussed in section I.A of this proposed rule, we believe that it is reasonable to assume that some Medicare beneficiaries will continue to be hospitalized with COVID–19 at IPPS hospitals and LTCHs in FY 2023. Accordingly, we believe it is appropriate to use FY 2021 data, specifically

the FY 2021 MedPAR claims file and the FY 2020 HCRIS dataset (which contains data from many cost reports ending in FY 2021 based on each hospital's cost reporting period) as the most recent available data during the period of the COVID–19 PHE, for purposes of the FY 2023 IPPS and LTCH PPS ratesetting. However, we also believe it is reasonable to assume based on the information available at this time that there will be fewer COVID 19 hospitalizations in FY 2023 than in FY 2021 given the more recent trends in the CDC hospitalization data since the Omicron variant peak in January, 2022. Accordingly, because we anticipate Medicare inpatient hospitalizations for COVID–19 will continue in FY 2023 but at a lower level, we are proposing to use FY 2021 data for purposes of the FY 2023 IPPS and LTCH PPS ratesetting but with modifications to our usual ratesetting methodologies to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries at IPPS hospitals and LTCHs as compared to FY 2021.

First, we are proposing to modify the calculation of the FY 2023 MS–DRG and MS LTC DRG relative weights. The proposal for modifying the methodology for determining the FY 2023 IPPS MS–DRG relative weights is discussed in section II.E. of the preamble of this proposed rule. The proposal for modifying the methodology for determining the FY 2023 LTCH PPS MS–LTC–DRG relative weights is discussed in greater detail in section VIII.B. of the preamble of this proposed rule.

Second, we also are proposing to modify our methodologies for determining the FY 2023 outlier fixed-loss amount for IPPS cases and LTCH PPS standard Federal payment rate cases. The proposal for modifying the methodology for determining the FY 2023 outlier fixed-loss amounts for IPPS cases is discussed in section II.A.4. of the addendum to this proposed rule. The proposal for modifying the methodology for determining the FY 2023 outlier fixed loss amounts for LTCH PPS standard Federal payment rate cases is discussed in section V.D.3. of the addendum to this proposed rule.

In section I.O. of Appendix A of this proposed rule, we are also considering as an alternative to this proposal, to use the FY 2021 data without any modifications to our usual methodologies for the calculation of the FY 2023 MS–DRG and MS–LTC–DRG relative weights or the usual methodologies used to determine the FY 2023 outlier fixed-loss amount for IPPS cases and LTCH PPS standard Federal payment rate cases, which we may consider finalizing based on consideration of comments received.

c. Proposed Cap on Reductions in Medicare Severity Diagnosis-Related Group (MS–DRG) Relative Weights

As described in section II.E.2. of the preamble of this proposed rule, we have further considered requests made by commenters that we address year-to-year fluctuations in relative weights, particularly for low volume MS–DRGs, and to mitigate the financial impacts of significant fluctuations. Consistent with our statutory authority under section 1886(d)(4)(B) and (C) of the Act to assign and update appropriate weighting factors, beginning in FY 2023, we are proposing a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year. This proposal is consistent with our general authority to assign and update appropriate weighting factors as part of our annual reclassifications of the MS–DRGs and recalibration of the relative weights under sections 1886(d)(4)(B) and (C)(i) of the Act, as well as the requirements of section 1886(d)(4)(C)(iii) of the Act, which specifies that the annual DRG reclassification and recalibration of the relative weights be made in a manner that ensures that aggregate payments to hospitals are not affected. In addition, we have authority to implement this proposed cap and the associated budget neutrality adjustment under our special exceptions and adjustments authority at section 1886(d)(5)(I)(i) of the Act, which similarly gives the Secretary broad authority to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate.

d. Add-On Payments for New Services and Technologies

Consistent with sections 1886(d)(5)(K) and (L) of the Act, CMS reviews applications for new technology add-on payments based on the eligibility criteria at 42 CFR 412.87. As set forth in 42 CFR 12.87(e)(1), CMS considers whether a technology meets the criteria for the new technology add-on payment and announces the results as part of its annual updates and changes to the IPPS.

(1) Proposal To Use National Drug Codes (NDCs) for Identification of Certain Therapeutic Agents Approved for New Technology Add-On Payment

CMS has received comments from stakeholders opposing the continued creation of new ICD–10–PCS (for example, Section X) procedure codes for the purpose of administering the new technology add-on payment for drugs and biologics. Specifically, public comments from the ICD–10 Coordination and Maintenance Committee Meetings have stated that the ICD–10–PCS classification system was not intended to represent unique drugs/therapeutic agents and is not an appropriate code set for this purpose.

In addition, the current process of requesting, proposing, finalizing and assigning new ICD–10–PCS procedure codes to identify and describe the administration of drugs involves several steps (described further in section II.F.8. of this proposed rule), and frequently results in a number of procedure codes that are created unnecessarily when the drug/therapeutic agents do not receive approval for the new technology add-on payments, as the administration of drugs/therapeutic agents is not typically coded in the inpatient hospital setting.

In section II.F.8. of this proposed rule, we are proposing to use National Drug Codes (NDCs) to identify cases involving use of therapeutic agents approved for new technology add-on payments. We also note that we have previously established the use of NDCs as an alternative code set for the purposes of administering the new technology add-on payment in circumstances where an ICD–10–PCS code was not available to uniquely identify the use of the technology.

Therefore, we are proposing for FY 2024 to instead use NDCs to identify cases involving the use of therapeutic agents approved for the new technology add-on payment. We believe that this proposal would address concerns raised by commenters regarding the use of the ICD–10–PCS classification system to identify these agents and reduce the need for applicants to seek a unique ICD–10–PCS code through the ICD–10–PCS Section X code request process in advance of a determination on their new technology add-on payment applications. We also expect this proposed change would address concerns regarding the creation of duplicative codes within the ICD–10–PCS procedure coding system and reduce efforts associated with determining the disposition of procedure codes describing therapeutic agents that have reached the end of their three-year new technology add-on payment timeframe.

(2) Proposal To Publicly Post Applications for New Technology Add-On Payments

As discussed in II.F.9. of this proposed rule, beginning with the FY 2024 application cycle for new technology add-on payments, we are proposing to post online the full contents of the applications, including updated application information submitted subsequent to the initial application submission, with the exception of certain cost and volume information and application attachments. CMS has received requests from the public to access and review the new technology add-on payment applications to further facilitate comment on whether a technology meets the new technology add-on payment criteria. Making this information publicly available may also foster greater input from experts in the stakeholder community based on their review of the original application materials.

Additionally, we believe that posting the applications online would reduce the risk that we may inadvertently omit or misrepresent relevant information submitted by applicants, or are perceived as misrepresenting such information, in our summaries in the rules. It also would streamline our evaluation process, including the identification of critical questions in the proposed rule, particularly as the number and complexity of the applications have been increasing over time. That is, by making the applications available to the public online, we would afford more time for CMS to process and analyze the supporting data and evidence rather than reiterate parts of the application in the rule.

e. Proposed Permanent Cap on Wage Index Decreases

Consistent with section 1886(d)(3)(E) of the Act, we adjust the IPPS standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level and update the wage index annually based on a survey of wages

and wage-related costs of short-term, acute care hospitals. As described in section III.N. of the preamble of this proposed rule, we have further considered the comments we received during the FY 2022 rulemaking recommending a permanent 5 percent cap policy to prevent large year-to-year variations in wage index values as a means to reduce overall volatility for hospitals. Under the authority at sections 1886(d)(3)(E) and 1886(d)(5)(I)(i) of the Act, we are proposing a permanent cap on wage index decreases, limiting overall reductions in a hospital's wage index value for the upcoming FY to be no greater than 5 percent of its wage index value for the current FY. That is, under this proposed policy, a hospital's wage index value would not be less than 95 percent of its prior year value. We are also proposing to apply this proposed permanent cap policy in a budget neutral manner through a national adjustment to the standardized amount under our authority in sections 1886(d)(3)(E) and 1886(d)(5)(I)(i) of the Act.

f. Continuation of the Low Wage Index Hospital Policy

To help mitigate wage index disparities between high wage and low wage hospitals, in the FY 2020 IPPS/LTCH PPS rule (84 FR 42326 through 42332), we adopted a policy to increase the wage index values for certain hospitals with low wage index values (the low wage index hospital policy). This policy was adopted in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals. We also indicated that this policy would be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. Therefore, as discussed in section III.G.4. of the preamble of this proposed rule, for FY 2023, we are continuing the low wage index hospital policy, and are also proposing to apply this policy in a budget neutral manner by applying an adjustment to the standardized amounts.

g. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs)

In this proposed rule, as required by section 1886(r)(2) of the Act, we are proposing to update our estimates of the three factors used to determine uncompensated care payments for FY 2023. We are proposing to adopt a multiyear averaging methodology to determine Factor 3 of the uncompensated care methodology, which will help to mitigate against large fluctuations in uncompensated care payments from year to year. Specifically, we are proposing to use a two-year average of audited data on uncompensated care costs from Worksheet S–10 from the FY 2018 and FY 2019 cost reports to calculate Factor 3 for the FY 2023 for all eligible hospitals, including Indian Health Service (IHS) and Tribal hospitals and hospitals located in Puerto Rico. In addition, for FY 2024 and subsequent fiscal years, we are proposing to use a three-year average of the data on uncompensated care costs from Worksheet S–10 for the three most recent fiscal years for which audited data are available.

We recognize that our proposal to discontinue the use of the low-income insured days proxy to calculate Factor 3 in the uncompensated care payment methodology for IHS and Tribal hospitals and Puerto Rico hospitals could result in a significant financial disruption for these hospitals. Accordingly, we are proposing to use our authority under section 1886(d)(5)(I) of the Act to establish a new supplemental payment for these hospitals for FY 2023 and subsequent fiscal years.

Additionally, as discussed in section IV.F. of the preamble of this proposed rule, we are proposing to revise our regulation governing the calculation of the Medicaid fraction of the DSH calculation. Under this proposal, we would revise our regulation to explicitly reflect our interpretation of the language ''regarded as'' ''eligible for medical assistance under a State plan approved under title XIX'' in section 1886(d)(5)(F)(vi) of the Act to mean patients who receive health insurance through a section 1115 demonstration itself or purchase such insurance with the use of premium assistance provided by a section 1115 demonstration. Moreover, of the groups we ''regard'' as Medicaid eligible, we propose that only the days of those individuals that obtain insurance coverage that provides essential health benefits (EHB) (defined as meeting the EHB requirements set forth in 42 CFR part 440, subpart C, for an Alternative Benefit Plan), and if bought with premium assistance, for which the premium assistance is equal to or greater than 90 percent of the cost of the coverage, would be included in the Medicaid fraction of the DSH calculation, provided the patient is not also entitled to Medicare Part A.

h. Effects of Implementation of the Rural Community Hospital Demonstration Program in FY 2023

The Rural Community Hospital Demonstration (RCHD) was authorized originally for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and it was extended for another 5-year period by section 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Section 15003 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255) extended the demonstration for an additional 5-year period, and section 128 of the Consolidated Appropriations Act of 2021 (Pub. L. 116–159) included an additional 5-year re-authorization through 2028. CMS has conducted the demonstration since 2004, which allows enhanced, cost-based payment for Medicare inpatient services for up to 30 small rural hospitals.

The authorizing legislation imposes a strict budget neutrality requirement. In this proposed rule, we summarize the status of the demonstration program, and the ongoing methodologies for implementation and budget neutrality.

2. Payments for Graduate Medical Education (GME)

On May 17, 2021, the U.S. District Court for the District of Columbia ruled against CMS's method of calculating direct GME payments to teaching hospitals when those hospitals' weighted full-time equivalent (FTE) counts exceed their direct GME FTE cap. In *Milton S. Hershey Medical Center, et al.* v. *Becerra,* the court ordered CMS to recalculate reimbursement owed, holding that CMS's regulation impermissibly modified the statutory weighting factors.

After reviewing the statutory language regarding the direct GME FTE cap and the court's opinion in *Milton S. Hershey Medical Center, et al.* v. *Becerra,* we are proposing, as described in greater detail in section V.F.2. of the preamble of this proposed rule, a modified policy to be applied retroactively and prospectively for all teaching hospitals. Specifically, effective for cost reporting periods beginning on or after October 1, 2001 that are open or reopenable, we are proposing that if the hospital's unweighted number of FTE residents exceeds the FTE cap, and the number of weighted FTE residents also exceeds that FTE cap, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the FTE cap. If the number of weighted FTE residents does not exceed that FTE cap, then the allowable weighted FTE count for direct GME payment is the actual weighted FTE count. We estimate the impact of this modified policy to be $170 million for FY 2023.

3. Frontier Community Health Integration Project (FCHIP) Demonstration

The Frontier Community Health Integration Project (FCHIP) demonstration was authorized under section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act (ACA) of 2010 (Pub. L. 114–158), and most recently re-authorized and extended by the Consolidated Appropriations Act of 2021 (Pub. L. 116–159). The legislation authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries in certain rural areas. The FCHIP demonstration initial period was conducted in 10 critical access hospitals (CAHs) from August 1, 2016, to July 31, 2019, and the demonstration ''extension period'' began on January 1, 2022, and run through June 30, 2027.

The authorizing legislation requires the FCHIP demonstration to be budget neutral. In this proposed rule, we propose to continue with the budget neutrality approach used in the demonstration initial period for the demonstration extension period—to offset payments across CAHs nationally—should the demonstration incur costs to Medicare.

4. Proposed Update to the LTCH PPS Payment Rates

As described in section VIII.C.2. of the preamble of this proposed rule, in order to update payments to LTCHs using the best available data, we are proposing to update the LTCH PPS standard Federal payment rate by 2.7 percent (that is, a 3.1 percent market basket update with a proposed reduction of 0.4 percentage point for the productivity adjustment, as required by section

1886(m)(3)(A)(i) of the Act). LTCHs that failed to submit quality data, as required by 1886(m)(5)(A)(i) of the Act and described in section VIII.C.2. of the preamble of this proposed rule, would receive a proposed update of 0.7 percent, which reflects a 2.0 percentage points reduction for failure to submit quality data.

5. Hospital Quality Programs

Section 1886(b)(3)(B)(viii) of the Act requires subsection (d) hospitals to report data in accordance with the requirements of the Hospital IQR Program for purposes of measuring and making publicly available information on health care quality, and links the quality data submission to the annual applicable percentage increase. Sections 1886(b)(3)(B)(ix), 1886(n), and 1814(l) of the Act require eligible hospitals and CAHs to demonstrate they are meaningful users of certified EHR technology for purposes of electronic exchange of health information to improve the quality of health care, and links the submission of information demonstrating meaningful use to the annual applicable percentage increase for eligible hospitals and the applicable percent for CAHs. Section 1886(m)(5) of the Act requires each LTCH to submit quality measure data in accordance with the requirements of the LTCH QRP for purposes of measuring and making publicly available information on health care quality, and in order to avoid a 2-percentage point reduction. Section 1886(o) of the Act requires the Secretary to establish a value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet the performance standards established on an announced set of quality and efficiency measures for the fiscal year. The purposes of the Hospital VBP Program include measuring the quality of hospital inpatient care, linking hospital measure performance to payment, and making publicly available information on hospital quality of care. Section 1886(p) of the Act requires a reduction in payment for subsection (d) hospitals that rank in the worst-performing 25 percent with respect to measures of hospital-acquired conditions under the HAC Reduction Program for the purpose of measuring, linking measure performance to payment, and making publicly available information on health care quality. Section 1886(q) of the Act requires a reduction in payment for subsection (d) hospitals for excess readmissions based on measures for applicable conditions under the Hospital Readmissions Reduction Program for the purpose of measuring, linking measure performance to payment, and making publicly available information on health care quality. Section 1866(k) of the Act applies to hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs'') and requires PCHs to report data in accordance with the requirements of the PCHQR Program for purposes of measuring and making publicly available information on the quality of care furnished by PCHs, however, there is no reduction in payment to a PCH that does not report data.

6. Other Proposed Provisions

a. Codification of the Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans

As discussed in section X.A. of the preamble of this proposed rule, we are proposing to clarify general requirements; definitions; requirements for costs of the plans to be allowable under the program; additional requirements for payments to funded defined benefit plans; data and documentation requirements to support payments/contributions to the plans; and allowable administrative and other costs associated with the plans, including costs related to the Pension Benefit Guarantee Corporation.

b. Condition of Participation (CoP) Requirements for Hospitals and CAHs To Report Data Elements To Address Any Future Pandemics and Epidemics as Determined by the Secretary

Section X.B. of the preamble of this proposed rule would revise the hospital and CAH infection prevention and control CoP requirements that would require hospitals and CAHs, after the conclusion of the current COVID–19 PHE, to continue COVID–19 and seasonal influenza related reporting. The proposed revisions would continue to apply upon conclusion of the COVID–19 Public Health Emergency (PHE) and would continue until April 30, 2024, unless the Secretary establishes an earlier ending date. In addition, the rule proposes to establish reporting requirements for future PHEs related to epidemics and pandemics by requiring hospitals and CAHs to electronically report information on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection), SARS–CoV–2/COVID–19, and other viral and bacterial pathogens or infectious diseases. This collection would only occur when the Secretary has declared a Public Health Emergency (PHE), as defined in § 400.200, directly related to such specific pathogens and infectious diseases. Specifically, when the Secretary has declared a PHE, we propose to require hospitals and CAHs to report specific data elements to the CDC's National Health Safety Network (NHSN), or other CDC-supported surveillance systems, as determined by the Secretary. The proposed requirements of this section would apply to local, state, and national PHEs as declared by the Secretary. Relevant to the declared PHE, the categories of data elements that this report would include are as follows: Suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff; total deaths attributed to the relevant infectious disease pathogen among patients and staff; personal protective equipment and other relevant supplies in the facility; capacity and supplies in the facility relevant to the immediate and long term treatment of the relevant infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies; total hospital bed and intensive care unit bed census, capacity, and capability; staffing shortages; vaccine administration status of patients and staff for conditions monitored under this section and where a specific vaccine is applicable; relevant therapeutic inventories and/or usage; isolation capacity, including airborne isolation capacity; and key co-morbidities and/or exposure risk factors of patients being treated for the pathogen or disease of interest in this section that are captured with interoperable data standards and elements.

In this proposed rule, we would also require that, unless the Secretary specifies an alternative format by which a hospital (or a CAH) must report each applicable infection (confirmed and suspected) and the applicable vaccination data in a format that provides person-level information, to include medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients. We are also proposing in this provision to limit any person-level, directly or potentially individually identifiable, information for affected patients to items outlined in this section or otherwise specified by the Secretary. Lastly, we are proposing that a hospital (or a CAH) would provide the information specified on a daily basis, unless the Secretary specifies a lesser frequency. For purposes of burden estimates, we do not differentiate among hospitals and CAHs as they all would complete the same data collection.

In regards to these proposals, we note that reporting frequency and requirements would be communicated to hospitals, stakeholders, and the public following a model similar to that which we used to inform regulated entities at the beginning of the COVID–19 PHE (see QSO–21–03–Hospitals/CAHs at *https://www.cms.gov/files/document/qso-21-03-hospitalscahs.pdf-0*).

As detailed in the Collection of Information section of the preamble of this proposed rule, our current estimate of the cost for all hospitals and CAHs to comply with the continued COVID–19 and influenza-related reporting requirements would be a total of $38,204,400 (approximately $6,162 per facility) annually, based on weekly reporting. These estimates are likely overestimates of the costs associated with reporting because it assumes that all hospitals and CAHs will report manually. Efforts are underway to automate hospital and CAH reporting that have the potential to significantly decrease reporting burden and improve reliability. For proposed reporting requirements associated with a future PHE declaration, we acknowledge that there are uncertainties in planning for future emergencies, and CMS understands that there are lots of incentives and pathways to consider with regard to preparedness. Therefore, we are soliciting public comment on how to best align and incentivize preparedness, while also reducing burden and costs on regulated entities, and ensuring flexibility to quickly be informed and respond during emergencies. We are soliciting comment on the burden impacts related to reporting for a specified infectious disease when a future PHE is declared.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order

12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with economically significant effects ($100 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

We estimate that the proposed changes for FY 2023 acute care hospital operating and capital payments would redistribute amounts in excess of $100 million to acute care hospitals. The proposed applicable percentage increase to the IPPS rates required by the statute, in conjunction with other proposed payment changes in this proposed rule, would result in an estimated $0.3 billion decrease in FY 2023 payments, primarily driven by: (a) A combined $0.6 billion increase in FY 2023 operating payments, including uncompensated care payments and proposed supplemental payments, and (b) a combined decrease of $1.02 billion resulting from estimated changes in new technology add-on payments, the proposed change to the GME weighting methodology, the expiration of the low-volume payment adjustment, and FY 2023 capital payments. These proposed changes are relative to payments made in FY 2022. The impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience an increase in payments by approximately $25 million in FY 2023 relative to FY 2022.

Our operating impact estimate includes the proposed 0.5 percentage point adjustment required under section 414 of the MACRA applied to the IPPS standardized amount, as discussed in section II.D. of the preamble of this proposed rule. In addition, our operating payment impact estimate includes the proposed 2.7 percent hospital update to the standardized amount (which includes the estimated 3.1 percent market basket update reduced by the proposed 0.4 percentage point for the productivity adjustment). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This proposed rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Office of Management and Budget has reviewed this proposed rule.

C. Objectives of the IPPS and the LTCH PPS

The primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the proposed changes in this proposed rule would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these proposed changes would ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

Because this proposed rule contains a range of policies, we refer readers to the section of the proposed rule where each policy is discussed. These sections include the rationale for our decisions, including the need for the proposed policy.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes effective for FY 2023, on various hospital groups. We estimate the effects of individual proposed policy changes by estimating payments per case, while holding all other payment policies constant. We use the best data available, but, generally unless specifically indicated, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, case mix, changes to the Medicare population, or incentives. In addition, we discuss limitations of our analysis for specific proposed policies in the discussion of those proposed policies as needed.

E. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital related- costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 27 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short term, acute care hospitals, hospitals in Maryland are paid in accordance with the Maryland Total Cost of Care Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 6 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As of March 2022, there were 3,141 IPPS acute care hospitals included in our analysis. This represents approximately 53 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,422 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs, rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, cancer hospitals, extended neoplastic disease care hospital, and short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of proposed changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this proposed rule. The impact of the proposed update and policy changes to the LTCH PPS for FY 2023 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As discussed in section II.A.4. of the Addendum to this proposed rule, consistent with our proposed use of the PSF, there were 91 children's hospitals, 11 cancer hospitals, 6 short term- acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, 1 extended neoplastic disease care hospital, and 14 RNHCIs being paid on a reasonable

cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, the rehabilitation hospitals and units, and the LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and the psychiatric hospitals and units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the proposed rate updates discussed in this proposed rule. The impacts of the proposed changes on LTCHs are discussed in section I.J. of this Appendix.

For the children's hospitals, cancer hospitals, short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCIs, the proposed update of the rate-of-increase limit (or target amount) is the estimated FY 2023 percentage increase in the 2018-based IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. Consistent with current law, based on IGI's 2021 fourth quarter forecast of the 2018-based IPPS market basket increase, we are estimating the proposed FY 2023 update to be 3.1 percent (that is, the estimate of the market basket rate-of-increase), as discussed in section V.A. of the preamble of this proposed rule. We are proposing that if more recent data become available for the final rule, we would use such data, if appropriate, to calculate the IPPS operating market basket update for FY 2023. However, the Affordable Care Act requires a productivity adjustment (proposed 0.4 percentage point reduction for FY 2023), resulting in a proposed 2.7 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section V.A. of the preamble of this proposed rule. Children's hospitals, cancer hospitals, short term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the proposed update is the percentage increase in the 2018-based IPPS operating market basket for FY 2023, estimated at 3.1 percent.

