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Contents

Federal Register

Vol. 87, No. 214

Monday, November 7, 2022

Separate Parts In This Issue

Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

Federal Register
Vol. 87, No. 214
Monday, November 7, 2022

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 430

[EERE–2021–BT–TP–0030]

RIN 1904–AF29

Energy Conservation Program: Test Procedure for Central Air Conditioners and Heat Pumps

Correction

In rule document 2022–22257, appearing on pages 64550–64607, in the issue of Tuesday, October 25, 2022, make the following correction:

■ Appendix M to Subpart B of Part 430 [Corrected]

On page 64588, in Appendix M to Subpart B of Part 430, in the third column, the equation in the 6th line down is corrected to read as set forth below.

$$X^{k=2}(T_j) = BL(T_j)/Q_n^{k=2}(T_j)$$

[FR Doc. C1–2022–22257 Filed 11–4–22; 8:45 am]

BILLING CODE 0099–10–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Chapter X

Consumer Financial Protection Circular 2022–06: Unanticipated Overdraft Fee Assessment Practices

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Consumer financial protection circular.

SUMMARY: The Consumer Financial Protection Bureau (Bureau or CFPB) has issued Consumer Financial Protection Circular 2022–06, titled, ''Unanticipated Overdraft Fee Assessment Practices.'' In this Circular, the Bureau responds to the question, ''Can the assessment of overdraft fees constitute an unfair act or practice under the Consumer Financial Protection Act (CFPA), even if the entity complies with the Truth in Lending Act (TILA) and Regulation Z, and the Electronic Fund Transfer Act (EFTA) and Regulation E?''

DATES: The Bureau released this Circular on its website on October 26, 2022.

ADDRESSES: Enforcers, and the broader public, can provide feedback and comments to *Circulars@cfpb.gov.*

FOR FURTHER INFORMATION CONTACT: Sonya Pass, Senior Legal Counsel, Legal Division, at 202–435–7700. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

Question Presented

Can the assessment of overdraft fees constitute an unfair act or practice under the Consumer Financial Protection Act (CFPA), even if the entity complies with the Truth in Lending Act (TILA) and Regulation Z, and the Electronic Fund Transfer Act (EFTA) and Regulation E?

Response

Yes. Overdraft fee practices must comply with TILA, EFTA, Regulation Z, Regulation E, and the prohibition against unfair, deceptive, and abusive acts or practices in section 1036 of the CFPA.[1] In particular, overdraft fees assessed by financial institutions on transactions that a consumer would not reasonably anticipate are likely unfair. These unanticipated overdraft fees are likely to impose substantial injury on consumers that they cannot reasonably avoid and that is not outweighed by countervailing benefits to consumers or competition.

As detailed in this Circular, unanticipated overdraft fees may arise in a variety of circumstances. For example, financial institutions risk charging overdraft fees that consumers would not reasonably anticipate when the transaction incurs a fee even though the account had a sufficient available balance at the time the financial institution authorized the payment (sometimes referred to as ''authorize positive, settle negative (APSN)'').

Background

An overdraft occurs when consumers have insufficient funds in their account to cover a transaction, but the financial institution nevertheless pays it. Unlike non-sufficient funds penalties, where a financial institution incurs no credit risk when it returns a transaction unpaid for insufficient funds, clearing an overdraft transaction is extending a loan that can create credit risk for the financial institution. Most financial institutions today charge a flat per-transaction fee, which can be as high as $36, for overdraft transactions, regardless of the amount of credit risk, if any, that they take.