The impact of the proposed update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that would not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit; or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

G. Quantitative Effects of the Proposed Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this proposed rule, we are announcing proposed policy changes and payment rate updates for the IPPS for FY 2023 for operating costs of acute care hospitals. The proposed FY 2023 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall proposed percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2023 operating payments would increase by 1.4 percent, compared to FY 2022. In addition to the proposed applicable percentage increase, this amount reflects the proposed +0.5 percentage point permanent adjustment to the standardized amount required under section 414 of MACRA. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which would also affect overall payment changes.

We have prepared separate impact analyses of the proposed changes to each system. This section deals with the proposed changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the best available claims data to enable us to estimate the impacts on payments per case of certain proposed changes in this proposed rule. As discussed in section I.A of this proposed rule, we believe that the FY 2021 claims data is the best available data for purposes of the proposed FY 2023 ratesetting and this impact analysis reflects the use of that data. However, there are other proposed changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of proposed changes in payments per case presented in this section are taken from the FY 2021 MedPAR file, as discussed previously in this proposed rule, and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the operating PPS do not incorporate cost data, data from the best available hospital cost reports were used to categorize hospitals, as also discussed previously in this proposed rule. Our analysis has several qualifications. First, in this analysis, we do not adjust for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each proposed change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2021 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of proposed payments under the capital IPPS, and the impact of proposed payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2023 are discussed in section I.I. of this Appendix.

We discuss the following proposed changes:

- The effects of the application of the proposed applicable percentage increase of 2.7 percent (that is, a 3.1 percent market basket update with a proposed reduction of 0.4 percentage point for the productivity adjustment), and a proposed 0.5 percentage point adjustment required under section 414 of the MACRA to the IPPS standardized amount, and the proposed applicable percentage increase (including the market basket update and the proposed productivity adjustment) to the hospital-specific rates.
- The effects of the proposed changes to the relative weights and MS–DRG GROUPER.
- The effects of the proposed changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2019, compared to the FY 2018 wage data, to calculate the proposed FY 2023 wage index.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this proposed rule) that will be effective for FY 2023.
- The effects of the proposed rural floor with the application of the national budget neutrality factor to the wage index.
- The effects of the proposed imputed floor wage index adjustment. This provision is not budget neutral.
- The effects of the proposed frontier State wage index adjustment under the statutory provision that requires hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes for FY 2023. This provision is not budget neutral.
- The effects of the expiration of the special payment status for MDHs at the end of FY 2022 under current law as a result of

which MDHs that currently receive the higher of payments made based on the Federal rate or the payments made based on the Federal rate plus 75 percent of the difference between payments based on the Federal rate and the hospital-specific rate will be paid based on the Federal rate starting in FY 2023.

- The total estimated change in payments based on the proposed FY 2023 policies relative to payments based on FY 2022 policies.

To illustrate the impact of the proposed FY 2023 changes, our analysis begins with a FY 2022 baseline simulation model using: The FY 2022 applicable percentage increase of 2.0 percent; the 0.5 percentage point adjustment required under section 414 of the MACRA applied to the IPPS standardized amount; the FY 2022 MS–DRG GROUPER (Version 39); the FY 2022 CBSA designations for hospitals based on the OMB definitions from the 2010 Census; the FY 2022 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 and each subsequent year through FY 2014, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner, and at a time specified by the Secretary. Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket update. Therefore, we are proposing that, hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act would receive an applicable percentage increase of 1.925 percent. At the time this impact was prepared, 25 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2023 because they failed the quality data submission process or did not choose to participate, but are meaningful EHR users. For purposes of the simulations shown later in this section, we modeled the proposed payment changes for FY 2023 using a reduced update for these hospitals.

For FY 2023, in accordance with section 1886(b)(3)(B)(ix) of the Act, a hospital that has been identified as not a meaningful EHR user will be subject to a reduction of three-quarters of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act. Therefore, we are proposing that hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act would receive an applicable percentage increase of 0.375 percent. At the time this impact analysis was prepared, 158 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2023 because they are identified as not meaningful EHR users that do submit quality information under section 1886(b)(3)(B)(viii) of the Act. For purposes of the simulations shown in this section, we modeled the proposed payment changes for FY 2023 using a reduced update for these hospitals.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act would receive a proposed applicable percentage increase of −0.4 percent, which reflects a one-quarter reduction of the market basket update for failure to submit quality data and a three-quarter reduction of the market basket update for being identified as not a meaningful EHR user. At the time this impact was prepared, 19 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2023 because they are identified as not meaningful EHR users that do not submit quality data under section 1886(b)(3)(B)(viii) of the Act.

Each proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2023 model incorporating all of the proposed changes. This simulation allows us to isolate the effects of each change.

Our comparison illustrates the proposed percent change in payments per case from FY 2022 to FY 2023. Two factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are proposing to update the standardized amounts for FY 2023 using a proposed applicable percentage increase of 2.7 percent. This includes the FY 2023 forecasted IPPS operating hospital market basket increase of 3.1 percent with a proposed 0.4 percentage point reduction for the productivity adjustment. Hospitals that fail to comply with the quality data submission requirements and are meaningful EHR users would receive a proposed update of 1.925 percent. This update includes a reduction of one-quarter of the market basket update for failure to submit these data. Hospitals that do comply with the quality data submission requirements but are not meaningful EHR users would receive a proposed update of 0.375 percent, which includes a reduction of three-quarters of the market basket update. Furthermore, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users would receive a proposed update of −0.4 percent. Under section 1886(b)(3)(B)(iv) of the Act, the update to the hospital-specific amounts for SCHs is also equal to the applicable percentage increase, or 2.7 percent, if the hospital submits quality data and is a meaningful EHR user.

A second significant factor that affects the proposed changes in hospitals' payments per case from FY 2022 to FY 2023 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2022 that are no longer reclassified in FY 2023. Conversely, payments may increase for hospitals not reclassified in FY 2022 that are reclassified in FY 2023.

2. Analysis of Table I

Table I displays the results of our analysis of the proposed changes for FY 2023. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,141 acute care hospitals included in the analysis.

The next two rows of Table I contain hospitals categorized according to their geographic location: urban and rural. There are 2,419 hospitals located in urban areas and 722 hospitals in rural areas included in our analysis. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The last groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2023 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have implications for capital payments) are 1,867, and 1,274, respectively.

The next three groupings examine the impacts of the proposed changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments. There are 1,939 nonteaching hospitals in our analysis, 932 teaching hospitals with fewer than 100 residents, and 270 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next six rows examine the impacts of the proposed changes on rural hospitals by special payment groups (SCHs and RRCs) and reclassification status from urban to rural in accordance with section 1886(d)(8)(E) of the Act. Of the hospitals that are not reclassified from urban to rural, there are 161 RRCs, 256 SCHs, and 120 hospitals that are both SCHs and RRCs. Of the hospitals that are reclassified from urban to rural, there are 460 RRCs, 47 SCHs, and 37 hospitals that are both SCHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare and Medicaid utilization expressed as a percent of total inpatient days. These data were taken from the most recent available Medicare cost reports.

The next grouping is based on hospitals' reporting of diagnosis codes describing patients experiencing homelessness. This row reflects hospitals whose claims indicate

that at least 5 percent of their IPPS cases involve these patients based on the reporting of ICD–10–CM diagnosis code Z59.0 (Homelessness). We note that hospitals are not required to identify these patients on their claims, and reporting this information on the claim does not currently impact Medicare payment. There may be other hospitals with at least 5 percent of their IPPS cases involving these patients, however we are unable to identify these hospitals. As discussed in section II.D.13.b. of the preamble to this proposed rule, we are soliciting public comments on how the reporting of ICD–10–CM diagnosis codes in categories Z55–Z65 (Persons with potential health hazards related to socioeconomic and psychosocial circumstances) that describe the social determinants of health may improve our ability to recognize severity of illness, complexity of illness, and/or utilization of resources under the MS–DRGs. Consistent with the Administration's goal of advancing health equity for all, we are also interested in receiving feedback on how we might otherwise foster the documentation and reporting of the diagnosis codes describing social and economic circumstances to more accurately reflect each health care encounter and improve the reliability and validity of the coded data including in support of efforts to advance health equity. As also noted in that section, stakeholders have shared several reasons for reduced documentation of social determinants of health in the inpatient setting. While homelessness was one of the more frequently reported codes that describe social determinants of health prior to FY 2022, we seek comment on whether including groupings of hospitals that report other social determinants of health in diagnosis codes categories Z55–Z65 could be informative.

The next grouping concerns the geographic reclassification status of hospitals. The first subgrouping is based on whether a hospital is reclassified or not. The second and third subgroupings are based on whether urban and rural hospitals were reclassified by the MGCRB for FY 2023 or not, respectively. The fourth subgrouping displays hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) of the Act. The fifth subgrouping displays hospitals deemed urban in accordance with section 1886(d)(8)(B) of the Act.

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TABLE I.—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2023

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2023 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	Proposed FY 2023 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2023 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	Expiration of MDH Status (7)[8]	All Proposed FY 2023 Changes (8)[9]
All Hospitals	3,141	3.1	0.0	0.0	0.0	0.0	0.3	-0.2	1.4
By Geographic Location:									
Urban hospitals	2,419	3.2	0.0	0.0	-0.1	0.0	0.3	-0.1	1.4
Rural hospitals	722	2.9	0.1	0.0	1.0	-0.2	0.1	-1.1	1.1
Bed Size (Urban):									
0-99 beds	640	3.1	0.1	0.0	-0.6	0.3	0.6	-1.7	0.2
100-199 beds	709	3.2	0.2	0.0	-0.1	0.2	0.4	-0.4	1.6
200-299 beds	423	3.2	0.1	0.1	0.1	0.0	0.3	0.0	1.8
300-499 beds	409	3.2	0.0	0.0	0.0	0.0	0.3	0.0	1.5
500 or more beds	236	3.1	-0.1	0.0	-0.2	0.0	0.2	0.0	1.2
Bed Size (Rural):									
0-49 beds	348	2.8	-0.1	-0.1	0.5	-0.2	0.2	-2.2	-0.2
50-99 beds	211	2.9	0.1	0.1	0.8	-0.2	0.3	-2.5	-0.1
100-149 beds	86	2.9	0.2	-0.2	1.2	-0.2	0.0	-0.3	2.0
150-199 beds	41	3.0	0.0	-0.2	1.0	-0.2	0.2	0.0	1.8
200 or more beds	36	2.9	0.1	0.1	1.7	-0.2	0.0	0.0	2.3
Urban by Region:									
New England	107	3.2	-0.1	-0.4	2.5	3.3	0.6	-0.2	2.1
Middle Atlantic	295	3.2	0.1	-0.1	0.4	-0.3	0.5	-0.1	1.2
East North Central	373	3.2	-0.1	-0.1	-0.5	-0.3	0.1	-0.4	1.0
West North Central	156	3.1	-0.2	-0.4	-0.6	-0.3	0.8	-0.1	1.1
South Atlantic	402	3.2	0.0	-0.1	-0.6	-0.3	0.3	-0.2	1.3
East South Central	140	3.2	0.1	-0.2	-0.6	-0.3	0.0	-0.1	1.5
West South Central	361	3.2	0.1	0.3	-0.8	-0.3	0.0	-0.1	1.8
Mountain	176	3.1	-0.1	-0.1	-0.2	0.3	0.3	0.0	1.7
Pacific	359	3.1	0.1	0.5	0.3	0.1	0.1	0.0	1.3
Puerto Rico	50	3.2	0.6	-0.5	-1.2	0.5	0.1	0.0	2.7
Rural by Region:									
New England	19	3.0	-0.2	0.7	0.0	-0.3	0.2	-2.2	-1.2
Middle Atlantic	49	3.0	0.0	-0.1	0.9	-0.2	0.0	-0.9	1.1
East North Central	113	2.9	-0.1	-0.2	1.2	-0.2	0.0	-3.1	-1.0
West North Central	86	2.7	0.0	-0.1	0.0	-0.1	0.3	-0.4	1.7
South Atlantic	109	2.9	0.3	0.1	1.8	-0.2	0.1	-0.8	2.2
East South Central	141	3.0	0.4	-0.3	1.2	-0.3	0.1	-0.6	1.8
West South Central	134	3.0	0.2	0.4	1.6	-0.3	0.0	-0.5	1.6
Mountain	47	2.5	-0.2	-0.1	0.3	0.0	1.2	0.0	1.9
Pacific	24	2.8	0.1	-0.1	0.9	-0.1	0.0	0.0	2.3
By Payment Classification:									
Urban hospitals	1,867	3.2	0.0	0.0	-0.7	0.0	0.4	0.0	1.4
Rural areas	1,274	3.1	0.0	0.0	0.8	0.0	0.2	-0.4	1.3
Teaching Status:									
Nonteaching	1,939	3.1	0.1	0.1	0.0	0.1	0.2	-0.5	1.3

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2023 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	Proposed FY 2023 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2023 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	Expiration of MDH Status (7)[8]	All Proposed FY 2023 Changes (8)[9]
Fewer than 100 residents	932	3.2	0.0	0.0	0.0	-0.1	0.4	-0.2	1.4
100 or more residents	270	3.1	0.0	-0.1	0.0	0.0	0.2	0.0	1.3
Urban DSH:									
Non-DSH	374	3.2	-0.2	0.1	-0.3	-0.2	0.6	-0.2	1.3
100 or more beds	1,140	3.2	0.1	0.0	-0.7	0.0	0.3	0.0	1.4
Less than 100 beds	353	3.2	0.2	0.0	-0.6	0.3	0.5	-0.5	1.5
Rural DSH:									
Non-DSH	95	3.1	-0.2	-0.2	0.6	1.1	0.2	-1.7	0.1
SCH	267	2.7	-0.1	0.0	0.1	0.0	0.1	0.0	2.5
RRC	663	3.1	0.0	0.0	0.9	-0.1	0.2	-0.1	1.4
100 or more beds	28	3.2	0.0	0.2	-0.4	0.7	0.0	-3.4	-0.9
Less than 100 beds	221	3.1	0.0	0.0	1.2	-0.4	0.2	-6.1	-4.2
Urban teaching and DSH:									
Both teaching and DSH	663	3.2	0.0	0.0	-0.7	0.0	0.4	0.0	1.4
Teaching and no DSH	62	3.2	-0.4	0.1	0.3	-0.1	0.5	-0.3	1.0
No teaching and DSH	830	3.2	0.1	0.1	-0.7	0.1	0.2	-0.1	1.6
No teaching and no DSH	312	3.2	-0.1	0.1	-0.6	-0.2	0.6	-0.1	1.4
Special Hospital Types:									
RRC	161	3.2	0.0	-0.2	1.5	0.7	0.2	-0.9	0.8
RRC with Section 401 Rural Reclassification	460	3.1	0.0	0.0	0.9	0.0	0.2	-0.1	1.4
SCH	256	2.7	0.0	0.1	0.1	0.0	0.1	0.0	2.5
SCH with Section 401 Rural Reclassification	47	2.7	-0.3	0.0	0.0	0.0	0.0	0.0	2.6
SCH and RRC	120	2.8	0.1	0.0	0.3	-0.1	0.1	0.0	2.3
SCH and RRC with Section 401 Rural Reclassification	37	2.8	-0.1	0.0	0.3	-0.1	0.0	0.0	2.4
Type of Ownership:									
Voluntary	1,907	3.2	0.0	0.0	0.1	0.0	0.3	-0.2	1.2
Proprietary	794	3.2	0.2	0.1	0.0	0.0	0.2	-0.1	2.3
Government	439	3.0	0.1	0.1	-0.3	-0.1	0.1	-0.2	1.3
Medicare Utilization as a Percent of Inpatient Days:									
0-25	683	3.1	0.2	0.1	-0.5	-0.2	0.1	0.0	1.7
25-50	2,072	3.1	0.0	0.0	0.1	0.0	0.3	-0.2	1.3
50-65	300	3.0	0.0	0.0	0.3	0.4	0.5	-1.1	1.0
Over 65	35	2.6	-1.0	-0.5	-1.1	-0.3	0.0	-1.3	-0.5
Medicaid Utilization as a Percent of Inpatient Days:									
0-25	2,073	3.1	-0.1	0.0	0.1	-0.1	0.3	-0.3	1.2
25-50	953	3.1	0.1	0.0	-0.1	0.1	0.2	-0.1	1.5
50-65	91	3.1	0.8	0.5	-0.6	0.5	0.2	0.0	2.5
Over 65	24	2.9	0.9	1.0	-0.7	-0.1	0.1	0.0	3.4
Hospitals with 5% or more of cases that reported experiencing homelessness	45	3.1	0.8	0.5	-0.7	-0.3	0.2	0.0	2.4
FY 2023 Reclassifications:									
All Reclassified Hospitals	1,071	3.1	0.0	0.0	1.0	0.1	0.2	-0.2	1.4
Non-Reclassified Hospitals	2,070	3.2	0.0	0.0	-1.0	-0.1	0.4	-0.2	1.3
Urban Hospitals Reclassified	893	3.1	0.0	0.0	0.9	0.1	0.2	-0.3	1.3

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	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2023 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	Proposed FY 2023 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2023 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	Expiration of MDH Status (7)[8]	All Proposed FY 2023 Changes (8)[9]
Urban Non-Reclassified Hospitals	1,539	3.2	0.0	0.0	-1.2	0.0	0.4	0.0	1.4
Rural Hospitals Reclassified Full Year	288	3.0	0.1	-0.1	2.0	-0.2	0.1	-0.9	1.4
Rural Non-Reclassified Hospitals Full Year	421	2.8	0.0	0.2	-0.4	-0.1	0.2	-1.3	0.7
All Section 401 Rural Reclassified Hospitals	608	3.1	-0.1	0.0	0.8	0.0	0.2	-0.3	1.3
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	3.1	0.1	0.0	3.1	-0.3	0.2	-2.6	-0.5

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2021, and hospital cost report data are from the latest available reporting periods.

[2] This column displays the payment impact of the proposed hospital rate update and other adjustments, including the proposed 2.7 percent update to the national standardized amount and the proposed hospital-specific rate (the proposed 3.1 percent market basket update reduced by 0.4 percentage point for the proposed productivity adjustment), and the proposed 0.5 percentage point adjustment to the national standardized amount required under section 414 of the MACRA.

[3] This column displays the payment impact of the proposed changes to the Version 40 GROUPER, the proposed changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2021 MedPAR data as the best available data, and the proposed permanent 10-percent cap where the relative weight for a MS-DRG would decrease by more than ten percent in a given fiscal year. This column displays the application of the proposed recalibration budget neutrality factors of 1.000491 and 0.999765.

[4] This column displays the payment impact of the proposed update to wage index data using FY 2019 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the proposed wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor. The proposed wage budget neutrality factor is 1.001303.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2023 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2023. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.985346.

[6] This column displays the effects of the proposed rural floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be a 100 percent national level adjustment. The proposed rural floor budget neutrality factor applied to the wage index is 0.993656.

[7] This column shows the combined impact of (1) the imputed floor for all-urban states (2) the policy that requires hospitals located in frontier States have a wage index no less than 1.0 and (3) the policy which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.

[8] This column displays the impact of the expiration of MDH status for FY 2023, a non-budget neutral payment provision.

[9] This column shows the estimated change in payments from FY 2022 to FY 2023.

a. Effects of the Proposed Hospital Update and Other Proposed Adjustments (Column 1)

As discussed in section V.A. of the preamble of this proposed rule, this column includes the proposed hospital update, including the proposed 3.1 percent market basket update reduced by the proposed 0.4 percentage point for the productivity adjustment. In addition, as discussed in section II.D. of the preamble of this proposed rule, this column includes the FY 2023 +0.5 percentage point adjustment required under section 414 of the MACRA. As a result, we are proposing to make a 3.2 percent update to the national standardized amount. This column also includes the proposed update to the hospital-specific rates which includes the proposed 3.1 percent market basket update reduced by the proposed 0.4 percentage point for the productivity adjustment. As a result, we are proposing to make a 2.7 percent update to the hospital-specific rates.

Overall, hospitals would experience a 3.1 percent increase in payments primarily due to the combined effects of the proposed hospital update to the national standardized amount and the proposed hospital update to the hospital-specific rate. Hospitals that are paid under the hospital-specific rate would experience a 2.7 percent increase in payments; therefore, hospital categories containing hospitals paid under the hospital-specific rate would experience a lower than average increase in payments.

b. Effects of the Proposed Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 2)

Column 2 shows the effects of the proposed changes to the MS–DRGs and relative weights with the application of the proposed recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we calculated a proposed recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral. We also proposed a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given year and an associated recalibration cap budget neutrality factor to account for the proposed 10-percent cap on relative weight reductions to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this proposed rule, the FY 2023 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2023, we are proposing to calculate the MS–DRGs using the FY 2021 MedPAR data grouped to the proposed Version 40 (FY 2023) MS–DRGs. The methodology to calculate the proposed relative weights and the reclassification changes to the GROUPER are described in more detail in section II.G. of the preamble of this proposed rule.

The ''All Hospitals'' line in Column 2 indicates that proposed changes due to the MS–DRGs and relative weights would result in a 0.0 percent change in payments with the application of the proposed recalibration budget neutrality factor of 1.000491 and the proposed recalibration cap budget neutrality factor of 0.999765 to the standardized amount.

c. Effects of the Proposed Wage Index Changes (Column 3)

Column 3 shows the impact of the proposed updated wage data, with the application of the proposed wage budget neutrality factor. The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core Based Statistical Areas (CBSAs) established by OMB. The current statistical standards used in FY 2023 are based on OMB standards published on February 28, 2013 (75 FR 37246 and 37252), and 2010 Decennial Census data (OMB Bulletin No. 13–01), as updated in OMB Bulletin Nos. 15–01, 17–01, 18–04, and 20–01. (We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion on our adoption of the OMB labor market area delineations, based on the 2010 Decennial Census data, effective beginning with the FY 2015 IPPS wage index; to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913) for a discussion of our adoption of the CBSA updates in OMB Bulletin No. 15–01, which were effective beginning with the FY 2017 wage index; to the FY 2020 IPPS/LTCH PPS final rule (83 FR 41362) for a discussion of our adoption of the CBSA update in OMB Bulletin No. 17–01 for the FY 2020 wage index; to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58743 through 58755) for a discussion of our adoption of the CBSA update in OMB Bulletin No. 18–04 for the FY 2021 wage index; and to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45163) for a discussion of our adoption of the CBSA update in OMB Bulletin No. 20–01 for the FY 2022 wage index.)

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the proposed wage index for acute care hospitals for FY 2023 is based on data submitted for hospital cost reporting periods, beginning on or after October 1, 2018 and before October 1, 2019. The estimated impact of the updated wage data and the OMB labor market area delineations on hospital payments is isolated in Column 3 by holding the other proposed payment parameters constant in this simulation. That is, Column 3 shows the proposed percentage change in payments when going from a model using the FY 2022 wage index, the labor-related share of 67.6 percent, under the OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the proposed FY 2023 pre-reclassification wage index with the proposed labor-related share of 67.6 percent, under the OMB delineations, also having a 100-percent occupational mix adjustment applied, while holding other payment parameters, such as use of the proposed Version 40 MS–DRG GROUPER constant. The FY 2023 occupational mix adjustment is based on the CY 2019 occupational mix survey.

In addition, the column shows the impact of the application of the proposed wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage index changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2023, we are proposing to calculate the proposed wage budget neutrality factor to ensure that payments under updated wage data and the proposed labor-related share of 67.6 percent are budget neutral, without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The proposed FY 2023 wage budget neutrality factor is 1.001303 and the overall proposed payment change is 0 percent.

Column 3 shows the impacts of updating the wage data. Overall, the new wage data and the proposed labor-related share, combined with the proposed wage budget neutrality adjustment, would lead to no change for all hospitals, as shown in Column 3.

In looking at the wage data itself, the national average hourly wage would increase 2.7 percent compared to FY 2022. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the proposed 2.7 percent increase in the national average hourly wage. Of the 3,093 hospitals with wage data for both FYs 2022 and 2023, 1,384 or 44.7 percent would experience an average hourly wage increase of 2.7 percent or more.

The following chart compares the shifts in wage index values for hospitals due to proposed changes in the average hourly wage data for FY 2023 relative to FY 2022. These figures reflect proposed changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the wage index before the application of geographic reclassification, the rural floor, the out-migration adjustment, and other wage index exceptions and adjustments. We note that the ''post-reclassified wage index'' or ''payment wage index,'' which is the wage index that includes all such exceptions and adjustments (as reflected in Tables 2 and 3 associated with this proposed rule) is used to adjust the labor-related share of a hospital's standardized amount, either 67.6 percent (as proposed) or 62 percent, depending upon whether a hospital's wage index is greater than 1.0 or less than or equal to 1.0. Therefore, the proposed pre-reclassified wage index figures in the following chart may illustrate a somewhat larger or smaller proposed change than would occur in a

hospital's payment wage index and total payment.

The following chart shows the projected impact of proposed changes in the area wage index values for urban and rural hospitals.

Proposed FY 2023 Percentage Change in Area Wage Index Values	Number of Hospitals	
	Urban	Rural
Increase 10 percent or more	2	0
Increase greater than or equal to 5 percent and less than 10 percent	24	0
Increase or decrease less than 5 percent	2,316	697
Decrease greater than or equal to 5 percent and less than 10 percent	47	7
Decrease 10 percent or more	0	0
Unchanged	0	0

d. Effects of MGCRB Reclassifications (Column 4)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on bases other than where they are geographically located). The proposed changes in Column 4 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2023.

By spring of each year, the MGCRB makes reclassification determinations that will be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials by the MGCRB of reclassification requests to the CMS Administrator. Further, hospitals have 45 days from the date the IPPS proposed rule is issued in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year (we refer readers to the discussion of our clarification of this policy in section III.I.2. of the preamble to this proposed rule.)

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for purposes of this impact analysis, we are proposing to apply an adjustment of 0.985346 to ensure that the effects of the reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this proposed rule).

Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification would increase payments to rural hospitals by an average of 1.0 percent. By region, most rural hospital categories would experience increases in payments due to MGCRB reclassifications.

Table 2 listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website reflects the reclassifications for FY 2023.

e. Effects of the Proposed Rural Floor, Including Application of National Budget Neutrality (Column 5)

As discussed in section III.B. of the preamble of the FY 2009 IPPS final rule, the FY 2010 IPPS/RY 2010 LTCH PPS final rule, the FYs 2011 through 2022 IPPS/LTCH PPS final rules, and this FY 2023 IPPS/LTCH PPS proposed rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index applicable to hospitals located in rural areas in the same state. We apply a uniform budget neutrality adjustment to the wage index. Column 5 shows the effects of the proposed rural floor.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally. We have calculated a proposed FY 2023 rural floor budget neutrality factor to be applied to the wage index of 0.993656, which would reduce wage indexes by 0.6 percent.

Column 5 shows the projected impact of the proposed rural floor with the national rural floor budget neutrality factor applied to the wage index based on the OMB labor market area delineations. The column compares the proposed post-reclassification FY 2023 wage index of providers before the rural floor adjustment and the proposed post-reclassification FY 2023 wage index of providers with the rural floor adjustment based on the OMB labor market area delineations. Only urban hospitals can benefit from the rural floor. Because the provision is budget neutral, all other hospitals that do not receive an increase to their wage index from the rural floor adjustment (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) would experience a decrease in payments due to the budget neutrality adjustment that is applied to the wage index nationally. (As finalized in the FY 2020 IPPS/LTCH PPS final rule, we calculate the rural floor without including the wage data of hospitals that have reclassified as rural under § 412.103.)

We estimate that 192 hospitals would receive the rural floor in FY 2023. All IPPS hospitals in our model would have their wage indexes reduced by the proposed rural floor budget neutrality adjustment of 0.993656. We project that, in aggregate, rural hospitals would experience a 0.2 percent decrease in payments as a result of the application of the proposed rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project that, in the aggregate, hospitals located in urban areas would experience no change in payments because increases in payments to hospitals benefitting from the rural floor offset decreases in payments to nonrural floor urban hospitals whose wage index is downwardly adjusted by the rural floor budget neutrality factor. Urban hospitals in the New England region would experience a 3.3 percent increase in payments primarily due to the application of the rural floor in Massachusetts.

f. Effects of the Application of the Proposed Imputed Floor, Proposed Frontier State Wage Index and Proposed Out-Migration Adjustment (Column 6)

This column shows the combined effects of the application of the following: (1) The imputed floor under section 1886(d)(3)(E)(iv)(I) and (II) of the Act, which provides that for discharges occurring on or after October 1, 2021, the area wage index applicable to any hospital in an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018; (2) section 10324(a) of the Affordable Care Act, which requires that we establish a minimum post-reclassified wage index of 1.00 for all hospitals located in ''frontier States;'' and (3) the effects of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index.

These three wage index provisions are not budget neutral and would increase payments overall by 0.3 percent compared to the provisions not being in effect.

Section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index for all-urban States shall not be applied in a budget neutral manner. Therefore, the

imputed floor adjustment is estimated to increase IPPS operating payments by approximately $140 million. There are an estimated 69 providers in Connecticut, Delaware, Washington, DC, New Jersey, and Rhode Island that will receive the imputed floor wage index.

The term ''frontier States'' is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, 5 States (Montana, Nevada, North Dakota, South Dakota, and Wyoming) are considered frontier States and an estimated 44 hospitals located in those States would receive a frontier wage index of 1.0000. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $64 million.

In addition, section 1886(d)(13) of the Act provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment would receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. There are an estimated 245 providers that would receive the out-migration wage adjustment in FY 2023. This out-migration wage adjustment is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase would be approximately $55 million.

g. Effects of the Expiration of MDH Special Payment Status (Column 7)

Column 7 shows our estimate of the changes in payments due to the expiration of MDH status, a nonbudget neutral payment provision. Section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted on February 9, 2018) extended the MDH program (which, under previous law, was to be in effect for discharges before October 1, 2017 only) for discharges occurring on or after October 1, 2017, through FY 2022 (that is, for discharges occurring on or before September 30, 2022). Therefore, under current law, the MDH program will expire at the end of FY 2022. Hospitals that qualified to be MDHs receive the higher of payments made based on the Federal rate or the payments made based on the Federal rate amount plus 75 percent of the difference between payments based on the Federal rate and payments based on the hospital-specific rate (a hospital-specific cost-based rate). Because this provision was not budget neutral, the expiration of this payment provision results in a 0.2 percent decrease in payments overall. There are currently 174 MDHs, of which we estimate 120 would have been paid under the blended payment of the Federal rate and hospital-specific rate if the MDH program had not expired. Because those 120 MDHs will no longer receive the blended payment and will be paid only under the Federal rate in FY 2023, it is estimated that those hospitals would experience an overall decrease in payments of approximately $219 million.

h. Effects of All FY 2022 Proposed Changes (Column 8)

Column 8 shows our estimate of the proposed changes in payments per discharge from FY 2022 and FY 2023, resulting from all changes reflected in this proposed rule for FY 2023. It includes combined effects of the year-to-year change of the previous columns in the table.

The proposed average increase in payments under the IPPS for all hospitals is approximately 1.4 percent for FY 2023 relative to FY 2022 and for this row is primarily driven by the proposed changes reflected in Column 1. Column 8 includes the proposed annual hospital update of 3.2 percent to the national standardized amount. This proposed annual hospital update includes the proposed 3.1 percent market basket update reduced by the proposed 0.4 percentage point productivity adjustment. As discussed in section II.D. of the preamble of this proposed rule, this column also includes the +0.5 percentage point adjustment required under section 414 of the MACRA. Hospitals paid under the hospital-specific rate would receive a 2.7 percent hospital update. As described in Column 1, the proposed annual hospital update with the proposed +0.5 percent adjustment for hospitals paid under the national standardized amount, combined with the proposed annual hospital update for hospitals paid under the hospital-specific rates, combined with the other adjustments described previously and shown in Table I, would result in a 1.4 percent increase in payments in FY 2023 relative to FY 2022.

This column also reflects the estimated effect of outlier payments returning to their targeted levels in FY 2023 as compared to the estimated outlier payments for FY 2022 produced from our payment simulation model. As discussed in section II.A.4.j. of the Addendum to this proposed rule, the statute requires that outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments, and also requires that the average standardized amount be reduced by a factor to account for the estimated proportion of total DRG payments made to outlier cases. We are proposing to continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount, just as we did for FY 2022. Therefore, our estimate of payments per discharge for FY 2023 from our payment simulation model reflects this 5.1 percent outlier payment target. Our payment simulation model shows that estimated outlier payments for FY 2022 exceed that target by approximately 1.8 percent. Therefore, our estimate of the proposed changes in payments per discharge from FY 2022 and FY 2023 in Column 8 reflects the estimated −1.8 percent change in outlier payments produced by our payment simulation model when returning to the 5.1 percent outlier target for FY 2023. There are also interactive effects among the various factors comprising the payment system that we are not able to isolate, which may contribute to our estimate of the proposed changes in payments per discharge from FY 2022 and FY 2023 in Column 8.

Overall payments to hospitals paid under the IPPS due to the proposed applicable percentage increase and proposed changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 1.4 percent for FY 2023. Hospitals in urban areas would experience a 1.4 percent increase in payments per discharge in FY 2023 compared to FY 2022. Hospital payments per discharge in rural areas are estimated to increase by 1.1 percent in FY 2023.

3. Impact Analysis of Table II

Table II presents the projected impact of the proposed changes for FY 2023 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2022 with the estimated proposed average payments per discharge for FY 2023, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the proposed changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 8 of Table I.

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TABLE II.--IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2023 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)

	Number of Hospitals (1)	Estimated Average FY 2022 Payment Per Discharge (2)	Estimated Proposed Average FY 2023 Payment Per Discharge (3)	Proposed FY 2023 Changes (4)
All Hospitals	3,141	15,052	15,256	1.4
By Geographic Location:				
Urban hospitals	2,419	15,440	15,652	1.4
Rural hospitals	722	11,247	11,371	1.1
Bed Size (Urban):				
0-99 beds	640	11,638	11,658	0.2
100-199 beds	709	12,409	12,608	1.6
200-299 beds	423	13,749	13,998	1.8
300-499 beds	409	15,283	15,515	1.5
500 or more beds	236	19,194	19,417	1.2
Bed Size (Rural):				
0-49 beds	348	9,710	9,695	-0.2
50-99 beds	211	10,850	10,842	-0.1
100-149 beds	86	11,095	11,317	2
150-199 beds	41	12,094	12,317	1.8
200 or more beds	36	12,976	13,278	2.3
Urban by Region:				
New England	107	16,922	17,275	2.1
Middle Atlantic	295	18,120	18,335	1.2
East North Central	373	14,664	14,818	1
West North Central	156	14,816	14,975	1.1
South Atlantic	402	13,333	13,512	1.3
East South Central	140	12,798	12,988	1.5
West South Central	361	13,497	13,744	1.8
Mountain	176	15,332	15,599	1.7
Pacific	359	19,815	20,071	1.3
Puerto Rico	50	8,990	9,237	2.7
Rural by Region:				
New England	19	15,949	15,756	-1.2
Middle Atlantic	49	10,973	11,097	1.1
East North Central	113	11,466	11,357	-1
West North Central	86	11,734	11,934	1.7
South Atlantic	109	10,394	10,619	2.2
East South Central	141	10,127	10,309	1.8
West South Central	134	9,757	9,912	1.6
Mountain	47	13,117	13,362	1.9
Pacific	24	15,490	15,843	2.3
By Payment Classification:				
Urban hospitals	1,867	14,353	14,558	1.4
Rural areas	1,274	15,962	16,165	1.3
Teaching Status:				
Nonteaching	1,939	11,864	12,024	1.3
Fewer than 100 residents	932	13,946	14,146	1.4
100 or more residents	270	21,994	22,274	1.3
Urban DSH:				
Non-DSH	374	12,561	12,719	1.3
100 or more beds	1,140	14,832	15,046	1.4
Less than 100 beds	353	10,739	10,900	1.5
Rural DSH:				
Non-DSH	95	14,321	14,335	0.1
SCH	267	13,366	13,706	2.5
RRC	663	16,643	16,880	1.4
100 or more beds	28	14,097	13,969	-0.9
Less than 100 beds	221	9,088	8,702	-4.2
Urban teaching and DSH:				
Both teaching and DSH	663	16,093	16,314	1.4

	Number of Hospitals (1)	Estimated Average FY 2022 Payment Per Discharge (2)	Estimated Proposed Average FY 2023 Payment Per Discharge (3)	Proposed FY 2023 Changes (4)
Teaching and no DSH	62	14,108	14,252	1
No teaching and DSH	830	12,085	12,278	1.6
No teaching and no DSH	312	11,732	11,897	1.4
Special Hospital Types:				
RRC	161	12,020	12,118	0.8
RRC with Section 401 Rural Reclassification	460	17,569	17,808	1.4
SCH	256	11,695	11,983	2.5
SCH with Section 401 Rural Reclassification	47	16,311	16,730	2.6
SCH and RRC	120	13,170	13,478	2.3
SCH and RRC with Section 401 Rural Reclassification	37	14,478	14,823	2.4
Type of Ownership:				
Voluntary	1,907	15,179	15,360	1.2
Proprietary	794	12,949	13,243	2.3
Government	439	17,091	17,314	1.3
Medicare Utilization as a Percent of Inpatient Days:				
0-25	683	17,881	18,189	1.7
25-50	2,072	14,661	14,849	1.3
50-65	300	12,048	12,170	1
Over 65	35	9,595	9,549	-0.5
Medicaid Utilization as a Percent of Inpatient Days:				
0-25	2,073	13,677	13,843	1.2
25-50	953	17,372	17,630	1.5
50-65	91	20,238	20,751	2.5
Over 65	24	19,805	20,475	3.4
Hospitals with 5% or more of cases that reported experiencing homelessness	45	19,286	19,740	2.4
FY 2023 Reclassifications:				
All Reclassified Hospitals	1,071	15,779	16,008	1.4
Non-Reclassified Hospitals	2,070	14,366	14,547	1.3
Urban Hospitals Reclassified	893	16,291	16,506	1.3
Urban Nonreclassified Hospitals	1,539	14,554	14,762	1.4
Rural Hospitals Reclassified Full Year	288	11,293	11,456	1.4
Rural Non-Reclassified Hospitals Full Year	421	11,195	11,276	0.7
All Section 401 Reclassified Hospitals:	608	17,116	17,336	1.3
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	10,487	10,438	-0.5

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H. Effects of Other Proposed Policy Changes

In addition to those proposed policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are proposing to make various other changes in this proposed rule. As noted in section I.D. of this Appendix A, our payment simulation model uses the most recent available claims data to estimate the impacts on payments per case of certain proposed changes in this proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes using that payment simulation model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data. Our estimates of the likely impacts associated with these other proposed changes are discussed in this section.

1. Effects of Policy Changes Relating to New Medical Service and Technology Add On Payments

a. Proposed FY 2023 Status of Technologies Approved for FY 2022 New Technology Add-On Payments

In section II.F.5.a of the preamble of this proposed rule, we are proposing to continue to make new technology add-on payments for the 15 technologies listed in the table later in this section in FY 2023 because these technologies would still be considered new for purposes of new technology add-on payments. Under § 412.88(a)(2), the new technology add-on payment for each case would be limited to the lesser of: (1) 65 percent of the costs of the new technology (or 75 percent of the costs for technologies designated as Qualified Infectious Disease Products (QIDPs) or approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway); or (2) 65 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case (or 75 percent of the amount for technologies designated as QIDPs or approved under the LPAD pathway). Because it is difficult to predict the actual new technology add-on payment for each case, our estimates in this proposed rule are based on the applicant's estimate at the time they submitted their original application and the increase in new technology add-on payments for FY 2023 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment. In the following table are estimates for the 15 technologies for which we are proposing to continue to make new technology add-on payments in FY 2023:

FY 2023 Estimates for New Technology Add-On Payments Proposed to Continue for FY 2023			
Technology Name	**Estimated Cases**	**Proposed FY 2023 NTAP amount (65 % or 75 %)**	**Estimated Total FY 2023 Impact**
Rybrevant™	349	$6,405.89	$2,235,655.61
Cosela™	435	$5,526.30	$2,403,940.50
ABECMA®	484	$272,675.00	$131,974,700.00
StrataGraft®	261	$44,200.00	$11,536,200.00
TECARTUS®	15	$259,350.00	$3,890,250.00
VEKLURY®	174,996	$2,028.00	$354,891,888.00
Zepzelca™	778	$8,622.90	$6,708,616.20
aprevo® Intervertebral Body Fusion Device	1,261	$40,950.00	$51,637,950.00
aScope® Duodeno	3,750	$1,715.59	$6,433,425.00
Caption Guidance™	2,592	$1,868.10	$4,842,115.20
Harmony™ Transcatheter Pulmonary Valve (TPV) System	171	$26,975.00	$4,612,725.00
Intercept® (PRCFC)	2,296	$2,535.00	$5,820,360.00
ShockWave C2 Intravascular Lithotripsy (IVL) System	3,760	$3,666.00	$13,784,160.00
Fetroja® (HABP/VABP)	379	$8,579.84	$3,251,759.36
Recarbrio™ (HABP/VABP)	928	$9,576.51	$8,887,001.28
Aggregate Estimated Total FY 2023 Impact			**$612,910,746.15**

b. Proposed FY 2023 Applications for New Technology Add-On Payments

In sections II.F.6. and 7. of the preamble to this proposed rule, we discuss 26 technologies for which we received applications for add-on payments for new medical services and technologies for FY 2023. We note that of the 37 applications (19 alternative and 18 traditional) we received, 11 applicants withdrew their application (6 alternative and 5 traditional) prior to the issuance of this proposed rule. As explained in the preamble to this proposed rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.F.7. of the preamble of this proposed rule, under the alternative pathway for new technology add-on payments, new technologies that are medical products with a QIDP designation, approved through the FDA LPAD pathway, or are part of the Breakthrough Device program will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to demonstrate that the technology represents a substantial clinical improvement. These technologies must still be within the 2–3 year newness period, as discussed in II.F.1.a.(1) of this proposed rule, and must also still meet the cost criterion.

As also discussed in section II.F.7. of the preamble of this proposed rule, we are proposing to approve 13 alternative pathway applications submitted for FY 2023 new technology add-on payments. We note that one technology is still pending Breakthrough Device Designation. We also note that one technology does not appear to include any operating costs and therefore no new technology add-on payment would be made because, as discussed in prior rulemaking and noted previously, we only make new technology add-on payments for operating costs (72 FR 47307 through 47308). We are inviting public comment on whether the technology has any operating costs; to the extent we determine that there are no operating costs associated with the use of the technology, it would not be eligible for new technology add-on payment.

Based on preliminary information from the applicants at the time of this proposed rule, we estimate that total payments for the 13 technologies that applied under the alternative pathway, if approved, would be in excess of approximately $82 million for FY 2023, based on the total estimated FY 2023 payments for new technologies that are part of the Breakthrough Device program. Because cost information has not yet been provided for two of the 13 technologies under the alternative pathway, including the sole QIDP applicant, we have not included those technologies in the estimate. We did not receive any LPAD applications for add-on payments for new technologies for FY 2023. We note that the estimated payments may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We have not yet determined whether any of the 13 technologies that applied under the traditional pathway discussed in section II.F.6. of the preamble of this proposed rule will meet the criteria for new technology add-on payments for FY 2023. Consequently, it is premature to estimate the potential payment impact of these 13 technologies for any potential new technology add-on payments for FY 2023. We note that, as in past years, if any of the technologies that applied under the traditional pathway are found to be eligible for new technology add-on payments for FY 2023, in the FY 2023 IPPS/LTCH PPS final rule, we would discuss the estimated payment impact for FY 2023.

2. Effects of the Proposed Changes to Medicare DSH and Uncompensated Care Payments for FY 2022

a. Effects of the Proposed Changes to Medicare DSH To Ensure Only Appropriate Days Are Counted in the Numerator of the Medicaid Fraction

As discussed in section IV.F. of the preamble of this proposed rule, we are proposing to revise the regulation governing the DSH calculation to ensure that the only section 1115 days that may be counted in the numerator of the Medicaid fraction are the days of patients who receive health insurance authorized by a section 1115 demonstration that provides essential health benefits (EHB) as set forth in 42 CFR part 440, subpart C, for an Alternative Benefit Plan (ABP). We further propose to include in the Medicaid fraction those days of patients who have bought health insurance that provides EHB using premium assistance authorized by a section 1115 demonstration that is equal to at least 90 percent of the cost of the health insurance, on that day. To the extent that this proposed policy has an impact on expenditures, that impact is not estimable because we do not have information on the number of section 1115 days by hospital, which would be required to make an estimate.

b. Medicare DSH Uncompensated Care Payment Proposals for FY 2023 and Proposed New Supplemental Payment for Indian Health Service Hospitals and Tribal Hospitals and Hospitals Located in Puerto Rico

As discussed in section IV.D. of the preamble of this proposed rule, under section

3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments under section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of uninsured individuals and any additional statutory adjustment (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. Each hospital eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's amount of uncompensated care relative to the aggregate amount of uncompensated care of all hospitals eligible for Medicare DSH payments (Factor 3). The change to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this proposed rule, we are proposing to establish the amount to be distributed as uncompensated care payments to DSH eligible hospitals, which for FY 2023 is $6,537,657,797.52. This figure represents 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a proposed Factor 2 of 65.71 percent. For FY 2022, the amount available to be distributed for uncompensated care was $7,192,008,709.70 or 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 68.57 percent. In addition, under our proposal to establish a new supplemental payment for Indian Health Service (IHS) and Tribal Hospitals and Puerto Rico Hospitals, these hospitals would receive approximately $91.6 million in supplemental payments, as determined based on the difference between each hospital's FY 2022 UCP (reduced by—9.1 percent, which is the projected change between the proposed FY 2023 total uncompensated care payment amount and the total uncompensated care payment amount for FY 2022) and its FY 2023 UCP as calculated using the proposed methodology for FY 2023. For this proposed rule, the total proposed uncompensated care payments and proposed supplemental payments equal approximately $6.629 billion. For FY 2023, we are proposing to use two years of data on uncompensated care costs from Worksheet S–10 of the FY 2018 and 2019 cost reports to calculate Factor 3 for all DSH-eligible hospitals, including IHS/Tribal hospitals and Puerto Rico hospitals. For a complete discussion regarding the proposed methodology for calculating Factor 3 for FY 2023 and the proposed methodology for calculating the proposed new supplemental payments, we refer readers to sections IV.D. and IV.E. of the preamble of this proposed rule.

To estimate the impact of the combined effect of the proposed changes in Factors 1 and 2, as well as the changes to the data used in determining Factor 3, on the calculation of Medicare uncompensated care payments along with our proposal to use our authority under section 1886(d)(5)(I) of the Act to establish a new supplemental payment for Puerto Rico hospitals and IHS and Tribal hospitals, we compared total uncompensated care payments estimated in the FY 2022 IPPS/LTCH PPS final rule to the combined total of proposed uncompensated care payments and proposed supplemental payments estimated in this FY 2023 IPPS/LTCH PPS proposed rule. For FY 2022, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 68.57 percent and multiplied by a Factor 3 calculated using the methodology described in the FY 2022 IPPS/LTCH PPS final rule. For FY 2023, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments during FY 2023 absent section 3133 of the Affordable Care Act, adjusted by a proposed Factor 2 of 65.71 percent and multiplied by a Factor 3 calculated using the methodology described previously. For the proposed supplemental payments for IHS/Tribal hospitals and Puerto Rico hospitals, we calculated the difference between the hospital's adjusted base year amount (as determined based on the hospital's FY 2022 uncompensated care payment) and the hospital's FY 2023 uncompensated care payment.