Overdraft programs started as courtesy programs under which financial institutions would decide on a manual, ad hoc basis to pay particular check transactions for which consumers lacked funds in their deposit accounts rather than to return the transactions unpaid, which may have other negative consequences for consumers. Although Congress did not exempt overdraft programs offered in connection with deposit accounts when it enacted TILA,[2] the Federal Reserve Board (Board) in issuing Regulation Z in 1969 created a limited exemption from the new regulation for financial institutions' overdraft programs at that time (also then commonly known as ''bounce protection programs'').[3]

Overdraft programs in the 1990s began to evolve away from this historical model in a number of ways. One major industry change was a shift away from manual ad hoc decision-making by financial institution employees to a system involving heavy reliance on automated programs to process transactions and to make overdraft decisions. A second was to impose higher overdraft fees. In addition, broader changes in payment transaction types increased the impacts of these other changes on overdraft programs. In particular, debit card use expanded dramatically, and financial institutions began charging overdraft

[1] CFPA section 1036, 12 U.S.C. 5536.

[2] Public Law 90–321, 82 Stat. 146 (May 29, 1968), codified as amended at 15 U.S.C. 1601 *et seq.*

[3] 34 FR 2002 (Feb. 11, 1969). *See also, e.g.,* 12 CFR 1026.4(c)(3) (excluding charges imposed by a financial institution for paying items that overdraw an account from the definition of ''finance charge,'' unless the payment of such items and the imposition of the charge were previously agreed upon in writing); 12 CFR 1026.4(b)(2) (providing that any charge imposed on a checking or other transaction account is an example of a finance charge only to the extent that the charge exceeds the charge for a similar account without a credit feature).

fees on debit card transactions, which, unlike checks, are authorized by financial institutions at the time consumers initiate the transactions. And unlike checks, there are no similar potential negative consequences to consumers from a financial institution's decision to decline to authorize a debit card transaction.

As a result of these operational changes, overdraft programs became a significant source of revenue for banks and credit unions as the volume of transactions involving checking accounts increased due primarily to the growth of debit cards.[4] Before debit card use grew, overdraft fees on check transactions formed a greater portion of deposit account overdrafts. Debit card transactions presented consumers with markedly more chances to incur an overdraft fee when making a purchase because of increased acceptance and use of debit cards for relatively small transactions (*e.g.,* fast food and grocery stores).[5] Over time, revenue from overdraft increased and began to influence significantly the overall pricing structure for many deposit accounts, as providers began relying heavily on back-end pricing while eliminating or reducing front-end pricing (*i.e.,* ''free'' checking accounts with no monthly fees).[6]

As a result of the rapid growth in overdraft programs, Federal banking regulators expressed increasing concern about consumer protection issues and began a series of issuances and rulemakings. In the late 2000s as the risk of significant harm regarding overdraft programs continued to mount despite the increase in regulatory activity, Federal agencies began exploring various additional measures with regard to overdraft, including whether to require that consumers affirmatively opt in before being charged for overdraft programs. In February 2005, the Board, the Federal Deposit Insurance Corporation (FDIC), the National Credit Union Administration (NCUA), and the Office of the Comptroller of the Currency (OCC) issued Joint Guidance on Overdraft Protection Programs.[7] In May 2005, the Board amended its Regulation DD (which implements the Truth in Savings Act) to expand disclosure requirements and revise periodic statement requirements for institutions that advertise their overdraft programs to provide aggregate totals for overdraft fees and for returned item fees for the periodic statement period and the year to date.[8] In May 2008, the Board along with the NCUA and the now-defunct Office of Thrift Supervision proposed to exercise their authority to prohibit unfair or deceptive acts or practices under section 5 of the Federal Trade Commission Act (FTC Act) [9] to prohibit institutions from assessing any fees on a consumer's account in connection with an overdraft program, unless the consumer was given notice and the right to opt out of the service, and the consumer did not opt out.[10] In January 2009, the Board finalized a Regulation DD rule that, among other things, expanded the previously mentioned disclosure and periodic statement requirements for overdraft programs to all depository institutions (not just those that advertise the programs).[11] In addition, although the three agencies did not finalize their FTC Act proposal, the Board ultimately adopted an opt-in requirement for overdraft fees assessed on ATM and one-time debit card transactions under Regulation E (which implements EFTA) [12] in late 2009.[13]

More recently, Federal financial regulators, such as the CFPB, the Board, and the FDIC, issued guidance around practices that lead to the assessment of overdraft fees. In 2010, the FDIC issued Final Overdraft Payment Supervisory Guidance on automated overdraft payment programs and warned about product over-use that may harm consumers.[14] In 2015, the CFPB issued public guidance explaining that one or more institutions had acted unfairly and deceptively when they charged certain overdraft fees.[15] Beginning in 2016, the Board publicly discussed issues with unfair fees related to transactions that authorize positive and settle negative.[16] In July 2018, the Board issued a Consumer Compliance Supervision Bulletin finding certain overdraft fees assessed based on the account's available balance to be an unfair practice in violation of section 5 of the FTC Act.[17] In June 2019, the FDIC issued its Consumer Compliance Supervisory Highlights and raised risks regarding certain use of the available balance method.[18] In September 2022, the CFPB found that a financial institution had engaged in unfair and abusive conduct when it charged APSN fees.

Analysis

Violations of the Consumer Financial Protection Act

The CFPA prohibits conduct that constitutes an unfair act or practice. An act or practice is unfair when: (1) It causes or is likely to cause substantial injury to consumers that is not reasonably avoidable by consumers; and (2) The injury is not outweighed by countervailing benefits to consumers or to competition.[19]

An unanticipated overdraft fee occurs when financial institutions assess overdraft fees on transactions that a consumer would not reasonably expect would give rise to such fees. The CFPB has observed that in many circumstances, financial institutions have created serious obstacles to consumers making informed decisions about their use of overdraft services. Overdraft practices are complex—and differ among institutions. Even if a consumer closely monitors their

[4] CFPB, Study of Overdraft Programs: A White Paper of Initial Data Findings, at 16 (June 2013), *available at https://files.consumerfinance.gov/f/201306_cfpb_whitepaper_overdraft-practices.pdf.*

[5] *Id.* at 11–12.

[6] *Id.* at 16–17.

[7] 70 FR 9127 (Feb. 24, 2005).

[8] 70 FR 29582 (May 24, 2005).

[9] 15 U.S.C. 45.

[10] 73 FR 28904 (May 19, 2008).

[11] 74 FR 5584 (Jan. 29, 2009). The rule also addressed balance disclosures that institutions provide to consumers through automated systems.

[12] Public Law 90–321, 92 Stat. 3728 (Nov. 10, 1978), codified as amended at 15 U.S.C. 1693 *et seq.*

[13] 74 FR 59033 (Nov. 17, 2009).

[14] FDIC, Final Overdraft Payment Supervisory Guidance, FIL–81–2010 (Nov. 24, 2010), *available at https://www.fdic.gov/news/financial-institution-letters/2010/fil10081.pdf.*

[15] CFPB Supervisory Highlights, Winter 2015, at 8–9, *available at https://files.consumerfinance.gov/f/201503_cfpb_supervisory-highlights-winter-2015.pdf.*

[16] Interagency Overdraft Services Consumer Compliance Discussion (Nov. 9, 2016), *available at https://www.consumercomplianceoutlook.org/outlook-live/2016/interagency-overdraft-services-consumer-compliance-discussion/* (follow ''Presentation Slides'' hyperlink), at slides 20–21.

[17] *See* Federal Reserve Board, Consumer Compliance Supervision Bulletin 12 (July 2018), *available at https://www.federalreserve.gov/publications/files/201807-consumer-compliance-supervision-bulletin.pdf* (stating that it had identified ''a UDAP violation . . . when a bank imposed overdraft fees on [point-of-sale] transactions based on insufficient funds in the account's available balance at the time of posting, even though the bank had previously authorized the transaction based on sufficient funds in the account's available balance when the consumer entered into the transaction'').