Our analysis included 2,380 hospitals that are projected to be eligible for DSH in FY 2023. It did not include hospitals that had terminated their participation in the Medicare program as of February 3, 2022, Maryland hospitals, new hospitals, and SCHs that are expected to be paid based on their hospital-specific rates. The 26 hospitals that are anticipated to be participating in the Rural Community Hospital Demonstration Program were excluded from this analysis, as participating hospitals are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. In addition, the data from merged or acquired hospitals were combined under the surviving hospital's CMS certification number (CCN), and the non-surviving CCN was excluded from the analysis. The estimated impact of the proposed changes in Factors 1, 2, and 3 on uncompensated care payments and of the proposal to establish a new supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals across all hospitals projected to be eligible for DSH payments in FY 2023, by hospital characteristic, is presented in the following table:

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Modeled Uncompensated Care Payments* and Proposed Supplemental Payments for Estimated FY 2023 DSHs by Hospital Type					
	Number of Estimated DSHs (1)	FY 2022 Final Rule Estimated Uncompensated Care Payments ($ in millions) (2)	FY 2023 Proposed Uncompensated Care Payments and Proposed Supplemental Payments** ($ in millions) (3)	Dollar Difference: FY 2022 - FY 2023 ($ in millions) (4)	Percent Change*** (5)
Total	**2,380**	**$7,192**	**$6,629**	**-$563**	**-7.82%**
By Geographic Location					
Urban Hospitals	1,918	6,789	6,260	-529	-7.79
Large Urban Areas	1,004	4,146	3,877	-269	-6.48
Other Urban Areas	914	2,643	2,383	-260	-9.83
Rural Hospitals	462	403	369	-34	-8.45
Bed Size (Urban)					0
0 to 99 Beds	354	273	251	-23	-8.32
100 to 249 Beds	794	1,548	1,434	-115	-7.42
250+ Beds	770	4,967	4,576	-391	-7.87
Bed Size (Rural)					
0 to 99 Beds	360	224	206	-18	-8
100 to 249 Beds	89	131	120	-12	-8.84
250+ Beds	13	48	44	-5	-9.44
Urban by Region					
New England	87	186	167	-19	-10.39
Middle Atlantic	235	819	726	-94	-11.42
South Atlantic	316	800	721	-79	-9.87
East North Central	104	354	339	-15	-4.29
East South Central	319	1,759	1,625	-134	-7.62
West North Central	130	439	408	-31	-7.05
West South Central	237	1,434	1,340	-93	-6.5
Mountain	135	299	276	-23	-7.68
Pacific	314	607	577	-30	-4.98
Puerto Rico	41	93	83	-10	-11.06
Rural by Region					
New England	8	15	13	-2	-11.28
Middle Atlantic	22	12	11	-1	-7.8
South Atlantic	65	43	40	-3	-7.27
East North Central	32	23	25	3	11.21
East South Central	79	117	103	-14	-11.91
West North Central	117	85	75	-10	-11.47
West South Central	110	88	81	-7	-7.55
Mountain	23	14	13	-1	-9.5
Pacific	6	5	6	1	17.96
By Payment Classification					
Urban Hospitals	1,461	4,508	4,182	-326	-7.24
Large Urban Areas	831	2,953	2,780	-173	-5.85
Other Urban Areas	630	1,555	1,401	-153	-9.87

Modeled Uncompensated Care Payments* and Proposed Supplemental Payments for Estimated FY 2023 DSHs by Hospital Type

	Number of Estimated DSHs (1)	FY 2022 Final Rule Estimated Uncompensated Care Payments ($ in millions) (2)	FY 2023 Proposed Uncompensated Care Payments and Proposed Supplemental Payments** ($ in millions) (3)	Dollar Difference: FY 2022 - FY 2023 ($ in millions) (4)	Percent Change*** (5)
Rural Hospitals	919	2,684	2,448	-236	-8.81
Teaching Status					
Nonteaching	1,332	1,975	1,845	-130	-6.58
Fewer than 100 residents	781	2,498	2,310	-188	-7.54
100 or more residents	267	2,719	2,474	-244	-8.99
Type of Ownership					
Voluntary	1,475	4,083	3,810	-273	-6.67
Proprietary	536	1,019	942	-77	-7.58
Government	369	2,090	1,877	-213	-10.19
Medicare Utilization Percent****					
0 to 25	606	3,092	2,839	-253	-8.19
25 to 50	1,591	3,980	3,671	-310	-7.78
50 to 65	160	114	115	0	0.12
Greater than 65	21	5	5	0	8.56
Medicaid Utilization Percent****					
0 to 25	1,377	3,313	3,080	-233	-7.05
25 to 50	880	3,162	2,939	-223	-7.06
50 to 65	97	637	532	-105	-16.55
Greater than 65	26	80	79	-1	-0.79

Source: Dobson | DaVanzo analysis of 2018 and 2019 Hospital Cost Reports.

*Dollar uncompensated care payments calculated by [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, uncompensated care payments are estimated to be $7,192 million in FY 2022 and uncompensated care payments and proposed supplemental payments are estimated to be $6,629 million in FY 2023.

** For IHS/Tribal hospitals and Puerto Rico hospitals, this impact table reflects the proposed supplemental payments.

*** Percentage change is determined as the difference between Medicare uncompensated care payments and proposed supplemental payments modeled for this FY 2023 IPPS/LTCH PPS proposed rule (column 3) and Medicare uncompensated care payments modeled for the FY 2022 IPPS/LTCH PPS final rule correction notice (column 2) divided by Medicare uncompensated care payments modeled for the FY 2022 IPPS/LTCH PPS final rule correction notice (column 2) times 100 percent.

****Hospitals with missing or unknown Medicare utilization or Medicaid utilization are not shown in the table.

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The changes in projected FY 2023 uncompensated care payments and proposed supplemental payments compared to the total uncompensated care payments in FY 2022 are driven by a proposed decrease in Factor 1 and a proposed decrease in Factor 2 and the proposal to establish a new supplemental payment for DSH-eligible IHS/Tribal hospitals and Puerto Rico hospitals. The proposed Factor 1 has decreased from the FY 2022 final rule's Factor 1 of $10.489 billion to this proposed rule's Factor 1 of $9.949 billion, while the proposed percent change in the percent of individuals who are uninsured (Factor 2) has decreased from 68.57 percent to 65.71 percent. In addition, we note that there is a slight increase in the number of projected DSHs to 2,380 at the time of the development for this proposed rule compared to the projected 2,366 DSHs in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45587). Based on the proposed changes, the impact analysis found that, across all projected DSH eligible hospitals, proposed FY 2023 uncompensated care payments and proposed supplemental payments are estimated at approximately $6.629 billion, or a proposed decrease of approximately 7.82 percent from FY 2022 uncompensated care payments (approximately $7.192 billion). While the proposed changes would result in a net decrease in the total amount available to be distributed in uncompensated care payments and proposed supplemental payments, the projected payment decreases vary by hospital type. This redistribution of payments is caused by proposed changes in Factor 3 and the proposal to establish a new supplemental payment for DSH-eligible IHS/Tribal hospitals and Puerto Rico hospitals. As seen in the previous table, a percent change of less than negative 7.82 percent indicates that hospitals within the specified category are projected to experience a larger decrease in payments, on average, compared to the universe of projected FY 2023 DSH hospitals. Conversely, a percent change greater than negative 7.82 percent indicates that a hospital type is projected to have a smaller decrease or an increase compared to the overall average. The variation in the distribution of overall payments by hospital characteristic is largely dependent on a given hospital's uncompensated care costs as reported on the Worksheet S–10 and used in the Factor 3 computation and whether the hospital is eligible to receive the proposed new supplemental payment.

Rural hospitals, in general, are projected to experience larger decreases in uncompensated care payments and proposed supplemental payments than their urban counterparts. Overall, rural hospitals are

projected to receive an 8.45 percent decrease in payments, which is a greater decrease than the overall hospital average, while urban hospitals are projected to receive a 7.79 percent decrease in payments, which is slightly smaller than the overall hospital average.

By bed size, larger rural hospitals are projected to receive the largest decreases in uncompensated care payments and proposed supplemental payments. Rural hospitals with 250+ beds are projected to receive a 9.44 percent payment decrease, and rural hospitals with 100–249 beds are projected to receive an 8.84 percent decrease. Smaller rural hospitals with 0–99 beds are projected to receive an 8.00 percent payment decrease. Among urban hospitals, the smallest and largest urban hospitals, those with 0–99 and 250+ beds, are projected to receive a decrease in payments that is greater than the overall hospital average, at 8.32 and 7.87 percent, respectively. In contrast, urban hospitals with 100–249 beds are projected to receive a 7.42 percent decrease in payments, which is a smaller decrease than the overall hospital average.

By region, rural hospitals are generally expected to receive similar or larger than average decreases in uncompensated care payments and proposed supplemental payments in all regions, except for rural hospitals in the Middle Atlantic Region, which are projected to receive a smaller than average decrease of 7.80 percent, rural hospitals in South Atlantic Region, which are projected to receive a decrease of 7.27 percent in payments, rural hospitals in the West South Central Region, which are projected to receive a smaller than average decrease of 7.55 percent, and rural hospitals in East North Central Region, which are projected to receive an increase of 11.21 percent. Rural hospitals in the Pacific Region are projected to receive an increase of 17.96 percent in payments. Regionally, urban hospitals are projected to receive a more varied range of payment changes. Urban hospitals in the New England, Middle Atlantic, and South Atlantic Regions, as well as hospitals in Puerto Rico, are projected to receive larger than average decreases in payments. Urban hospitals in the East North Central, East South Central, West North Central, West South Central, Mountain, and Pacific Regions are projected to receive smaller than average decreases in payments.

By payment classification, although hospitals in urban payment areas overall are expected to receive a 7.24 percent decrease in uncompensated care payments and proposed supplemental payments, hospitals in large urban payment areas are expected to see a decrease in payments of 5.85 percent, while rural hospitals are expected to receive a decrease in payments of 8.81 percent. Hospitals in other urban payment areas are projected to receive the largest decrease of 9.87 percent.

Nonteaching hospitals are projected to receive a payment decrease of 6.58 percent, teaching hospitals with fewer than 100 residents are projected to receive a payment decrease of 7.54 percent, and teaching hospitals with 100+ residents have a projected payment decrease of 8.99 percent. Proprietary and voluntary hospitals are projected to receive smaller than average decreases of 7.58 and 6.67 percent respectively, while government hospitals are expected to receive a larger payment decrease of 10.19 percent. Hospitals with less than 25 percent Medicare utilization and hospitals with 25 to 50 percent Medicare utilization are projected to receive decreases of 8.19 and 7.78 percent, respectively, while hospitals with 50–65 percent are projected to receive a small increase of 0.12 percent and hospitals with greater than 65 percent Medicare utilization are projected to receive a large increase of 8.56 percent. All hospitals with less than 50 percent Medicaid utilization are projected to receive smaller decreases in uncompensated care payments and proposed supplemental payments than the overall hospital average percent change, while hospitals with 50–65 percent Medicaid utilization are projected to receive larger decreases of 16.55 percent. Hospitals with greater than 65 percent Medicaid utilization are projected to receive the smallest decrease of 0.79 percent.

The above impact table reflects the modeled FY 2023 uncompensated care payments and proposed supplemental payments for IHS/Tribal and Puerto Rico hospitals. In FY 2023, we note that the IHS/Tribal hospitals' and Puerto Rico hospitals' proposed uncompensated care payments are estimated to decrease by approximately $103 million. However, the proposed supplemental payments to IHS/Tribal hospitals and Puerto Rico hospitals are estimated to be approximately $92 million.

3. Effects of Proposed Reductions Under the Hospital Readmissions Reduction Program for FY 2023

In section V.H of the preamble of this proposed rule, we discuss our proposed policies for the FY 2023 Hospital Readmissions Reduction Program. This program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions and procedures. The table and analysis in this proposed rule illustrate the estimated financial impact of the Hospital Readmissions Reduction Program payment adjustment methodology by hospital characteristic. For the purpose of modeling the estimated FY 2023 payment adjustment factors that account for the suppression of the pneumonia readmission measure for this proposed rule, we used the data from the FY 2022 Hospital Readmissions Reduction Program for the five non-suppressed measures (acute myocardial infarction—AMI, heart failure—HF, chronic obstructive pulmonary disease—COPD, coronary artery bypass graft—CABG, and total hip arthroplasty/total knee arthroplasty—THA/TKA) and the FY 2022 Hospital IPPS Proposed Rule Impact File to analyze results by hospital characteristics. Hospitals are stratified into quintiles based on the proportion of dual-eligible stays among Medicare fee-for-service (FFS) and managed care stays between July 1, 2017, and December 1, 2019 (that is, the FY 2022 Hospital Readmissions Reduction Program's applicable period).[1] Hospitals' excess readmission ratios (ERRs) are assessed relative to their peer group median and a neutrality modifier is applied in the payment adjustment factor calculation to maintain budget neutrality. In the FY 2023 IPPS/LTCH PPS final rule, we will provide an updated estimate of the financial impact using the proportion of dually-eligible beneficiaries, ERRs, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2023 Hospital Readmissions Reduction Program applicable period (that is, July 1, 2018, through June 30, 2021). We note that for the FY 2023 applicable period, we will only be assessing data from July 1, 2018, through December 1, 2019, and from July 1, 2020, through June 30, 2021, due to the COVID–19 public health emergency (PHE) nationwide Extraordinary Circumstance Exception (ECE) waiver which excluded data from January 1, 2020, through June 30, 2020 from the Hospital Readmissions Reduction Program calculations.[2]

The results in the table include 2,987 non-Maryland hospitals eligible to receive a penalty during the performance period. Hospitals are eligible to receive a penalty if they have 25 or more eligible discharges for at least one measure between July 1, 2017, and December 1, 2019. The second column in the table indicates the total number of non-Maryland hospitals with available data for each characteristic that have an estimated payment adjustment factor less than 1 (that is, penalized hospitals).

The third column in the table indicates the percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. For example, 77.83 percent of eligible hospitals characterized as non-teaching hospitals are expected to be penalized. Among teaching hospitals, 86.71 percent of eligible hospitals with fewer than 100 residents and 91.34 percent of eligible hospitals with 100 or more residents are expected to be penalized. The fourth column in the table estimates the financial impact on hospitals by hospital characteristic. The table shows the share of penalties as a percentage of all base operating DRG payments for hospitals with each characteristic. This is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all base operating DRG payments for those hospitals between January 1, 2019 and December 31, 2019 (CY 2019). For example,

[1] Although the FY 2022 performance period is July 1, 2017, through June 30, 2020, we note that first and second quarter data from CY 2020 is excluded from program calculations due to the nationwide ECE that was granted in response to the COVID–19 PHE. Taking into consideration the 30-day window to identify readmissions, the period for calculating DRG payments will be adjusted to July 1, 2017, through December 1, 2019.

[2] Although the FY 2023 performance period is July 1, 2018, through June 30, 2021, we note that first and second quarter data from CY 2020 is excluded from program calculations due to the nationwide ECE that was granted in response to the COVID–19 PHE. Taking into consideration the 30-day window to identify readmissions, the period for calculating DRG payments will be adjusted to July 1, 2018, through December 1, 2019, and then July 1, 2020, through June 30, 2021.

the penalty as a share of payments for non-teaching hospitals is 0.60 percent. This means that total penalties for all non-teaching hospitals are 0.60 percent of total payments for non-teaching hospitals.

Measuring the financial impact on hospitals as a percentage of total base operating DRG payments accounts for differences in the amount of base operating DRG payments for hospitals with the characteristic when comparing the financial impact of the program on different groups of hospitals.

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Estimated Percentage of Hospitals Penalized and Penalty as Share of Payments for FY 2023 Hospital Readmissions Reduction Program with the Pneumonia Readmission Measure Suppressed, by Hospital Characteristic

Hospital Characteristic	Number of Eligible Hospitals[a]	Number of Penalized Hospitals[b]	Percentage of Hospitals Penalized[c] (%)	Penalty as a share of payments[d] (%)
All Hospitals	2,897	2,364	81.60	0.50
By Geographic Location (n= 2,897)				
Urban hospitals	2,198	1,829	83.21	0.50
1-99 beds	487	323	66.32	0.66
100-199 beds	680	586	86.18	0.63
200-299 beds	404	357	88.37	0.59
300-399 beds	270	247	91.48	0.50
400-499 beds	137	118	86.13	0.48
500 or more beds	220	198	90.00	0.37
Rural hospitals	699	535	76.54	0.50
1-49 beds	278	191	68.71	0.43
50-99 beds	251	191	76.10	0.46
100-149 beds	92	80	86.96	0.53
150-199 beds	39	35	89.74	0.49
200 or more beds	39	38	97.44	0.56
By Teaching Status[e] (n= 2,897)				
Non-teaching	1,800	1,401	77.83	0.60
Fewer than 100 Residents	843	731	86.71	0.52
100 or more Residents	254	232	91.34	0.35
By Ownership Type (n= 2,897)				
Government	431	327	75.87	0.44
Proprietary	708	553	78.11	0.71
Voluntary	1,758	1,484	84.41	0.46
By Safety-net Status[f] (n= 2,897)				
Safety-net hospitals	562	460	81.85	0.38
Non-safety-net hospitals	2,335	1,904	81.54	0.53
By Disproportionate Share Hospital (DSH) Patient Percentage[g] (n= 2,897)				
0-24	1,182	922	78.00	0.60
25-49	1,404	1,186	84.47	0.46
50-64	182	156	85.71	0.41
65 and over	129	100	77.52	0.24
By Medicare Cost Report (MCR) Percentage[h, i] (n= 2,893)				
0-24	490	403	82.24	0.39

25-49	2,034	1,679	82.55	0.51
50-64	337	262	77.74	0.68
65 and over	32	19	59.38	0.81
By Region (n= 2,897)				
New England	125	113	90.40	0.66
Middle Atlantic	329	294	89.36	0.44
East North Central	465	378	81.29	0.54
West North Central	234	176	75.21	0.31
South Atlantic	491	434	88.39	0.59
East South Central	263	224	85.17	0.61
West South Central	438	347	79.22	0.50
Mountain	212	144	67.92	0.48
Pacific	340	254	74.71	0.34

Source: The table results are based on the data used to calculate the FY 2022 payment adjustment factors of open, non-Maryland, subsection (d) hospitals only. The FY 2022 payment adjustment factors are based on discharges between July 1, 2017, and December 1, 2019. The shortened data period is due to the COVID-19 public health emergency (PHE) nationwide Extraordinary Circumstances Exception (ECE) which excluded data from January 1, 2020, through June 30, 2020 from the Hospital Readmissions Reduction Program (HRRP) calculations. For this analysis, the payment adjustment factors were estimated using only data for the five non-pneumonia readmission measures because the pneumonia readmission measure is suppressed for the FY 2023 program year). Although data from all subsection (d) and Maryland hospitals are used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals and hospitals that are not open as of the October 2021 public reporting open hospital list because these hospitals are not eligible for a penalty under the program. Hospitals are stratified into five peer groups based on the proportion of FFS and managed care dual-eligible stays for the 3-year performance period. Hospital characteristics are from the FY 2022 Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule Impact File.

For the FY 2023 applicable period, CMS will only be assessing data from July 1, 2018, through December 1, 2019, and July 1, 2020, through June 30, 2021, due to the COVID-19 PHE nationwide ECE which excluded data from January 1, 2020, through June 30, 2020, from the Hospital Readmissions Reduction Program (HRRP) calculations.

[a] This column is the number of applicable hospitals within the characteristic that are eligible for a penalty (that is, they have 25 or more eligible discharges for at least one measure).

[b] This column is the number of applicable hospitals that are penalized (that is, they have 25 or more eligible discharges for at least one measure and an estimated payment adjustment factor less than 1) within the characteristic.

[c] This column is the percentage of applicable hospitals that are penalized among hospitals that are eligible to receive a penalty by characteristic.

[d] This column is calculated as the sum of all penalties for the group of hospitals with that characteristic divided by total base operating DRG payments for all those hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments in this way allows for comparisons across hospital characteristics that accounts for differences in the amount of base operating DRG payments for different groups of hospitals. MedPAR data from January 1, 2019, through December 31, 2019 (CY 2019), are used to estimate the total base operating DRG payments.

[e] A hospital is considered a teaching hospital if it has an Indirect Medical Education adjustment factor for Operation PPS (TCHOP) greater than zero.

[f] A hospital is considered a safety-net hospital if it is in the top DSH quintile.

[g] DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[h] The total number of hospitals with hospital characteristics data may not add up to the total number of hospitals because not all hospitals have data for all characteristics. Not all hospitals had data for MCR percentage (n=2,893; missing=4).

[i] MCR [Medicare Cost Report] percentage is the percentage of total inpatient stays from Medicare patients.

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4. Effects of Changes Under the FY 2023 Hospital Value-Based Purchasing (VBP) Program

In section V.I. of the preamble of this proposed rule, we discuss the Hospital VBP Program under which the Secretary makes value-based incentive payments to hospitals based on their performance on measures during the performance period with respect to a fiscal year. We are proposing to suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey and five healthcare-associated infection (HAI) measures, as well as to change the scoring and payment methodologies for the FY 2023 program year, such that hospitals would receive a value-based incentive payment percentage that results in a value-based incentive payment amount that is equal to the applicable percentage (2 percent). Specifically, we are proposing that we would calculate the measure rates for all of the measures we have selected for the FY 2023 program year, but we would not generate achievement or improvement points for any of the measures we are proposing to suppress. Additionally, we are proposing to not award domain scores for the Person and Community Engagement and Safety domains. We would also not award hospitals a TPS, and would instead award hospitals a payment incentive multiplier that results in a value-based incentive payment amount that is equal to the amount withheld for the fiscal year (2 percent). That is, each hospital would receive a 2-percent reduction to its base operating DRG payment amount for each FY 2023 discharge and would then receive a value-based incentive payment percentage that would result in a value-based incentive payment amount that is equal to the 2 percent withheld. If these proposals are finalized, the impact for every hospital under the Hospital VBP Program would be a net percentage payment adjustment of zero. We are also providing the estimated impact of the FY 2023 program because those impacts would apply if the proposals, as previously discussed, are not finalized. We used TPSs from FY 2021 to calculate the proxy adjustment factors used for this impact analysis. We note that these FY 2021 TPSs were calculated using measure data from before the COVID–19 PHE was declared, and that if our proposals are not finalized, actual TPSs for the FY 2023 program year could be more variable than the FY 2021 TPSs due to the impacts of the COVID–19 PHE on FY 2023 data. These are the most recently available scores that hospitals were given an opportunity to review and correct. The proxy adjustment factors use estimated annual base operating DRG payment amounts derived from the December 2021 update to the FY 2021 MedPAR file. The proxy adjustment factors can be found in Table 16 associated with this proposed rule (available via the internet on the CMS website).

This impact analysis shows that, for the FY 2023 program year, the number of hospitals that would receive an increase in their base operating DRG payment amount is lower than the number of hospitals that would receive a decrease in their base operating DRG payment amount. On average, urban hospitals in the West North Central region and rural hospitals in the Pacific region would have the highest positive percentage change in the base operating DRG payment amount. Urban hospitals in the South Atlantic, West South Central, Mountain and Pacific regions, as well as rural hospitals in the New England, South Atlantic, West South Central and Mountain regions would have a negative percentage change in the base operating DRG payment amount. Hospitals in all other regions (both urban and rural) would experience an average positive percentage change in base operating DRG payment amounts.

With respect to hospitals' Medicare utilization as a percent of inpatient days (MCR), as the MCR percent increases, the average percentage change in the base operating DRG payment amounts would generally increase, except for hospitals with over 65 percent MCR. As DSH percent increases, the average percentage change in the base operating DRG payment amounts would generally increase. On average, teaching hospitals would have a higher percentage change in their base operating DRG payment amounts compared to non-teaching hospitals; however, on average, both non-teaching hospitals and teaching hospitals would have a positive percentage change in their base operating DRG payment amounts.

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Estimated Adjustments to Base Operating DRG Payment Amounts Resulting from the FY 2023 Hospital VBP Program if Proposals Are Not Finalized			
		Number of Hospitals	**Average Net Percentage Payment Adjustment**
BY GEOGRAPHIC LOCATION:			
	All Hospitals	**2,595**	**0.012**
	Urban Area	1,993	0.001
	Rural Area	602	0.048
	Missing	.	.
	Urban Hospitals	***1,993***	***0.001***
	0-99 beds	336	0.009
	100-199 beds	665	0.020
	200-299 beds	398	-0.063
	300-499 beds	386	0.034
	500 or more beds	208	-0.015
	Rural Hospitals	***602***	***0.048***
	0-49 beds	203	0.051
	50-99 beds	237	0.073
	100-149 beds	88	0.032
	150-199 beds	37	-0.058
	200 or more beds	37	0.019
BY REGION:			
	Urban By Region	**1,993**	**0.001**
	New England	102	0.027

	Middle Atlantic	259	0.058
	South Atlantic	371	-0.166
	East North Central	325	0.063
	East South Central	117	0.045
	West North Central	127	0.205
	West South Central	239	-0.002
	Mountain	136	-0.027
	Pacific	317	-0.007
	Rural By Region	**602**	**0.048**
	New England	18	-0.206
	Middle Atlantic	42	0.170
	South Atlantic	94	-0.089
	East North Central	100	0.068
	East South Central	112	0.101
	West North Central	76	0.215
	West South Central	92	-0.071
	Mountain	43	-0.017
	Pacific	25	0.270
BY MCR PERCENT:			
	0-25	469	0.000
	25-50	1,843	0.013
	50-65	271	0.035
	Over 65	10	-0.389
	Missing	2	0.374
BY DSH PERCENT:			
	0-25	1,024	-0.008
	25-50	1,296	0.020
	50-65	162	0.017
	Over 65	113	0.087
	Missing	.	.
BY TEACHING STATUS:			
	Non-Teaching	1,542	0.010
	Teaching	1,053	0.014

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The actual FY 2023 program year's TPSs would not be reviewed and corrected by hospitals until after the FY 2023 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2021 program year would be used for the updated impact analysis in the final rule, if the proposals, as previously described, for FY 2023 are not finalized.

5. Effects of Proposed Requirements Under the HAC Reduction Program for FY 2023

We are presenting the estimated impact of the FY 2023 Hospital-Acquired Condition (HAC) Reduction Program on hospitals by hospital characteristic in the following two tables. The tables in this section present the estimated proportion of hospitals in the worst-performing quartile of Total HAC Scores by hospital characteristic. Both tables later in the section include 3,067 non-Maryland hospitals that participate in the HAC Reduction Program. The first column presents a breakdown of each characteristic and the second column indicates the number of hospitals for the respective characteristic. The third column in the tables indicate the number of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores. The fourth column in the table indicates the proportion

of hospitals for each characteristic that would be in the worst performing quartile of Total HAC Scores.

In section V.J.2.b.(2). of the preamble of this proposed rule, we are proposing to suppress all six measures from the HAC Reduction Program, calculate only measure results for the HAI measures for the FY 2023 program, and not calculate measure scores or Total HAC Scores. Accordingly, if the proposal is finalized, then no hospitals will be in the worst-performing quartile and no hospitals will receive a payment reduction in the FY 2023 HAC Reduction Program.[3] In Table 1 later in the section, we are presenting the estimated impact of the FY 2023 HAC Reduction Program on hospitals by hospital characteristic if the proposal in section V.J.2.b.(2). of the preamble of this proposed rule is finalized and FY 2023 HAC Reduction Program measure scores and Total HAC scores are not calculated. Therefore, Table 1 illustrates the number of hospitals participating in the FY 2023 HAC Reduction Program by hospital characteristic; however, the remaining two columns reflect values of zero because no hospital would be in the worst-performing quartile.

In Table 2 later in the section, we are presenting the estimated impact of the FY 2023 HAC Reduction Program on hospitals by hospital characteristic if the proposal in section V.J.2.b.(2). of the preamble of this proposed rule is not finalized. If the proposal in section V.J.2.b.(2). of the preamble of this proposed rule is not finalized, these FY 2023 HAC Reduction Program results would be calculated using the previously finalized HAC Reduction Program scoring methodology approach finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41486 through 41489). Each hospital's Total HAC Score was calculated as the equally weighted average of the hospital's measure scores.

In Table 2 later in the section, we calculate hospitals' CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure results based on Medicare fee-for-service (FFS) discharges from July 1, 2019, to December 31, 2019, and version 11.0 of the CMS PSI software. Hospitals' measure results for the Centers for Disease Control and Prevention (CDC) Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), Colon and Abdominal Hysterectomy Surgical Site Infection (SSI), Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia, and *Clostridium difficile* Infection (CDI) measures are derived from standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the National Healthcare Safety Network (NHSN) for infections occurring between January 1, 2019, and December 31, 2019. To analyze the results by hospital characteristic, we used the FY 2022 Proposed Rule Impact File.

The hospitals indicated in the third column of Table 2 later in the section, would receive a payment reduction under the FY 2023 HAC Reduction Program if the proposal in section V.J.2.b.(2). of the preamble of this proposed rule is not finalized. For example, with regard to teaching status, as illustrated by Table 2, if the proposal in section V.J.2.b.(2). of the preamble of this proposed rule is not finalized, 426 hospitals out of 1,929 hospitals characterized as non-teaching hospitals would be subject to a payment reduction. Among teaching hospitals, 221 out of 875 hospitals with fewer than 100 residents and 117 out of 257 hospitals with 100 or more residents would be subject to a payment reduction.

The fourth column in Table 2 indicates the proportion of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores and thus receive a payment reduction under the FY 2023 HAC Reduction Program if the proposal in section V.J.2.b.(2). is not finalized. For example, 22.1 percent of the 1,929 hospitals characterized as non-teaching hospitals, 25.3 percent of the 875 teaching hospitals with fewer than 100 residents, and 45.5 percent of the 257 teaching hospitals with 100 or more residents would be subject to a payment reduction.

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[3] If this proposal is finalized, we anticipate reduced savings to the Medicare trust fund that is otherwise estimated at approximately $350 million.

Table 1- Estimated Proportion of Hospitals in the Worst-Performing Quartile (>75th percentile) of the Total HAC Scores for the FY 2023 HAC Reduction Program (by Hospital Characteristic)-If the Proposal in Section V.J.2.b.(2). of the Preamble of this Proposed Rule is Finalized			
Hospital Characteristic	**Number of Hospitals**	**Number of Hospitals in the Worst-performing Quartile[a]**	**Percent of Hospitals in the Worst-performing Quartile[b]**
Total[c]	3,067	0	0
By Geographic Location (n = 3,061)[d]			
Urban hospitals	**2,327**	**0**	**0**
1-99 beds	572	0	0
100-199 beds	704	0	0
200-299 beds	417	0	0
300-399 beds	273	0	0
400-499 beds	139	0	0
500 or more beds	222	0	0
Rural hospitals	**734**	**0**	**0**
1-49 beds	311	0	0
50-99 beds	252	0	0
100-149 beds	93	0	0
150-199 beds	39	0	0
200 or more beds	39	0	0
By Safety-Net Status[e] (n = 3,061)			
Non-safety net	2,442	0	0
Safety-net	619	0	0
By DSH Percent[f] (n = 3,061)			
0-24	1,270	0	0
25-49	1,438	0	0
50-64	194	0	0
65 and over	159	0	0
By Teaching Status[g] (n =3,061)			
Non-teaching	1,929	0	0
Fewer than 100 residents	875	0	0
100 or more residents	257	0	0
By Ownership (n = 3,061)			
Voluntary	1,818	0	0
Proprietary	773	0	0
Government	470	0	0
By MCR Percent[h] (n = 3,054)			
0-24	584	0	0
25-49	2,081	0	0
50-64	349	0	0
65 and over	40	0	0
By Region[i] (n= 3,067)			
New England	130	0	0
Mid-Atlantic	339	0	0
South Atlantic	507	0	0
East North Central	479	0	0
East South Central	282	0	0
West North Central	244	0	0
West South Central	476	0	0
Mountain	229	0	0
Pacific	381	0	0

Source: FY 2023 HAC Reduction Program proposed rule results are based on CMS PSI 90 data from July 1, 2019, through December 31, 2019, and CDC NHSN HAI results from January 1, 2019 through December 31, 2019. Hospital Characteristics are based on the FY 2022 Proposed Rule Impact File

[a] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

[b] This column is the percent of non-Maryland hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

[c] The number of non-Maryland hospitals with a FY 2023 Total HAC Score (N = 3,067). Note that not all hospitals have data for all hospital characteristics.

[d] The number of hospitals that had information for geographic location with bed size, Safety-net status, DSH percent, teaching status, and Ownership (n = 3,061).

[e] A hospital is considered a Safety-net hospital if it is in the top quintile for DSH percent.

[f] The DSH patient percentage is equal to the sum of: (1) the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income; and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[g] A hospital is considered a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.

[h] Not all hospitals had data for MCR percent (n = 3,054).

[i] All hospitals had data for Region (n = 3,067). For the 6 hospitals that were not in the FY 2022 Proposed Rule Impact File region data were identified using the hospital CCN.

Table 2- Estimated Proportion of Hospitals in the Worst-Performing Quartile (>75th percentile) of the Total HAC Scores for the FY 2023 HAC Reduction Program (by Hospital Characteristic)- If the Proposal in Section V.J.2.b.(2). is Not Finalized			
Hospital Characteristic	**Number of Hospitals**	**Number of Hospitals in the Worst-performing Quartile[a]**	**Percent of Hospitals in the Worst-performing Quartile[b]**
Total[c]	3,067	766	25
By Geographic Location (n = 3,061)[d]			
Urban hospitals	**2,327**	**589**	**25.3**
1-99 beds	572	100	17.5
100-199 beds	704	191	27.1
200-299 beds	417	101	24.2
300-399 beds	273	69	25.3
400-499 beds	139	45	32.4
500 or more beds	222	83	37.4
Rural hospitals	**734**	**175**	**23.8**
1-49 beds	311	70	22.5
50-99 beds	252	63	25.0
100-149 beds	93	20	21.5
150-199 beds	39	11	28.2
200 or more beds	39	11	28.2
By Safety-Net Status[e] (n = 3,061)			
Non-safety net	2,442	564	23.1
Safety-net	619	200	32.3
By DSH Percent[f] (n = 3,061)			
0-24	1,270	265	20.9
25-49	1,438	377	26.2
50-64	194	64	33.0
65 and over	159	58	36.5
By Teaching Status[g] (n =3,061)			
Non-teaching	1,929	426	22.1
Fewer than 100 residents	875	221	25.3
100 or more residents	257	117	45.5
By Ownership (n = 3,061)			
Voluntary	1,818	477	26.2
Proprietary	773	136	17.6
Government	470	151	32.1
By MCR Percent[h] (n = 3,054)			
0-24	584	163	27.9
25-49	2,081	508	24.4
50-64	349	82	23.5
65 and over	40	6	15.0
By Region[i] (n= 3,067)			
New England	130	49	37.7
Mid-Atlantic	339	110	32.4
South Atlantic	507	132	26.0
East North Central	479	123	25.7
East South Central	282	68	24.1
West North Central	244	55	22.5
West South Central	476	80	16.8
Mountain	229	54	23.6
Pacific	381	95	24.9

Source: FY 2023 HAC Reduction Program proposed rule results are based on CMS PSI 90 data from July 1, 2019, through December 31, 2019, and CDC NHSN HAI results from January 1, 2019 through December 31, 2019. Hospital Characteristics are based on the FY 2022 Proposed Rule Impact File

[a] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

[b] This column is the percent of non-Maryland hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

[c] The number of non-Maryland hospitals with a FY 2023 Total HAC Score (N = 3,067). Note that not all hospitals have data for all hospital characteristics.

[d] The number of hospitals that had information for geographic location with bed size, Safety-net status, DSH percent, teaching status, and Ownership (n = 3,061).

[e] A hospital is considered a Safety-net hospital if it is in the top quintile for DSH percent.

[f] The DSH patient percentage is equal to the sum of: (1) the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income; and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[g] A hospital is considered a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.

[h] Not all hospitals had data for MCR percent (n = 3,054).

[i] All hospitals had data for Region (n = 3,067). For the 6 hospitals that were not in the FY 2022 Proposed Rule Impact File region data were identified using the hospital CCN.

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6. Effects of the Proposed Changes to IME and Direct GME Payments

a. Change to Direct GME Calculation in Response to Decision in *Milton S. Hershey Medical Center et al.* v. *Azar II*

As discussed in section V.F.2. of the preamble of this proposed rule, we are proposing to implement a modified direct GME payment policy for all teaching hospitals. Specifically, effective for cost reporting periods beginning on or after October 1, 2001, for cost reports that are reopenable or open, we are proposing that if the hospital's unweighted number of FTE residents exceeds the FTE cap, and the number of weighted FTE residents also exceeds that FTE cap, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the FTE cap. If the number of weighted FTE residents does not exceed that FTE cap, then the allowable weighted FTE count for direct GME payment is the actual weighted FTE count. We have estimated the impact of this proposed change for FY 2023 to be $170 million.

b. Effects of the Proposal To Allow Medicare GME Affiliation Agreements Within Certain Rural Track FTE Limitations

In section V.F.4. of the preamble of this proposed rule, we are proposing to allow urban and rural hospitals that participate in the same separately accredited 1–2 family medicine rural track program and have rural track FTE limitations to enter into ''rural track Medicare GME affiliation agreements'' in order to share those cap slots, and facilitate the cross-training of residents. In addition, we propose to only allow urban and rural hospitals to participate in rural track Medicare GME affiliated groups if they have rural track FTE limitations in place prior to October 1, 2022. We propose that eligible urban and rural hospitals may enter into rural track Medicare GME affiliation agreements effective with the July 1, 2023, academic year. Because no newly funded cap slots will be created, only existing funded cap slots would be shared between the participating affiliated hospitals, there is no financial impact to this proposal.

7. Effects of Implementation of the Rural Community Hospital Demonstration Program in FY 2022

In section V.K. of the preamble of this proposed rule for FY 2023, we discussed our implementation and budget neutrality methodology for section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, by section 15003 of Public Law 114–255, and most recently, by section 128 of Public Law 116–260, which requires the Secretary to conduct a demonstration that would modify payments for inpatient services for up to 30 rural hospitals.

Section 128 of Public Law 116–255 requires the Secretary to conduct the Rural Community Hospital Demonstration for a 15-year extension period (that is, for an additional 5 years beyond the previous extension period). In addition, the statute provides for continued participation for all hospitals participating in the demonstration program as of December 30, 2019.

Section 410A(c)(2) of Public Law 108–173 requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented (budget neutrality). We propose to adopt the general methodology used in previous years, whereby we estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration, and then adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we have applied budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented, but does not identify the range across which aggregate payments must be held equal.

For this proposed rule, the resulting amount applicable to FY 2023 is $71,955,710, which we are proposing to include in the budget neutrality offset adjustment for FY 2023. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical and currently finalized update factors for cost and payment.

In previous years, we have incorporated a second component into the budget neutrality offset amounts identified in the final IPPS rules. As finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We have calculated this difference for FYs 2005 through 2016 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

With the extension of the demonstration for another 5-year period, as authorized by section 128 of Public Law 116–260, we will continue this general procedure. At this time, for the FY 2023 proposed rule, all of the finalized cost reports are available for the 17 hospitals that completed cost report periods beginning in FY 2017 under the demonstration payment methodology; these cost reports show the actual costs of the demonstration for this fiscal year to be $35,989,928. We note that the FY 2017 IPPS final rule included no budget neutrality offset amount for that fiscal year. The final rule for FY 2017 preceded the re-authorization of the demonstration under the Cures Act. Anticipating that the demonstration would end in 2016, we projected no demonstration cost estimate for the upcoming fiscal year, FY

2017, while we stated that we would continue to reconcile actual costs when all finalized cost reports for previous fiscal years under the demonstration became available (81 FR 57037). Thus, keeping with past practice, for this proposed rule we are including the actual costs of the demonstration as determined from finalized cost reports for FY 2017 within the budget neutrality offset amount for this upcoming fiscal year.

Therefore, for this FY 2023 IPPS/LTCH PPS proposed rule, the proposed budget neutrality offset amount for FY 2023 is based on the sum of two amounts:

- The amount representing the difference applicable to FY 2023 between the sum of the estimated reasonable cost amounts that would be paid under the demonstration for covered inpatient services to the 26 hospitals participating in the fiscal year and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. This estimated amount is $71,955,710.
- The amount by which the actual costs of the demonstration in FY 2017 (as shown by finalized cost reports from that fiscal year) differ from the amount determined for FY 2017. Since no budget neutrality offset was conducted in FY 2017, the amount of this difference is the actual cost amount for FY 2017, or $35,989,928.

We propose to subtract the sum of these amounts ($107,945,638) from the national IPPS rates for FY 2023.

We note that the total amount of the adjustment may change if there are any revisions prior to the final rule to the data used to formulate this estimate. We will also revise the budget neutrality offset amount in case of any re-settlement to finalized cost reports or changes to statutory provisions that affect the methodology for determining the budget neutrality estimate for the upcoming year.

8. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VIIB.2. of the preamble of this proposed rule we discuss the implementation of the FCHIP Demonstration, which allows eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care, and other health care services to Medicare beneficiaries in no more than four States. Section 123 of Public Law 110–275 initially required a 3-year period of performance. The FCHIP Demonstration began on August 1, 2016, and concluded on July 31, 2019 (referred to in this section as the ''initial period''). Section 129 of the Consolidated Appropriations Act (Pub. L. 116–159) extended the FCHIP Demonstration by 5 years (referred to in this section as the ''extension period'' of the demonstration). The FCHIP Demonstration resumed on January 1, 2022 and CAHs participating in the demonstration project during the extension period shall begin such participation in the cost reporting year that begins on or after January 1. Budget neutrality estimates for the demonstration described in the preamble of this proposed rule are based on the demonstration extension period.

As described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS waived certain Medicare rules for CAHs participating in the demonstration initial period to allow for alternative reasonable cost-based payment methods in the three distinct intervention service areas: Telehealth services, ambulance services, and skilled nursing facility/nursing facility services. These waivers were implemented with the goal of increasing access to care with no net increase in costs. As we explained in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), 10 CAHs were selected for participation in the demonstration initial period. Section 129 of Public Law 116–159, stipulates that only the 10 CAHs that participated in the initial period of the FCHIP Demonstration are eligible to participate during the extension period. Among the eligible CAHs, six elected to participate in the extension period. The selected CAHs are located in two states—Montana and North Dakota—and are implementing the three intervention services. In the FY 2022 IPPS/LTCH PPS final rule, CMS concluded that the initial period of the FCHIP Demonstration had satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, CMS did not apply a budget neutrality payment offset policy for the initial period of the demonstration. In addition, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), we finalized a policy to address the budget neutrality requirement for the demonstration initial period. We also discussed this policy in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42427 through 42428) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58894 through 58996).

As explained in the FY 2022 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms meaning that the demonstration would produce savings from reduced transfers and admissions to other health care providers, offsetting any increase in Medicare payments as a result of the demonstration. However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we finalized for the demonstration initial period of performance in the FY 2022 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met.

For this proposed rule, CMS is proposing to adopt the same budget neutrality policy contingency plan used during the demonstration initial period to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met during the demonstration extension period. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for the participating CAHs, shows that increases in Medicare payments under the demonstration during the 5-year extension period is not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide.

Under the policy finalized in the FY 2022 IPPS/LTCH PPS final rule, we adopted the policy finalized in the FY 2017 IPPS/LTCH PPS final rule, in the event the demonstration initial period was found not to have been budget neutral, any excess costs would be recouped over a period of 3 cost reporting years. For the FY 2023 proposed rule, we seek public comment on this proposal, as we are revising an aspect of the policy finalized in the FY 2022 IPPS/LTCH PPS final rule. Our new proposed policy is in the event the demonstration extension period is found not to have been budget neutral, any excess costs would be recouped within one fiscal year. We believe our new proposed policy is a more efficient timeframe for the government to conclude the demonstration operational requirements (such as analyzing claims data, cost report data and/or other data sources) to adjudicate the budget neutrality payment recoupment process due to any excess cost that occurred as result of the demonstration extension period. As explained in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality for the demonstration initial period by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration extension period is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration extension period were not implemented, CMS policy is to comply with the budget neutrality requirement finalized in the FY 2022 IPPS/LTCH PPS final rule, by reducing payments to all CAHs, not just those participating in the demonstration extension period. We stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP Demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. As we explained in the FY 2022 IPPS/LTCH PPS final rule, we believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

As explained in the FY 2022 IPPS/LTCH PPS final rule, we finalized a policy to address the demonstration budget neutrality methodology and analytical approach for the

initial period of the demonstration. Therefore, for this proposed rule, we propose to adopt the same budget neutrality methodology and analytical approach used during the demonstration initial period to ensure budget neutrality for the extension period. While we expect to use the same methodology that was used to assess the budget neutrality of the FCHIP Demonstration during initial period of the demonstration to assess the financial impact of the demonstration during this extension period, upon receiving data for the extension period, we may update and/or modify the FCHIP budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured. Therefore, we are not proposing to apply a budget neutrality payment offset to payments to CAHs in FY 2023. This policy will have no impact for any national payment system for FY 2023.

9. Effects of Codification of the Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans

In section X.A. of the preamble of the proposed rule, we set forth our proposals to codify the costs incurred for qualified and non-qualified deferred compensation plans. We do not beleive that there are any costs associated with proposed codification of this policy.

10. Effects of Condition of Participation (CoP) Requirements for Hospitals and CAHs To Report Data Elements To Address Any Future Pandemics and Epidemics as Determined by the Secretary

Section X.B. of the preamble of this proposed rule would revise the hospital and CAH infection prevention and control CoP requirements to require hospitals and CAHs, after the conclusion of the current COVID–19 PHE, to continue COVID–19 and seasonal influenza related reporting. The proposed revisions would continue to apply upon conclusion of the COVID–19 Public Health Emergency (PHE) and would continue until April 30, 2024, unless the Secretary establishes an earlier ending date. For COVID–19 reporting, the categories of data elements that this report would, to the extent as determined by the Secretary, include are as follows: Suspected and confirmed COVID–19 infections among patients and staff; total COVID–19 deaths among patients and staff; personal protective equipment and testing supplies in the facility; ventilator use, capacity and supplies in the facility; total hospital bed and intensive care unit bed census and capacity; staffing shortages; COVID–19 vaccine administration data of patients and staff; and relevant therapeutic inventories and/or usage. For seasonal influenza, the categories of data elements that this report would, to the extent as determined by the Secretary, include are as follows: Confirmed influenza infections among patients and staff; total influenza deaths among patients and staff; and confirmed co-morbid influenza and COVID–19 infections among patients and staff. We propose to require hospitals and CAHs to report specific data elements to the CDC's National Health Safety Network (NHSN), or other CDC-supported surveillance systems, as determined by the Secretary. Furthermore, this proposal would also allow for the scope and frequency of data collection to be reduced and limited responsive to evolving clinical and epidemiological circumstances. We are also proposing to require that, unless the Secretary specifies an alternative format by which a hospital (or a CAH) must report each applicable infection (confirmed and suspected) and the applicable vaccination data in a format that provides person-level information, to include medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients, unless the Secretary specifies an alternative format by which the hospital (or CAH) would be required report these data elements. We are also proposing in this provision to limit any person-level, directly or potentially individually identifiable, information for affected patients to items outlined in this section or otherwise specified by the Secretary. We note that the provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Section 304, 306, and 308(d) of the Public Health Service Act (42 U.S.C. 242b, 242k, and 242m(d)). Reporting frequency and requirements would be communicated to hospitals, stakeholders, and the public following a model similar to that which we used to inform regulated entities at the beginning of the COVID–19 PHE (see QSO–21–03-Hospitals/CAHs at *https://www.cms.gov/files/document/qso-21-03-hospitalscahs.pdf-0*). As discussed in section XII.B. of the preamble of this proposed rule, Collection of Information Requirements, we expect a burden increase of $38,204,400 or approximately $6,162 per facility annually for weekly reporting. This estimate likely overestimates the costs associated with reporting because it assumes that all hospitals and CAHs will report manually. Efforts are underway to automate hospital and CAH reporting that have the potential to significantly decrease reporting burden and improve reliability.

In addition, the rule proposes to establish reporting requirements for future PHEs related to epidemics and pandemics by requiring hospitals and CAHs to electronically report information on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection), SARS-CoV–2/COVID–19, and other viral and bacterial pathogens or infectious diseases of pandemic or epidemic potential. This collection would only occur when the Secretary has declared a Public Health Emergency (PHE), as defined in § 400.200, directly related to such specific pathogens and infectious diseases. Specifically, when the Secretary has declared a PHE, we propose to require hospitals and CAHs to report specific data elements to the CDC's National Health Safety Network (NHSN), or other CDC-supported surveillance systems, as determined by the Secretary. The proposed requirements of this section would apply to local, state, and national PHEs as declared by the Secretary. Relevant to the declared PHE, the categories of data elements that this report would include are as follows: Suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff; total deaths attributed to the relevant infectious disease pathogen among patients and staff; personal protective equipment and other relevant supplies in the facility; capacity and supplies in the facility relevant to the immediate and long term treatment of the relevant infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies; total hospital bed and intensive care unit bed census, capacity, and capability; staffing shortages; vaccine administration status of patients and staff for conditions monitored under this section and where a specific vaccine is applicable; relevant therapeutic inventories and/or usage; isolation capacity, including airborne isolation capacity; and key co-morbidities and/or exposure risk factors of patients being treated for the pathogen or disease of interest in this section that are captured with interoperable data standards and elements. We are also proposing to require that, unless the Secretary specifies an alternative format by which a hospital (or a CAH) must report each applicable infection (confirmed and suspected) and the applicable vaccination data in a format that provides person-level information, to include medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients, unless the Secretary specifies an alternative format by which the hospital (or CAH) would be required report these data elements. We are also proposing in this provision to limit any person-level, directly or potentially individually identifiable, information for affected patients to items outlined in this section or otherwise specified by the Secretary. We note that the provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Section 304, 306, and 308(d) of the Public Health Service Act (42 U.S.C. 242b, 242k, and 242m(d)). Lastly, we are proposing that a hospital (or a CAH) would provide the information specified on a daily basis, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) or other CDC-supported surveillance systems as determined by the Secretary. We expect that as a result of the need to comply with existing COVID–19 reporting requirements, hospitals have already established some infrastructure to collect, maintain, and report data related to infectious diseases, and we anticipate that providers will continue to build on and maintain these systems. Therefore, we believe that most hospitals would need a

minimal amount of time to begin reporting data in the event a new PHE is declared. CMS will notify regulated entities stakeholders, and the public of the start date of necessary reporting, reporting frequency and other requirements via subregulatory guidance, following a model similar to that which we used to inform regulated entities at the beginning of the COVID–19 PHE (see QSO–21–03–Hospitals/CAHs at *https://www.cms.gov/files/document/qso-21-03-hospitalscahs.pdf-0*). We would also note that extensive delays would prevent the proposed reporting from fully serving the intended purposes of quickly responding to a PHE in ways that minimize health and safety risks. We acknowledge that there are uncertainties in planning for future emergencies, and CMS understands that there are lots of incentives and pathways to consider with regard to preparedness. Therefore, we are soliciting public comment on how to best align and incentivize preparedness, while also reducing ongoing burden and costs on regulated entities, and ensuring flexibility to quickly respond to emergencies. We are also soliciting comment on the burden impacts related to reporting for a specified infectious disease when a future PHE is declared. We also acknowledge that respondents may have to track and invest in infrastructure in order to be prepared to timely and accurately report on the specified frequency. Thus, respondents may face ongoing burdens associated with this collection even in the case of reduced frequency of submissions. We solicit comment on this potentiality.

I. Effects of Proposed Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented in this section, we used data from the December 2021 update of the FY 2021 MedPAR file and the December 2021 update of the Provider-Specific File (PSF) that was used for payment purposes. Although the analyses of the proposed changes to the capital prospective payment system do not incorporate cost data, we used the December 2021 update of the most recently available hospital cost report data to categorize hospitals. Our analysis has several qualifications and uses the best data available, as described later in this section.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each proposed change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the December 2021 update of the FY 2021 MedPAR file, we simulated payments under the capital IPPS for FY 2022 and the proposed payments for FY 2023 for a comparison of total payments per case. Short-term, acute care hospitals not paid under the general IPPS (for example, hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the proposed capital IPPS payments in FY 2023 is as follows:

(Standard Federal rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH adjustment factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. Then we added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- The capital Federal rate was updated, beginning in FY 1996, by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1. of the Addendum to this proposed rule, the proposed update to the capital Federal rate is 1.70 percent for FY 2023.
- In addition to the proposed FY 2023 update factor, the proposed FY 2023 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality adjustment factor of 1.0023, a proposed budget neutrality factor for the lowest quartile hospital wage index adjustment and the proposed 5 percent cap on wage index decreases policy of 0.9971, and a proposed outlier adjustment factor of 0.9445.

2. Results

We used the payment simulation model previously described in section I.I. of Appendix A of this proposed rule to estimate the potential impact of the proposed changes for FY 2023 on total capital payments per case, using a universe of 3,141 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the December 2021 update of the FY 2021 MedPAR file, the December 2021 update to the PSF, and the most recent available cost report data from the December 2021 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2022 and estimated proposed total payments per case for FY 2023 based on the proposed FY 2023 payment policies. Column 2 shows estimates of payments per case under our model for FY 2022. Column 3 shows estimates of proposed payments per case under our model for FY 2023. Column 4 shows the proposed total percentage change in payments from FY 2022 to FY 2023. The change represented in Column 4 includes the proposed 1.70 percent update to the capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2023 are expected to decrease 0.4 percent compared to capital payments per case in FY 2022. This expected decrease is primarily due to the proposed 1.70 percent update to the capital Federal rate for FY 2023 being more than offset by an expected decrease in capital outlier payments. As discussed in section III.A.2. of the Addendum to this proposed rule, we estimate for FY 2023 that outlier payments for capital-related PPS payments would equal 5.55 percent of inpatient capital-related payments. Although in the FY 2022 IPPS/LTCH PPS final rule we estimated for FY 2022 that outlier payments for capital-related PPS payments would equal 5.29 percent of inpatient capital related payments, our payment simulation model for this proposed rule shows that for FY 2022, estimated outlier payments for capital-related PPS payments are approximately 7.5 percent of inpatient capital-related payments. This difference in our estimate of FY 2022 outlier payments compared to our estimate of FY 2023 outlier payments is reflected in the average change in capital payments per case in FY 2023 as compared to FY 2022. In addition, an estimated decrease in capital DSH payments due to the estimated increase in the number of hospitals that reclassify from urban to rural under § 412.103 contributes to the overall expected decrease in average capital payments per case in FY 2023 as compared to FY 2022. We approximate that there are 72 hospitals classified as urban (for payment purposes) and receiving capital DSH payments in FY 2022, that will be classified as rural (for payment purposes) and will not receive capital DSH payments in FY 2023. Under § 412.320, to receive capital DSH payments a hospital must be located in an urban area for payment purposes and have 100 or more beds, and paragraph (a)(1)(iii) specifies that the geographic classification of an urban hospital that is reclassified as rural as set forth in § 412.103 is rural. In general, regional variations in estimated capital payments per case in FY 2023 as compared to capital payments per case in FY 2022 are primarily due to the proposed changes in GAFs, and are generally consistent with the projected changes in payments due to proposed changes in the wage index (and proposed policies affecting the wage index), as shown in Table I in section I.G. of this Appendix A.

The net impact of these proposed changes is an estimated 0.4 percent decrease in capital payments per case from FY 2022 to FY 2023 for all hospitals (as shown in Table III).

The geographic comparison shows that, on average, hospitals in both urban and rural classifications would experience a decrease in capital IPPS payments per case in FY 2023 as compared to FY 2022. Capital IPPS payments per case would decrease by an estimated 0.4 percent for hospitals in urban areas while payments to hospitals in rural areas would decrease by 0.3 percent in FY 2022 to FY 2023.

The comparisons by region show that the change in capital payments per case from FY 2022 to FY 2023 for urban areas range from a 0.7 percent decrease for the New England region to a 0.6 percent increase for Puerto Rico. Meanwhile, the change in capital

payments per case from FY 2022 to FY 2023 for rural areas range from a 1.6 percent decrease for the Mountain rural region to a 0.6 percent increase for the South Atlantic rural region. These regional differences are primarily due to the proposed changes in the GAFs and estimated changes in outlier and DSH payments.

The comparison by hospital type of ownership (Voluntary, Proprietary, and Government) shows that proprietary hospitals are expected to experience an increase in capital payments per case from FY 2022 to FY 2023 of 0.1 percent. Meanwhile, voluntary hospitals and government hospitals are expected to experience a decrease in capital payments per case from FY 2022 to FY 2023 of 0.5 percent and 0.1 percent, respectively.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2023. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this proposed rule for FY 2023, we show the proposed average capital payments per case for reclassified hospitals for FY 2023. Urban reclassified hospitals are expected to experience a decrease in capital payments of 0.6 percent; urban nonreclassified hospitals are expected to experience a decrease in capital payments of 0.1 percent. The higher expected decrease in payments for urban reclassified hospitals compared to urban nonreclassified hospitals is primarily due to estimated decreases in capital DSH payments to urban reclassified hospitals caused by the number of hospitals that reclassify from urban to rural under § 412.103. Rural reclassified hospitals are expected to experience an increase in capital payments of 0.1 percent; rural nonreclassified hospitals are expected to experience a decrease in capital payments of 0.8 percent.

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TABLE III.-- COMPARISON OF TOTAL PAYMENTS PER CASE [FY 2022 PAYMENTS COMPARED TO PROPOSED FY 2023 PAYMENTS]

	Number of Hospitals	Average FY 2022 Payments/Case	Proposed Average FY 2023 Payments/Case	Change
All Hospitals	3,141	1,086	1,082	-0.4
By Geographic Location:				
Urban hospitals	2,419	1,119	1,115	-0.4
Rural hospitals	722	761	759	-0.3
Bed Size (Urban):				
0-99 beds	640	875	870	-0.6
100-199 beds	709	945	945	0.0
200-299 beds	423	1,023	1,021	-0.2
300-499 beds	409	1,111	1,108	-0.3
500 or more beds	236	1,339	1,331	-0.6
Bed Size (Rural):				
0-49 beds	348	653	648	-0.8
50-99 beds	211	718	717	-0.1
100-149 beds	86	755	754	-0.1
150-199 beds	41	843	835	-0.9
200 or more beds	36	884	884	0.0
Urban by Region:				
New England	107	1,200	1,192	-0.7
Middle Atlantic	295	1,256	1,250	-0.5
East North Central	373	1,058	1,052	-0.6
West North Central	156	1,074	1,071	-0.3
South Atlantic	402	982	977	-0.5
East South Central	140	945	945	0.0
West South Central	361	1,025	1,020	-0.5
Mountain	176	1,113	1,110	-0.3
Pacific	359	1,449	1,449	0.0
Puerto Rico	50	627	631	0.6
Rural by Region:				
New England	19	1,046	1,034	-1.1
Middle Atlantic	49	729	726	-0.4
East North Central	113	752	747	-0.7
West North Central	86	777	770	-0.9
South Atlantic	109	712	716	0.6
East South Central	141	721	723	0.3
West South Central	134	709	707	-0.3
Mountain	47	838	825	-1.6
Pacific	24	970	963	-0.7

	Number of Hospitals	Average FY 2022 Payments/Case	Proposed Average FY 2023 Payments/Case	Change
By Payment Classification:				
Urban hospitals	1,867	1,081	1,079	-0.2
Rural areas	1,274	1,093	1,086	-0.6
Teaching Status:				
Nonteaching	1,939	901	899	-0.2
Fewer than 100 residents	932	1,028	1,024	-0.4
100 or more residents	270	1,479	1,472	-0.5
Urban DSH:				
Non-DSH	374	967	964	-0.3
100 or more beds	1,140	1,113	1,112	-0.1
Less than 100 beds	353	817	811	-0.7
Rural DSH:				
Non-DSH	95	1,026	1,017	-0.9
SCH	267	835	835	0.0
RRC	663	1,144	1,136	-0.7
100 or more beds	28	988	961	-2.7
Less than 100 beds	221	640	640	0.0
Urban teaching and DSH:				
Both teaching and DSH	663	1,179	1,178	-0.1
Teaching and no DSH	62	1,045	1,044	-0.1
No teaching and DSH	830	957	956	-0.1
No teaching and no DSH	312	925	921	-0.4
Special Hospital Types:				
RRC	161	904	901	-0.3
RRC with section 401 Rural Reclassification	460	1,217	1,208	-0.7
SCH	256	744	740	-0.5
SCH with section 401 Rural Reclassification	47	1,000	1,004	0.4
SCH and RRC	120	845	842	-0.4
SCH and RRC with section 401 Rural Reclassification	37	939	934	-0.5
Type of Ownership:				
Voluntary	1,907	1,093	1,088	-0.5
Proprietary	794	983	984	0.1
Government	439	1,182	1,181	-0.1
Medicare Utilization as a Percent of Inpatient Days:				
0-25	683	1,239	1,237	-0.2
25-50	2,072	1,070	1,065	-0.5
50-65	300	877	874	-0.3
Over 65	35	707	701	-0.8
Medicaid Utilization as a Percent of Inpatient Days:				
0-25	2,073	1,005	1,001	-0.4
25-50	953	1,219	1,216	-0.2
50-65	91	1,448	1,454	0.4
Over 65	24	1,481	1,507	1.8
Hospitals with 5% or more of cases that reported experiencing homelessness	45	1,397	1,411	1.0
FY 2023 Reclassifications:				
All Reclassified Hospitals	1,071	1,106	1,100	-0.5
Non-Reclassified Hospitals	2,070	1,068	1,065	-0.3
Urban Hospitals Reclassified	893	1,143	1,136	-0.6
Urban Non-Reclassified Hospitals	1,539	1,094	1,093	-0.1
Rural Hospitals Reclassified Full Year	288	777	778	0.1
Rural Non-Reclassified Hospitals Full Year	421	739	733	-0.8
All section 401 Rural Reclassified Hospitals	608	1,176	1,167	-0.8
Other Reclassified Hospitals (section 1886(d)(8)(B))	56	757	756	-0.1

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J. Effects of Proposed Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule, we set forth the proposed annual update to the payment rates for the LTCH PPS for FY 2023. In the preamble of this proposed rule, we specify the statutory authority for the provisions that are presented, identify the policies for FY 2023, and present rationales for our proposals as well as alternatives that were considered. In this section of Appendix A to this proposed rule, we discuss the impact of the proposed changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this proposed rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 339 LTCHs included in this impact analysis. We note that, although there are currently approximately 346 LTCHs, for purposes of this impact analysis, we

excluded the data of all-inclusive rate providers consistent with the development of the FY 2023 MS–LTC–DRG relative weights (discussed in section VII.B.3.c. of the preamble of this proposed rule). Moreover, in the claims data used for this proposed rule, 2 of these 339 LTCHs only have claims for site neutral payment rate cases and, therefore, do not affect our impact analysis for LTCH PPS standard Federal payment rate cases.

In the impact analysis, we used the proposed payment rate, factors, and policies presented in this proposed rule, the proposed 2.7 percent annual update to the LTCH PPS standard Federal payment rate, the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed update to the wage index values and labor-related share, and the best available claims and CCR data to estimate the change in payments for FY 2023.

Under the dual rate LTCH PPS payment structure, payment for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) is based on the LTCH PPS standard Federal payment rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a), reduced by 4.6 percent for FYs 2018 through 2026; or 100 percent of the estimated cost of the case as determined under § 412.529(d)(2). In addition, there are two separate high cost outlier targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. We note that section 3711(b)(2) of the CARES Act has provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID–19 PHE period. At the time of development of this proposed rule, the COVID–19 PHE is still in effect. Therefore, all LTCH PPS cases up to this point in FY 2022 have been paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria. Since the expiration date of the COVID–19 PHE is not yet known, for purposes of this impact analysis, estimates of total LTCH PPS payments for site neutral payment rate cases in FYs 2022 and 2023 were calculated using the site neutral payment rate determined under § 412.522(c) and the provisions of the CARES Act were not considered.

Based on the best available data for the 339 LTCHs in our database that were considered in the analyses used for this proposed rule, we estimate that overall LTCH PPS payments in FY 2023 would increase by approximately 0.8 percent (or approximately $25 million) based on the proposed rates and factors presented in section VII. of the preamble and section V. of the Addendum to this proposed rule.

Based on the FY 2021 LTCH cases that were used for the analysis in this proposed rule, approximately 28 percent of those cases were classified as site neutral payment rate cases (that is, 28 percent of LTCH cases did not meet the statutory patient-level criteria for exclusion from the site neutral payment rate). Our Office of the Actuary currently estimates that the percent of LTCH PPS cases that will be paid at the site neutral payment rate in FY 2023 will not change significantly from the most recent historical data. We estimate IPPS comparable per diem amounts using the prior year's IPPS rates and factors, updated to reflect estimated changes to the IPPS rates and payments proposed for FY 2023. Taking this into account along with other proposed changes that would apply to the site neutral payment rate cases in FY 2023, we estimate that aggregate LTCH PPS payments for these site neutral payment rate cases will increase by approximately 2.3 percent (or approximately $8 million). This projected increase in payments to LTCH PPS site neutral payment rate cases is primarily due to the proposed updates to the IPPS rates and payments reflected in our estimate of the IPPS comparable per diem amount, as well as an estimated increase in costs for these cases determined using the charge and CCR adjustment factors described in section V.D.3.b. of the Addendum to this proposed rule. We note, we estimate payments to site neutral payment rate cases in FY 2023 represent approximately 11 percent of estimated aggregate FY 2023 LTCH PPS payments.

Based on the FY 2021 LTCH cases that were used for the analysis in this proposed rule, approximately 72 percent of LTCH cases will meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2023, and will be paid based on the LTCH PPS standard Federal payment rate for the full year. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2023 will increase approximately 0.7 percent (or approximately $18 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2023 is primarily due to the proposed 2.7 percent annual update to the LTCH PPS standard Federal payment rate for FY 2023 and the projected 1.7 percent decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments, which is discussed later in this section.

Based on the 339 LTCHs that were represented in the FY 2021 LTCH cases that were used for the analyses in this proposed rule presented in this Appendix, we estimate that aggregate FY 2022 LTCH PPS payments will be approximately $2.993 billion, as compared to estimated aggregate proposed FY 2023 LTCH PPS payments of approximately $3.018 billion, resulting in an estimated overall increase in LTCH PPS payments of approximately $25 million. We note that the estimated $25 million increase in LTCH PPS payments in FY 2023 does not reflect changes in LTCH admissions or case-mix intensity, which will also affect the overall payment effects of the policies in this proposed rule.

The LTCH PPS standard Federal payment rate for FY 2022 is $44,713.67. For FY 2023, we are proposing to establish an LTCH PPS standard Federal payment rate of $45,952.67 which reflects the proposed 2.7 percent annual update to the LTCH PPS standard Federal payment rate and the proposed budget neutrality factor for proposed updates to the area wage level adjustment of 1.000691 (discussed in section V.B.6. of the Addendum to this proposed rule). For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are proposing to establish an LTCH PPS standard Federal payment rate of $45,057.78. This proposed LTCH PPS standard Federal payment rate reflects the updates and factors previously described, as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP.

Table IV shows the estimated impact for LTCH PPS standard Federal payment rate cases. The estimated change attributable solely to the proposed annual update of 2.7 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 2.6 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023, on average, for all LTCHs (Column 6). The estimated increase of 2.6 percent shown in Column 6 of Table IV also includes estimated payments for short-stay outlier (SSO) cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit the required LTCH QRP data. For most hospital categories, the projected increase in payments based on the LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases also rounds to approximately 2.6 percent.

For FY 2023, we are proposing to update the wage index values based on the most recent available data (data from cost reporting periods beginning during FY 2019 which is the same data used for the proposed FY 2023 IPPS wage index). We also are proposing a labor-related share of 68.2 percent for FY 2023, based on the most recent available data (IGI's fourth quarter 2021 forecast) on the relative importance of the labor-related share of operating and capital costs of the 2017-based LTCH market basket. We also are proposing to apply an area wage level budget neutrality factor of 1.000691 to ensure that the proposed changes to the area wage level adjustment would not result in any change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases.

For LTCH PPS standard Federal payment rate cases, we currently estimate high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments will decrease from FY 2022 to FY 2023. Based on the FY 2021 LTCH cases that were used for the analyses in this proposed rule, we estimate that the FY 2022 high cost outlier threshold of $33,015 (as established in the FY 2022 IPPS/LTCH PPS final rule) would result in estimated high cost outlier payments for LTCH PPS standard Federal payment rate cases in FY 2022 that are projected to exceed the 7.975 percent target. Specifically, we currently estimate that high cost outlier payments for LTCH PPS standard Federal payment rate cases will be approximately 9.7 percent of the estimated total LTCH PPS standard Federal payment

rate payments in FY 2022. Combined with our estimate that FY 2023 high cost outlier payments for LTCH PPS standard Federal payment rate cases will be 7.975 percent of estimated total LTCH PPS standard Federal payment rate payments in FY 2023, this will result in an estimated decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments of approximately 1.7 percent between FY 2022 and FY 2023. We note that, in calculating these estimated high cost outlier payments, we inflated charges reported on the FY 2021 claims by the charge inflation factor proposed in section V.D.3.b. of the Addendum to this proposed rule. We also note that, in calculating these estimated high cost outlier payments, we estimated the cost of each case by multiplying the inflated charges by the adjusted CCRs that we determined using our proposed methodology described in section V.D.3.b. of the Addendum to this proposed rule.

Table IV shows the estimated impact of the payment rate and policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2023 by comparing estimated FY 2022 LTCH PPS payments to estimated FY 2023 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) We note that these impacts do not include LTCH PPS site neutral payment rate cases for the reasons discussed in section I.J.3. of this Appendix.

As we discuss in detail throughout this proposed rule, based on the best available data, we believe that the provisions of this proposed rule relating to the LTCH PPS, which are projected to result in an overall increase in estimated aggregate LTCH PPS payments, and the resulting LTCH PPS payment amounts will result in appropriate Medicare payments that are consistent with the statute.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 0.7 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases for LTCHs located in a rural area. This estimated impact is based on the FY 2021 data for the 17 rural LTCHs (out of 337 LTCHs) that were used for the impact analyses shown in Table IV.

3. Anticipated Effects of LTCH PPS Payment Rate Changes and Policy Changes

a. Proposed Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal payment rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges paid at the site neutral payment rate are generally paid the lower of the IPPS comparable per diem amount, reduced by 4.6 percent for FYs 2018 through 2026, including any applicable high cost outlier (HCO) payments, or 100 percent of the estimated cost of the case, reduced by 4.6 percent.

As discussed in section I.J.2. of this Appendix, we project an increase in aggregate LTCH PPS payments in FY 2023 of approximately $25 million. This estimated increase in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $18 million and the projected increase in payments to site neutral payment rate cases of approximately $8 million under the dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016.

As discussed in section V.D. of the Addendum to this proposed rule, our actuaries project cost and resource changes for site neutral payment rate cases due to the site neutral payment rates required under the statute. Specifically, our actuaries project that the costs and resource use for cases paid at the site neutral payment rate will likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate, and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG. While we are able to incorporate this projection at an aggregate level into our payment modeling, because the historical claims data that we are using in this proposed rule to project estimated FY 2023 LTCH PPS payments (that is, FY 2021 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the change in LTCH PPS payments for site neutral payment rate cases at the same level of detail with which we are able to model the impacts of the changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV only reflects changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.3. of this Appendix refers only to the impact on LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our proposed provider impact analysis for the changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Proposed Impact on Providers

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is currently set forth under §§ 412.515 through 412.533 and 412.535. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS–LTC–DRG relative weight, we make adjustments to account for area wage levels and SSOs. LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate). LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate, which we are calculating as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), reduced by 4.6 percent for FYs 2018 through 2026, including any applicable outlier payments, or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, when certain thresholds are met, LTCHs also receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this proposed rule on different categories of LTCHs for FY 2023, it is necessary to estimate payments per discharge for FY 2022 using the rates, factors, and the policies established in the FY 2022 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2023 using the proposed rates, factors, and the policies in this FY 2023 IPPS/LTCH PPS proposed rule (as discussed in section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule). As discussed elsewhere in this proposed rule, these estimates are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for HCO cases in each year. The resulting analyses can then be used to compare how our policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

For the following analysis, we group hospitals based on characteristics provided in the OSCAR data, cost report data in HCRIS, and PSF data. Hospital groups included the following:

- Location: Large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

c. Proposed Calculation of LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FY 2022 and proposed FY 2023 payments on a case-by-case basis using historical LTCH claims from the FY 2021 MedPAR files that met or would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for all cases in the FY 2021

MedPAR files. For modeling FY 2022 LTCH PPS payments, we used the FY 2022 standard Federal payment rate of $44,713.67 (or $43,836.08 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). Similarly, for modeling payments based on the proposed FY 2023 LTCH PPS standard Federal payment rate, we used the proposed FY 2023 standard Federal payment rate of $45,952.67 (or $45,057.78 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). In each case, we applied the applicable adjustments for area wage levels and the COLA for LTCHs located in Alaska and Hawaii. Specifically, for modeling FY 2022 LTCH PPS payments, we used the current FY 2022 labor-related share (67.9 percent), the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2022 IPPS/LTCH PPS final rule (which are available via the internet on the CMS website), the FY 2022 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $33,015 (as reflected in the FY 2022 IPPS/LTCH PPS final rule), and the FY 2022 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2022 nonlabor-related share (32.1 percent) for LTCHs located in Alaska and Hawaii. Similarly, for modeling proposed FY 2023 LTCH PPS payments, we used the proposed FY 2023 LTCH PPS labor-related share (68.2 percent), the proposed FY 2023 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (which are available via the internet on the CMS website), the proposed FY 2023 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $44,182 (as discussed in section V.D.3. of the Addendum to this proposed rule), and the proposed FY 2023 COLA factors (shown in the table in section V.C. of the Addendum to this proposed rule) to adjust the proposed FY 2023 nonlabor-related share (31.8 percent) for LTCHs located in Alaska and Hawaii. We note that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we inflated charges reported on the FY 2021 claims by the charge inflation factors proposed in section V.D.3.b. of the Addendum to this proposed rule. We also note that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we estimated the cost of each case by multiplying the inflated charges by the adjusted CCRs that we determined using our proposed methodology described in section V.D.3.b. of the Addendum to this proposed rule.

The impacts that follow reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2022 to FY 2023 based on the payment rates and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2022 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The fifth column shows the estimated proposed FY 2023 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2022 to FY 2023 due to the proposed annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 for changes to the area wage level adjustment (that is, the updated hospital wage data and labor-related share) and the application of the proposed corresponding budget neutrality factor (as discussed in section V.B.6. of the Addendum to this proposed rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 (Column 4) to FY 2023 (Column 5) for all proposed changes.

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TABLE IV: IMPACT OF PROPOSED PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR LTCH PPS STANDARD FEDERAL PAYMENT RATE CASES FOR FY 2023 (ESTIMATED FY 2022 PAYMENTS COMPARED TO ESTIMATED FY 2023 PAYMENTS)

LTCH Classification (1)	No. of LTCHS (2)	Number of LTCH PPS Standard Payment Rate Cases (3)	Average FY 2022 LTCH PPS Payment Per Standard Payment Rate (4)	Average FY 2023 LTCH PPS Payment Per Standard Payment Rate[1] (5)	Change Due to Change to the Annual Update to the Standard Federal Rate[2] (6)	Percent Change Due to Changes to Area Wage Adjustment with Wage Budget Neutrality[3] (7)	Percent Change Due to All Standard Payment Rate Changes[4] (8)
ALL PROVIDERS	337	50,536	52,606	52,954	2.6	0.0	0.7
BY LOCATION:							
RURAL	17	1,949	42,483	42,768	2.6	-0.5	0.7
URBAN	320	48,587	53,012	53,362	2.6	0.0	0.7
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	10	1,235	50,677	50,454	2.7	-0.6	-0.4
OCT. 1983 - SEPT. 1993	38	6,321	59,508	60,095	2.5	0.2	1.0
OCT. 1993 - SEPT. 2002	135	20,665	51,860	52,318	2.6	0.2	0.9
AFTER OCTOBER 2002	154	22,315	51,448	51,657	2.6	-0.3	0.4
BY OWNERSHIP TYPE:							
VOLUNTARY	54	5,646	54,777	54,722	2.6	-0.1	-0.1
PROPRIETARY	272	44,042	52,062	52,468	2.6	0.0	0.8
GOVERNMENT	11	848	66,375	66,404	2.6	-0.1	0.0
BY REGION:							
NEW ENGLAND	10	1,583	45,529	45,507	2.6	-0.6	0.0
MIDDLE ATLANTIC	20	3,356	62,004	62,655	2.6	0.0	1.1
SOUTH ATLANTIC	61	10,031	51,880	52,149	2.6	-0.3	0.5
EAST NORTH CENTRAL	49	7,417	53,255	53,315	2.6	-0.3	0.1
EAST SOUTH CENTRAL	31	3,696	49,199	49,398	2.7	-0.3	0.4
WEST NORTH CENTRAL	22	3,123	49,143	48,554	2.7	-0.7	-1.2
WEST SOUTH CENTRAL	94	13,228	44,968	45,518	2.6	0.2	1.2
MOUNTAIN	27	2,753	52,131	52,750	2.6	-0.1	1.2
PACIFIC	23	5,349	72,774	73,597	2.4	0.7	1.1
BY BED SIZE:							
BEDS: 0-24	26	2,045	48,937	49,623	2.6	0.1	1.4
BEDS: 25-49	157	18,204	48,738	48,999	2.6	-0.2	0.5
BEDS: 50-74	84	13,941	51,272	51,625	2.6	-0.1	0.7
BEDS: 75-124	47	10,210	59,733	60,246	2.5	0.2	0.9
BEDS: 125-199	19	4,759	57,265	57,371	2.6	0.2	0.2
BEDS: 200+	4	1,377	53,748	54,289	2.6	0.5	1.0

[1] Estimated FY 2023 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the proposed payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this proposed rule.

[2] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 for the proposed annual update to the LTCH PPS standard Federal payment rate.

[3] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 for changes due to the proposed changes to the area wage level adjustment under § 412.525(c) (that is., updated hospital wage data and the proposed labor related share).

[4] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 (shown in Column 4) to FY 2023 (shown in Column 5), including all of the changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this proposed rule. We note that this column, which shows the percent change in estimated payments per discharge for all changes, does not equal the sum of the percent changes in estimated payments per discharge for the annual update to the LTCH PPS standard Federal payment rate (Column 6) and the changes due to the changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in estimated payments to aggregate HCO payments for LTCH PPS standard Federal payment rate cases (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

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d. Results

Based on the FY 2021 LTCH cases (from 337 LTCHs) that were used for the analyses in this proposed rule, we have prepared the following summary of the impact (as shown in Table IV) of the LTCH PPS payment rate and proposed policy changes for LTCH PPS standard Federal payment rate cases presented in this proposed rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate cases are projected to increase 0.7 percent, on average, for all LTCHs from FY 2022 to FY 2023 as a result of the proposed payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. This estimated 0.7 percent increase in LTCH PPS payments per discharge was determined by comparing estimated proposed FY 2023 LTCH PPS payments (using the proposed payment rates and factors discussed in this proposed rule) to estimated FY 2022 LTCH PPS payments for LTCH discharges which will be LTCH PPS standard Federal payment rate cases if the dual rate LTCH PPS payment structure was or had been in effect at the time of the discharge (as described in section I.J.3. of this Appendix).

As stated previously, we are proposing to update the LTCH PPS standard Federal payment rate for FY 2023 by 2.7 percent. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the annual update to the LTCH PPS standard Federal payment rate. Consistent with § 412.523(d)(4), we also are applying a proposed budget neutrality factor for proposed changes to the area wage level adjustment of 1.000691 (discussed in section V.B.6. of the Addendum to this proposed rule), based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. As we also explained earlier in this section, for most categories of LTCHs (as shown in Table IV, Column 6), the estimated payment increase due to the proposed 2.7 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 2.6 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2022 to FY 2023. We note our estimate of the changes in payments due to the proposed update to the LTCH PPS standard Federal payment rate also includes estimated payments for short-stay outlier (SSO) cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit the required LTCH QRP.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 4 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. The impact analysis presented in Table IV shows that the overall average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 for all hospitals is 0.7 percent. The projected increase for both urban and rural hospitals is also 0.7.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) Before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) October 2002 and after. Based on the best available data, the categories of LTCHs with the largest expected percentage of LTCH PPS standard Federal payment rate cases (approximately 41 percent and 44 percent, respectively) are in LTCHs that began participating in the Medicare program between October 1993 and September 2002 and after October 2002. These LTCHs are expected to experience an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 of 0.9 percent and 0.4 percent, respectively. LTCHs that began participating in the Medicare program between October 1983 and September 1993 are projected to experience an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 of 1.0 percent, as shown in Table IV. Approximately 3 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience a decrease in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 of 0.4 percent.

(3) Ownership Control

LTCHs are grouped into three categories based on ownership control type: Voluntary, proprietary, and government. Based on the best available data, approximately 16 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 81 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 3 percent of LTCHs. Based on ownership type, proprietary LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases of 0.8 percent. Voluntary LTCHs are expected to experience a decrease in payments to LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 of 0.1 percent. Meanwhile, government owned and operated LTCHs are expected to experience no change in payments to LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023.

(4) Census Region

The comparisons by region show that the changes in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 are projected to range from a 1.2 percent decrease in the West North Central region to a 1.2 percent increase in the West South Central and Mountain regions. These regional variations are primarily due to the proposed changes to the area wage adjustment and estimated changes in outlier payments.

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 Beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds. We project that LTCHs with 125–199 beds will experience the lowest increase in payments for LTCH PPS standard Federal payment rate cases, 0.2 percent. LTCHs with 0–24 beds are projected to experience the largest increase in payments of 1.4 percent. The remaining bed size categories are projected to experience an increase in payments in the range of 0.5 to 1.0 percent.

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this proposed rule will result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2023 relative to FY 2022 of approximately $25 million (or approximately 0.8 percent) for the 339 LTCHs in our database. Although, as stated previously, the hospital-level impacts do not include LTCH PPS site neutral payment rate cases, we estimate that the provisions of this proposed rule will result in an increase in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2023 relative to FY 2022 of approximately $8 million (or approximately 2.3 percent) for the 339 LTCHs in our database. (As noted previously, we estimate payments to site neutral payment rate cases in FY 2023 represent approximately 11 percent of total estimated FY 2023 LTCH PPS payments.) Therefore, we project that the provisions of this proposed rule will result in an increase in estimated aggregate LTCH PPS payments for all LTCH cases in FY 2023 relative to FY 2022 of approximately 25 million (or approximately 0.8 percent) for the 339 LTCHs in our database.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this proposed rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program. As discussed previously, we do not expect the continued implementation of the site neutral payment system to have a negative impact on access to or quality of care, as demonstrated in areas where there is little or no LTCH presence, general short-term acute care hospitals are effectively providing treatment for the same types of patients that are treated in LTCHs.

K. Effects of Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section IX.E. of the preamble of this proposed rule, we discuss our current requirements and proposals for hospitals to report quality data under the Hospital IQR Program to receive the full annual percentage

increase for the FY 2023 payment determination and subsequent years.

In this proposed rule, we are proposing to adopt the following measures: (1) Hospital Commitment to Health Equity, beginning with the CY 2023 reporting period/FY 2025 payment determination; (2) Screening for Social Drivers of Health beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (3) Screen Positive Rate for Social Drivers of Health beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (4) Cesarean Birth electronic clinical quality measure (eCQM) with inclusion in the measure set beginning with the CY 2023 reporting period/FY 2025 payment determination, and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (5) Severe Obstetric Complications eCQM with inclusion in the measure set beginning with the CY 2023 reporting period/FY 2025 payment determination, and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (6) Hospital-Harm—Opioid-Related Adverse Events eCQM beginning with the CY 2024 reporting period/FY 2026 payment determination; (7) Global Malnutrition Composite Score eCQM, beginning with the CY 2024 reporting period/FY 2026 payment determination; (8) Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA), beginning with two voluntary periods followed by mandatory reporting beginning with the reporting period which runs from July 1, 2025, through June 30, 2026, impacting the FY 2028 payment determination; (9) Medicare Spending Per Beneficiary (MSPB) Hospital beginning with the FY 2024 payment determination; and (10) Hospital-Level Risk-Standardized Complications Rate (RSCR) Following Elective Primary THA/TKA beginning with the FY 2024 payment determination. We are proposing refinements to two current measures beginning with the FY 2024 payment determination: (1) Hospital-Level, Risk-Standardized Payment Associated with an Episode of Care for Primary Elective THA/TKA; and (2) Excess Days in Acute Care (EDAC) After Hospitalization for Acute Myocardial Infarction (AMI). We are also proposing to: (1) Establish a hospital designation related to maternal care to be publicly-reported on a public-facing website beginning in Fall 2023, and are seeking comments on other potential associated activities regarding this designation; (2) modify our eCQM reporting and submission requirements whereby we are increasing the total number of eCQMs to be reported from four to six eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination; (3) modify our case threshold exemptions and zero denominator declaration policies for hybrid measures as we believe they are not applicable for those measure types beginning with the FY 2026 payment determination; (4) adopt reporting and submission requirements for PRO–PMs; and (5) modify our eCQM validation policy to increase the reporting of medical requests from 75 percent of records to 100 percent of records beginning with the FY 2025 payment.

As shown in the summary table in section XII.B.4. of the preamble of this proposed rule, we estimate a total information collection burden increase for 3,150 IPPS hospitals of 746,300 hours at a cost of $23,437,906 annually associated for our proposed policies and updated burden estimates across a 4-year period from the CY 2023 reporting period/FY 2025 payment determination through the CY 2026 reporting period/FY 2028 payment determination, compared to our currently approved information collection burden estimates.

In section IX.E.5.a. of the preamble of this proposed rule, we are proposing the Hospital Commitment to Health Equity structural measure. In order for hospitals to receive a point for each of the five domains in the measure, affirmative attestations are required for each of the elements within a domain. For hospitals that are unable to attest affirmatively for an element, there are likely to be additional costs associated with activities such as updating hospital policies, engaging senior leadership, participating in new quality improvement activities, performing additional data analysis, and training staff. The extent of these costs will vary from hospital to hospital depending on what activities the hospital is already performing, hospital size, and the individual choices each hospital makes in order to meet the criteria necessary to attest affirmatively.

In section IX.E.5.b.(1). of the preamble of this proposed rule, we are proposing the Screening for Social Drivers of Health measure. For hospitals that are not currently administering some screening mechanism and elect to begin doing so as a result of this policy, there would be some non-recurring costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different hospitals may utilize different modes of data collection (for example paper-based, electronically patient-directed, clinician-facilitated, etc.). In addition, depending on the method of data collection utilized, the time required to complete the survey may add a negligible amount of time to patients visits.

In section IX.E.5.g. of the preamble of this proposed rule, we are proposing the THA/TKA PRO–PM. For hospitals that are not currently collecting this data and elect to begin doing so as a result of this policy, there would be some non-recurring costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different hospitals may utilize different modes of data collection (for example paper-based, electronically patient-directed, clinician-facilitated, etc.). While we assume the majority of hospitals will report data for this measure via the HQR System, we assume some hospitals may elect to submit measure data via a third-party CMS-approved survey vendor, for which there are associated costs. Under OMB control number 0938–0981 for the HCAHPS Survey measure (expiration date September 30, 2024), an estimate of approximately $4,000 per hospital is used to account for these costs. This estimate originates from 2012, therefore, to account for inflation (assuming end of CY 2012 to end of CY 2021), we adjust the price using the Bureau of Labor Statistics Consumer Price Index and estimate an updated cost of approximately $4,856 ($4,000 × 121.4 percent).[4]

We note that in sections IX.E.5.c., IX.E.5.d., IX.E.5.e, and IX.E.5.f. of the preamble of this proposed rule, we are proposing to adopt four new eCQMs. Similar to the FY 2019 IPPS/LTCH PPS final rule regarding removal of eCQM measures, while there is no change in information collection burden related to those finalized provisions, we believe that costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining Hospital IQR Program measures in hospitals' EHR systems for all of the eCQMs available for use in the Hospital IQR Program (83 FR 41771). Additionally, two of the four eCQMs are being proposed as mandatory beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years; we account for the burden of collection of information in section XII.B.4. (Collection of Information) in our proposed policy to increase our eCQM reporting and submission requirements from four eCQMs to six eCQMs. Because hospitals are already reporting eCQMs, we do not believe there are any additional costs associated with increasing the number of eCQMs hospitals must report beyond the burden discussed in the collection of information section and the costs previously discussed related to adopting new eCQMs.

Historically, 100 hospitals, on average, that participate in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year due to the failure to meet all requirements of the Hospital IQR Program. We anticipate that the number of hospitals not receiving the full annual percentage increase will be approximately the same as in past years.

L. Effects of Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section IX.F. of the preamble of this proposed rule, we discuss our proposed policies for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act, which was added by section 3005 of the Affordable Care Act. There is no financial impact to PCH Medicare reimbursement if a PCH does not submit data.

In section IX.F.4. of the preamble of this proposed rule, we are proposing to: (1) Adopt and codify a patient safety exception for the

[4] U.S. Bureau of Labor Statistics. Historical CPI–U data. Accessed on March 10, 2022. Available at: *https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-202112.pdf.*

measure removal policy; (2) begin public display of the End-of-Life (EOL) measures beginning with the FY 2024 program year data; and (3) begin public display of the 30-Day Unplanned Readmissions for Cancer Patients measures beginning with the FY 2024 program year data. We do not believe any of these provisions will result in additional financial impact beyond the information collection burden of 0 hours discussed in section XII.B.XX of the preamble of this proposed rule.

M. Effects of Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In section IX.G. of the preamble of this proposed rule, we are soliciting comment on several issues but are not proposing any policy changes. Given that there are no costs for this provision.

N. Effects of Requirements Regarding the Medicare Promoting Interoperability Program

In section IX.H. of this proposed rule, we are proposing the following changes for eligible hospitals and critical access hospitals (CAHs) that attest to CMS under the Medicare Promoting Interoperability Program: (1) To require and modify the Electronic Prescribing Objective's Query of PDMP measure while maintaining the associated points at 10 points beginning with the electronic health record (EHR) reporting period in CY 2023; (2) to expand the Query of Prescription Drug Monitoring Program (PDMP) measure to include Schedule II, III, and IV drugs beginning with the CY 2023 EHR reporting period; (3) to add a new Health Information Exchange (HIE) Objective option, the Enabling Exchange Under Trusted Exchange Framework and Common Agreement (TEFCA) measure (requiring a yes/no response) beginning with the CY 2023 EHR reporting period; (4) to modify the Public Health and Clinical Data Exchange Objective by adding an Antibiotic Use and Resistance (AUR) measure in addition to the current four required measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting) beginning in the CY 2023 EHR reporting period; (5) to consolidate the current options from three to two levels of active engagement for the Public Health and Clinical Data Exchange Objective and to require the reporting of active engagement for the measures under the objective beginning with the CY 2023 EHR reporting period; (6) to institute public reporting of certain Medicare Promoting Interoperability Program data beginning with the CY 2023 EHR reporting period; (7) to modify the scoring methodology for the Promoting Interoperability Program beginning in the CY 2023 reporting period; and (8) to remove regulation text for the objectives and measures in the Medicare Promoting Interoperability Program from paragraph (e) under 42 CFR 495.24 and add new paragraph (f) beginning in CY 2023. We are also proposing to adopt four eCQMs: (1) Severe Obstetric Complications eCQM beginning with the CY 2023 reporting period, followed by mandatory reporting beginning with the CY 2024 reporting period; (2) Cesarean Birth (ePC–02) eCQM beginning with the CY 2023 reporting period followed by mandatory reporting beginning with the CY 2024 reporting period; (3) Hospital-Harm—Opioid-Related Adverse Events eCQM beginning with the CY 2024 reporting period; and (4) Global Malnutrition Composite Score eCQM beginning with the CY 2024 reporting period. Lastly, we are proposing a modification to our eCQM reporting and submission requirements whereby we are increasing the total number of eCQMs to be reported from four to six eCQMs beginning with the CY 2024 reporting period.

As shown in summary table in section XII.B.9.k. of the preamble of this proposed rule, we estimate a total information collection burden increase for 4,500 eligible hospitals and CAHs of 5,513 hours at a cost of $233,730 annually associated with our proposed policies and updated burden estimates across the CY 2023 and CY 2024 EHR reporting periods compared to our currently approved information collection burden estimates. We refer readers to section XII.B.9. of the preamble of this proposed rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Medicare.

In section IX.H.4. of the preamble of this proposed rule, we are proposing to add the Enabling Exchange Under TEFCA measure to the Health Information Exchange Objective. Eligible hospitals and CAHs currently may choose to report the two Support Electronic Referral Loop measures or may choose to report the HIE Bi-Directional Exchange measure. With the addition of this measure, eligible hospitals and CAHs would be able to choose to attest to Enabling Exchange Under TEFCA as an alternative to reporting on other measures in the objective. This proposal seeks to provide an opportunity for eligible hospitals and CAHs that are already voluntarily connecting to and exchanging information with the TEFCA network to earn credit for the Health Information Exchange Objective. Because attesting to this measure is voluntary and we assume eligible hospitals and CAHs would already be engaging in the activities necessary to attest ''yes'', we assume no additional financial impact as a result of this policy.

In section IX.H.5.b. of the preamble of this proposed rule, we are proposing to adopt a new Antimicrobial Use and Resistance (AUR) Surveillance measure for eligible hospitals and CAHs under the Promoting Interoperability Program's Public Health and Clinical Data Exchange Objective with associated exclusions beginning in the CY 2023 reporting period. To attest successfully, an eligible hospital or CAH must be in active engagement with CDC's National Healthcare Safety Network (NHSN) to submit AUR data and receive a report from NHSN indicating their successful submission of AUR data for the EHR reporting period. Participation in NHSN's surveillance requires the purchase or building of an AUR reporting solution. While thousands of hospitals have voluntarily done this to date, for hospitals who would be required to, we estimate the cost to range between $17,000 and $388,500 annually, with a median of $187,400.[5] We believe these associated costs are outweighed by the more than $4.6 billion in health care costs spent annually treating antibiotic resistance threats.[6]

In section IX.H.5.c. of the preamble of this proposed rule, we are proposing to reduce the number of active engagement options from three to two and combine the ''completed registration to submit data'' option with the ''testing'' and validation option. Because these options were first available in 2016 and the vast majority of eligible hospitals and CAHs have completed the ''completed registration to submit data'' option in the years since, we believe any financial impact associated with this proposal to be negligible. Regarding the proposal to allow eligible hospitals and CAHs to spend only one EHR reporting period at the Pre-production and Validation phase, because the goal for all eligible hospitals and CAHs has historically been to eventually be at the Validated Data Production option, we do not believe there is any additional financial impact associated with this proposal.

In section IX.H.10.a.(2). of the preamble of this proposed rule, we are proposing to adopt four new eCQMs. Similar to the FY 2019 IPPS/LTCH PPS final rule regarding removal of eCQM measures, while there is no change in information collection burden related to those finalized provisions, we believe that costs are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining program measures in hospitals' EHR systems for all of the eCQMs available for use in the Promoting Interoperability Program (83 FR 41771). Additionally, for two of the four eCQMs being proposed as mandatory beginning with the CY 2024 reporting period and for subsequent years, we account for the burden of collection of information in section XII.B.9.e. (Collection of Information) in our proposed policy to increase our eCQM reporting and submission requirements from four eCQMs to six eCQMs.

O. Alternatives Considered

This proposed rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

1. Proposed Use of FY 2021 Data and Proposed Methodology Modifications for the FY 2023 IPPS and LTCH PPS Ratesetting

As discussed in section I.F. of the preamble of this proposed rule, we primarily use two data sources in the IPPS and LTCH PPS ratesetting: Claims data and cost report data. The claims data source is the MedPAR file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital bills for discharges in a fiscal year.

[5] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5051263/.*

[6] *https://www.cdc.gov/drugresistance/solutions-initiative/stories/partnership-estimates-healthcare-cost.html.*

The cost report data source is the Medicare hospital cost report data files from the most recent quarterly Healthcare Cost Report Information System (HCRIS) release. Our goal is always to use the best available data overall for ratesetting. Ordinarily, the best available MedPAR data is the most recent MedPAR file that contains claims from discharges for the fiscal year that is 2 years prior to the fiscal year that is the subject of the rulemaking. Ordinarily, the best available cost report data is based on the cost reports beginning 3 fiscal years prior to the fiscal year that is the subject of the rulemaking.

We also stated that given the persistence of the effects of the virus that causes COVID–19 in the Medicare FY 2020 data, the Medicare FY 2021 data, and the CDC hospitalization data, coupled with the expectation for future variants, we believe that it is reasonable to assume that some Medicare beneficiaries will continue to be hospitalized with COVID–19 at IPPS hospitals and LTCHs in FY 2023. Accordingly, we believe it is appropriate to use FY 2021 data, as the most recent available data during the period of the COVID–19 PHE, for purposes of the FY 2023 IPPS and LTCH PPS ratesetting. However, we also believe it is reasonable to assume based on the information available at this time that there will be fewer COVID–19 hospitalizations in FY 2023 than in FY 2021 given the more recent trends in the CDC hospitalization data since the Omicron variant peak in January, 2022. Accordingly, because we anticipate Medicare inpatient hospitalizations for COVID–19 will continue in FY 2023 but at a lower level, we are proposing to use FY 2021 data for purposes of the FY 2023 IPPS and LTCH PPS ratesetting but with the following modifications to our usual ratesetting methodologies to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries at IPPS hospitals and LTCHs as compared to FY 2021.

- Calculate the relative weights for FY 2023 by first calculating two sets of weights, one including and one excluding COVID–19 claims in the FY 2021 data, and then averaging the two sets of relative weights to determine the proposed FY 2023 relative weight values.
- Modify our methodologies for determining the FY 2023 outlier fixed-loss amount for IPPS cases and LTCH PPS standard Federal payment rate cases to use charge inflation factors based on the increase in charges that occurred from FY 2018 to FY 2019, which is the last 1-year period prior to the COVID–19 PHE and to use CCR adjustment factors based on the change in CCRs that occurred between the March 2019 PSF and the March 2020 PSF, which is the last 1-year period prior to the COVID–19 PHE.

We refer the reader to section II.E.2.c. of the preamble and section II.A.4.j. of the Addendum of this proposed rule for a complete discussion regarding these proposed modifications to our usual ratesetting methodologies.

As an alternative to our proposal, we considered not making any of these proposed modifications to our usual methodologies for the calculation of the FY 2023 MS–DRG and MS–LTC–DRG relative weights or the usual methodologies used to determine the FY 2023 outlier fixed-loss amount for IPPS cases and LTCH PPS standard Federal payment rate cases. Specifically, under this alternative approach, we would—

- Calculate the relative weights using our usual methodology for FY 2023 by including all COVID–19 claims in the FY 2021 data with no averaging of the relative weights as calculated with and without the COVID–19 cases to determine the proposed FY 2023 relative weight values; and
- Use the same data we would ordinarily use for purposes of this FY 2023 rulemaking to compute the charge inflation factors and CCR adjustment factors in determining the FY 2023 outlier fixed-loss amount for IPPS cases and LTCH PPS standard Federal payment rate cases; specifically:

++ Charge inflation factors based on the increase in charges that occurred from FY 2020 to FY 2021, which is the latest full fiscal year period of MedPAR data available to determine the increase in charges.

++ CCR adjustment factors based on the change in CCRs that occurred between the December 2020 PSF and the December 2021 PSF, which is the latest 1-year period of the PSF to determine the adjustment factors to the CCRs for this proposed rule (for the final rule, we typically use updated PSF data to determine the CCR adjustment factor which for FY 2023 would be based on the change in CCRs that occurred between the March 2021 PSF and the March 2022 PSF).

We note the FY 2023 outlier fixed-loss amount would be significantly higher under this alternative considered.

We further note that this alternative approach and the related supplemental data files reflect the application of the proposed permanent 10 percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, beginning in FY 2023, as discussed in section II.E.2.d. of the preamble of this proposed rule.

In order to facilitate comments on this alternative approach as well as comments on our proposed modifications to our usual methodologies, we are making available the following files:

- MS–DRG and MS–LTC–DRG relative weighting factors and length of stay information calculated using the FY 2021 data without the proposed averaging approach described previously.
- A file with the budget neutrality and other ratesetting adjustments calculated under this alternative considered.
- Other proposed rule supporting data files based on this alternative considered that will assist in facilitating comments, including: The IPPS and LTCH PPS Impact Files; the AOR/BOR File; the Case Mix Index File; and, the Standardizing File.

These IPPS specific files can be found on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps,* along with the data files and information for our proposed FY 2023 IPPS ratesetting. The LTCH PPS specific files can be found on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/longtermcarehospitalpps,* along with the data files and information for our proposed FY 2023 LTCH PPS ratesetting.

P. Overall Conclusion

1. Acute Care Hospitals

Acute care hospitals are estimated to experience a decrease of approximately $0.263 billion in FY 2023, including operating, capital, and new technology changes, as well as increased GME payments under our proposed changes in response to *Milton S. Hershey Medical Center, et al.* v. *Becerra* and payments under the proposal to establish a new supplemental payment for IHS/Tribal and Puerto Rico hospitals. The estimated change in operating payments is approximately $0.6 billion (discussed in section I.G. and I.H. of this Appendix). The estimated change in capital payments is approximately -$0.028 billion (discussed in section I.I. of this Appendix). The estimated change in new technology add-on payments is approximately -$0.835 billion as discussed in section I.H. of this Appendix. The change in new technology add-on payments reflects the net impact of new applications under the alternative pathways and continuing new technology add-on payments. Total may differ from the sum of the components due to rounding.

Table I. of section I.G. of this Appendix also demonstrates the estimated redistributional impacts of the IPPS budget neutrality requirements for the proposed MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB.

We estimate that hospitals would experience a 0.4 percent decrease in capital payments per case, as shown in Table III. of section I.I. of this Appendix. We project that there would be a $28 million decrease in capital payments in FY 2023 compared to FY 2022.

The discussions presented in the previous pages, in combination with the remainder of this proposed rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments in FY 2023. In the impact analysis, we are using the proposed rates, factors, and policies presented in this proposed rule based on the best available claims and CCR data to estimate the proposed change in payments under the LTCH PPS for FY 2023. Accordingly, based on the best available data for the 339 LTCHs included in our analysis, we estimate that overall FY 2023 LTCH PPS payments would increase approximately $25 million relative to FY 2022 primarily due to the proposed annual update to the LTCH PPS standard Federal rate.

Q. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will

be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we believe that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $115.22 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 23.99 hours for the staff to review half of this proposed or final rule. For each entity that reviews the rule, the estimated cost is $2,764.23 (23.99 hours × $115.22). Therefore, we estimate that the total cost of reviewing this regulation is $77,614,146 ($2,764.23 × 28,078 reviewers).

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in Table V. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this proposed rule. All expenditures are classified as transfers to Medicare providers.

As shown in Table V. of this Appendix, the net costs to the Federal Government associated with the policies proposed in this proposed rule are estimated at −$0.263 billion.

TABLE V.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2022 TO FY 2023

Category	Transfers
Annualized Monetized Transfers	-$0.263 billion
From Whom to Whom	Federal Government to IPPS Medicare Providers

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis of the proposed payment rates and factors presented in this proposed rule under the LTCH PPS is projected to result in an increase in estimated aggregate LTCH PPS payments in FY 2023 relative to FY 2022 of approximately $25 million based on the data for 339 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in Table VI. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to the changes to the LTCH PPS. Table VI. of this Appendix provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the proposed payment rates and factors and other provisions presented in this proposed rule based on the data for the 339 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

As shown in Table VI. of this Appendix, the net cost to the Federal Government associated with the policies for LTCHs in this proposed rule are estimated at $25 million.

TABLE VI.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2022 LTCH PPS TO THE FY 2023 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	$25 million
From Whom to Whom	Federal Government to LTCH Medicare Providers

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 38 of the Table of Small Business Size Standards for NAIC 622 found on the SBA website at *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Because all hospitals are considered to be small entities for purposes of the RFA, the hospital impacts described in this proposed rule are impacts on small entities. Individuals and States are not included in the definition of a small entity. MACs are not considered to be small entities because they do not meet the SBA definition of a small business.

HHS's practice in interpreting the RFA is to consider effects economically ''significant'' if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. We believe that the provisions of this proposed rule relating to IPPS hospitals would have an economically significant impact on small entities as explained in this Appendix. Therefore, the Secretary has certified that this proposed rule will have a significant economic impact on a substantial number of small entities. For example, the majority of the 3,141 IPPS hospitals included in the impact analysis shown in ''Table I.—Impact Analysis of Proposed Changes to the IPPS for Operating Costs for FY 2023,'' on average are expected to see increases in the range of 1.4 percent, primarily due to the proposed hospital rate update, as discussed in section I.G. of this

Appendix. On average, the proposed rate update for these hospitals is estimated to be 3.1 percent.

The majority of the 339 LTCH PPS hospitals included in the impact analysis shown in ''Table IV. Impact of Proposed Payment Rate and Policy Changes to LTCH PPS Payments and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Payment Rate Cases for FY 2023 (Estimated FY 2023 Payments Compared to Estimated FY 2022 Payments)'' on average are expected to see an increase of approximately 0.7 percent, primarily due to the proposed 2.7 percent annual update to the LTCH PPS standard Federal payment rate for FY 2023 and the projected 1.7 percent decrease in high cost outlier payments, as discussed in section I.J. of this Appendix.

This proposed rule contains a range of proposed policies. It provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered. The analyses discussed in this Appendix and throughout the preamble of this proposed rule constitutes our regulatory flexibility analysis. We are soliciting public comments on our estimates and analysis of the impact of our proposals on small entities. Public comments that we receive and our responses will be presented in the final rule.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals.

As shown in Table I. in section I.G. of this Appendix, rural IPPS hospitals with 0–49 beds (348 hospitals) and 50–99 beds (211 hospitals) are expected to experience a decrease in payments from FY 2022 to FY 2023 of 0.2 percent and 0.1 percent, respectively, primarily driven by the proposed hospital rate update and the expiration of the MDH provision, as discussed in section I.G of this Appendix. We refer readers to Table I. in section I.G. of this Appendix for additional information on the quantitative effects of the proposed policy changes under the IPPS for operating costs.

All rural LTCHs (17 hospitals) shown in Table IV. in section I.J. of this Appendix have less than 100 beds. These hospitals are expected to experience an increase in payments from FY 2022 to FY 2023 of 0.7 percent, primarily due to the proposed 2.7 percent annual update to the LTCH PPS standard Federal payment rate for FY 2023 and the projected 1.7 percent decrease in high cost outlier payments, as discussed in section I.J. of this Appendix.

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold level is approximately $165 million. This proposed rule would not mandate any requirements that meet the threshold for State, local, or tribal governments, nor would it affect private sector costs.

VI. Executive Order 13132

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This proposed rule would not have a substantial direct effect on state or local governments, preempt states, or otherwise have a federalism implication.

VII. Executive Order 13175

Executive Order 13175 directs agencies to consult with Tribal officials prior to the formal promulgation of regulations having tribal implications. Section 1880(a) of the Act states that a hospital of the Indian Health Service, whether operated by such Service or by an Indian tribe or tribal organization, is eligible for Medicare payments so long as it meets all of the conditions and requirements for such payments which are applicable generally to hospitals. Consistent with section 1880(a) of the Act, this proposed rule contains general provisions also applicable to hospitals and facilities operated by the Indian Health Service or Tribes or Tribal organizations under the Indian Self-Determination and Education Assistance Act.

As discussed in prior rulemaking, we have engaged in consultation with Tribal officials on the methodology for determining uncompensated care payments to IHS and Tribal hospitals. As discussed in section IV.D of the preamble of this proposed rule, we are proposing, beginning in FY 2023, to discontinue the use of low-income insured days as a proxy for the uncompensated care costs of IHS and Tribal hospitals and to begin using data on uncompensated care costs from Worksheet S–10 to determine uncompensated care payments to IHS and Tribal hospitals. In addition, as discussed in section IV.E of the preamble of this proposed rule, after considering input received from these consultations with Tribal officials, we are proposing to establish a new supplemental payment for IHS/Tribal hospitals also beginning in FY 2023 to avoid undue long-term financial disruption to these hospitals as a result of our proposal to discontinue the use of low-income insured days as a proxy for uncompensated care. Consistent with Executive Order 13175, we also continue to engage in consultation with Tribal officials on this issue. We intend to use input received from these consultations with Tribal officials, as well as the comments on this proposed rule, to inform this rulemaking.

VIII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this proposed rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2023, consistent with our approach for FY 2022, we are including the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2023

A. Proposed FY 2023 Inpatient Hospital Update

As discussed in section IV.A. of the preamble to this proposed rule, for FY 2023, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic

health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the productivity adjustment). Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the productivity adjustment may result in the applicable percentage increase being less than zero. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.)

We note that, in compliance with section 404 of the MMA, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45204), we replaced the 2014-based IPPS operating and capital market baskets with the rebased and revised 2018-based IPPS operating and capital market baskets beginning in FY 2022.

In this FY 2023 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2023 market basket update used to determine the applicable percentage increase for the IPPS on IGI's fourth quarter 2021 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through third quarter 2021, which is estimated to be 3.1 percent. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B. of the preamble of this FY 2023 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2021 forecast, we are proposing a productivity adjustment of 0.4 percentage point for FY 2023. We are also proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2023 market basket update and productivity adjustment for the FY 2023 IPPS/LTCH PPS final rule.

Therefore, based on IGI's fourth quarter 2021 forecast of the 2018-based IPPS market basket update and the productivity adjustment, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), we are proposing four possible applicable percentage increases that could be applied to the standardized amount, as shown in the following table.

FY 2023	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	3.1	3.1	3.1	3.1
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.775	-0.775
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.325	0	-2.325
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.4	-0.4	-0.4	-0.4
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.7**	**0.375**	**1.925**	**-0.4**

B. Proposed Update for SCHs for FY 2023

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2023 applicable percentage increase in the hospital-specific rate for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS).

Under current law, the MDH program is effective for discharges through September 30, 2022, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429 through 41430). Therefore, under current law, the MDH program will expire at the end of FY 2022. We refer readers to section V.D. of the preamble of this proposed rule for further discussion of the expiration of the MDH program.

As previously stated, the update to the hospital specific rate for SCHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are proposing the same four possible applicable percentage increases in the previous table for the hospital-specific rate applicable to SCHs.

C. Proposed FY 2023 Puerto Rico Hospital Update

Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to make an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.A.1. of the preamble of this proposed rule.

In addition, as discussed in section IV.A.2. of the preamble of this proposed rule, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022.

Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have ''three-quarters'' of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket rate-of-increase, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users increases to 66⅔ percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674).

Based on IGI's fourth quarter 2021 forecast of the 2018-based IPPS market basket update with historical data through third quarter 2021, for this FY 2023 proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as previously discussed, for Puerto Rico hospitals, we are proposing a market basket update of 3.1 percent and a productivity adjustment of 0.4 percentage point. Therefore, for FY 2023, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we are proposing the following applicable percentage increases to the standardized amount for FY 2023 for Puerto Rico hospitals:

• For a Puerto Rico hospital that is a meaningful EHR user, we are proposing an applicable percentage increase to the FY 2023 operating standardized amount of 2.7 percent (that is, the FY 2023 estimate of the proposed market basket rate-of-increase of 3.1 percent less an adjustment of 0.4 percentage point for the proposed productivity adjustment).

• For a Puerto Rico hospital that is not a meaningful EHR user, we are proposing an applicable percentage increase to the operating standardized amount of 1.15 percent (that is, the FY 2023 estimate of the proposed market basket rate-of-increase of 3.1 percent, less an adjustment of 1.55 percentage point (the proposed market basket rate-of-increase of 3.1 percent × 0.75 × (⅔) for failure to be a meaningful EHR user), and less an adjustment of 0.4 percentage point for the proposed productivity adjustment).

As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2023 market basket update and the productivity adjustment for the FY 2023 IPPS/LTCH PPS final rule.

D. Proposed Update for Hospitals Excluded From the IPPS for FY 2023

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. In addition, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (described in § 412.22(i) of the regulations) also are subject to the rate-of-increase limits. As discussed in section VI. of the preamble of this proposed rule, we are proposing to use the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals for FY 2023 and subsequent fiscal years. Accordingly, for FY 2023, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, extended neoplastic disease care hospitals, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is the FY 2023 percentage increase in the 2018-based IPPS operating market basket. For this proposed rule, the current estimate of the IPPS operating market basket percentage increase for FY 2023 is 3.1 percent. We are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2023 market basket update for the FY 2023 IPPS/LTCH PPS final rule.

E. Proposed Update for LTCHs for FY 2023

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this proposed rule, we are proposing to update the LTCH PPS standard Federal payment rate for FY 2023 by 2.7 percent, consistent with section 1886(m)(3) of the Act which provides that any annual update be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, the productivity adjustment). Furthermore, in accordance with the LTCHQR Program under section 1886(m)(5) of the Act, we are proposing to reduce the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. Accordingly, we are proposing to establish an update factor of 1.027 in determining the LTCH PPS standard Federal rate for FY 2023. For LTCHs that fail to submit quality data for FY 2023, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 0.7 percent (that is, the proposed annual update for FY 2023 of 2.7 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying a proposed update factor of 1.007 in determining the LTCH PPS standard Federal rate for FY 2023. (We note that, as discussed in section VII.D. of the preamble of this proposed rule, the proposed update to the LTCH PPS standard Federal payment rate of 2.7 percent for FY 2023 does not reflect any budget neutrality factors.)

III. Secretary's Recommendations

MedPAC is recommending inpatient hospital rates be updated by the amount specified in current law. MedPAC's rationale for this update recommendation is described in more detail in this section. As previously stated, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix B. We are recommending that the same applicable percentage increases apply to SCHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa and extended neoplastic disease care hospitals of 3.1 percent.

For FY 2023, consistent with policy set forth in section VII. of the preamble of this proposed rule, for LTCHs that submit quality data, we are recommending an update of 2.7 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2022, we are recommending an annual update to the LTCH PPS standard Federal rate of 0.7 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2022 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates by the amount specified in current law. MedPAC stated that their payment adequacy indicators are mixed but generally positive, and MedPAC anticipates changes caused by the PHE to be temporary. MedPAC anticipates that their recommendation to update the IPPS payment rate by the amount specified under current law in 2023 will be enough to maintain beneficiaries' access to hospital inpatient and outpatient care and keep IPPS payment rates close to the cost of delivering high-quality care efficiently. We refer readers to the March 2022 MedPAC report, which is available for download at *www.medpac.gov,* for a complete discussion on these recommendations.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to the amount specified in current law, section 1886(b)(3)(B) of the Act sets the requirements for the FY 2023 applicable percentage increase. Therefore, consistent with the statute, we are proposing an applicable percentage increase for FY 2023 of 2.7 percent, provided the hospital submits quality data and is a meaningful EHR user consistent with these statutory requirements.

We note that, because the operating and capital payments in the IPPS remain separate, we are continuing to use separate updates for operating and capital payments in the IPPS. The proposed update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

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Part III

The President

Notice of May 9, 2022—Continuation of the National Emergency With Respect to the Actions of the Government of Syria

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Presidential Documents

Title 3—

The President

Notice of May 9, 2022

Continuation of the National Emergency With Respect to the Actions of the Government of Syria

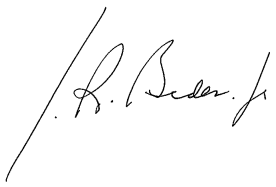
On May 11, 2004, pursuant to his authority under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) and the Syria Accountability and Lebanese Sovereignty Restoration Act of 2003 (Public Law 108–175), the President issued Executive Order 13338, in which he declared a national emergency with respect to the actions of the Government of Syria. The national emergency was modified in scope and relied upon for additional steps taken in Executive Order 13399 of April 25, 2006, Executive Order 13460 of February 13, 2008, Executive Order 13572 of April 29, 2011, Executive Order 13573 of May 18, 2011, Executive Order 13582 of August 17, 2011, Executive Order 13606 of April 22, 2012, and Executive Order 13608 of May 1, 2012.

The President took these actions to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by the actions of the Government of Syria in supporting terrorism, maintaining its then-existing occupation of Lebanon, pursuing weapons of mass destruction and missile programs, and undermining United States and international efforts with respect to the stabilization and reconstruction of Iraq.

The regime's brutality and repression of the Syrian people, who have called for freedom and a representative government, not only endangers the Syrian people themselves, but also generates instability throughout the region. The Syrian regime's actions and policies, including with respect to chemical weapons and supporting terrorist organizations, continue to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. As a result, the national emergency declared in Executive Order 13338, which was expanded in scope in Executive Order 13572, and with respect to which additional steps were taken in Executive Order 13399, Executive Order 13460, Executive Order 13573, Executive Order 13582, Executive Order 13606, and Executive Order 13608, must continue in effect beyond May 11, 2022. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared with respect to the actions of the Government of Syria.

In addition, the United States condemns the brutal violence and human rights violations and abuses of the Assad regime and its Russian and Iranian enablers. The United States calls on the Assad regime, and its backers, to stop its violent war against its own people, enact a nationwide ceasefire, facilitate the unhindered delivery of humanitarian assistance to all Syrians in need, and negotiate a political settlement in Syria in line with United Nations Security Council Resolution 2254. The United States will consider changes in policies and actions of the Government of Syria in determining whether to continue or terminate this national emergency in the future.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
May 9, 2022.

[FR Doc. 2022–10180
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