[18] FDIC, Consumer Compliance Supervisory Highlights 2–3 (June 2019), *available at https://www.fdic.gov/regulations/examinations/consumercomplsupervisoryhighlights.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery.* The agency referred to the available balance method as assessing overdraft fees based on the consumer's ''available balance'' rather than the consumer's ''ledger balance.'' The agency stated that use of the available balance method ''creates the possibility of an institution assessing overdraft fees in connection with transactions that did not overdraw the consumer's account,'' and that entities could mitigate risk ''[w]hen using an available balance method, [by] ensuring that any transaction authorized against a positive available balance does not incur an overdraft fee, even if the transaction later settles against a negative available balance.''

[19] CFPA sections 1031, 1036, 12 U.S.C. 5531, 5536.

account balances and carefully calibrates their spending in accordance with the balances shown, they can easily incur an overdraft fee they could not reasonably anticipate because financial institutions use processes that are unintelligible for many consumers and that consumers cannot control. Though financial institutions may provide disclosures related to their transaction processing and overdraft assessment policies, these processes are extraordinarily complex, and evidence strongly suggests that, despite such disclosures, consumers face significant uncertainty about when transactions will be posted to their account and whether or not they will incur overdraft fees.[20]

For example, even when the available balance on a consumer's account—that is, the balance that, at the time the consumer initiates the transaction, would be displayed as available to the consumer—is sufficient to cover a debit card transaction at the time the consumer initiates it, the balance on the account may not be sufficient to cover it at the time the debit settles. The account balance that is not reduced by any holds from pending transactions is often referred to as the ledger balance. The available balance is generally the ledger balance plus any deposits that have not yet cleared but are made available, less any pending (*i.e.,* authorized but not yet settled) debits. Since consumers can easily access their available balance via mobile application, online, at an ATM, or by phone, they reasonably may not expect to incur an overdraft fee on a debit card transaction when their balance showed there were sufficient available funds in the account to pay the transaction at the time they initiated it. Such transactions, which industry commonly calls ''authorize positive, settle negative'' or APSN transactions, thus can give rise to unanticipated overdraft fees.

This Circular highlights potentially unlawful patterns of financial institution practices regarding unanticipated overdraft fees and provides some examples of practices that might trigger liability under the CFPA. This list of examples is illustrative and not exhaustive.[21] Enforcers should closely scrutinize whether and when charging overdraft fees may contravene Federal consumer financial law. A ''substantial injury'' typically takes the form of monetary harm, such as fees or costs paid by consumers because of the unfair act or practice. In addition, actual injury is not required; a significant risk of concrete harm is sufficient.[22] An injury is not reasonably avoidable by consumers when consumers cannot make informed decisions or take action to avoid that injury. Injury that occurs without a consumer's knowledge or consent, when consumers cannot reasonably anticipate the injury, or when there is no way to avoid the injury even if anticipated, is not reasonably avoidable. Finally, an act or practice is not unfair if the injury it causes or is likely to cause is outweighed by its consumer or competitive benefits.

Charging an unanticipated overdraft fee may generally be an unfair act or practice. Overdraft fees inflict a substantial injury on consumers. Such fees can be as high as $36; thus consumers suffer a clear monetary injury when they are charged an unexpected overdraft fee. Depending on the circumstances of the fee, such as when intervening transactions settle against the account or how the financial institution orders the transactions at the end of the banking day, consumers could be assessed more than one such fee, further exacerbating the injury. These overdraft fees are particularly harmful for consumers, as consumers likely cannot reasonably anticipate them and thus plan for them.

As a general matter, a consumer cannot reasonably avoid unanticipated overdraft fees, which by definition are assessed on transactions that a consumer would not reasonably anticipate would give rise to such fees. There are a variety of reasons consumers might believe that a transaction would not incur an overdraft fee, because financial institutions use complex policies to assess overdraft fees that are likely to be unintelligible to many consumers. These policies include matters such as the timing gap between authorization and settlement and the significance of that gap, the amount of time a credit may take to be posted on an account, the use of one kind of balance over another for fee calculation purposes, or the order of transaction processing across different types of credit and debits. Mobile banking and the widespread use of debit card transactions could create a consumer expectation that account balances can be closely monitored. Consumers who make use of these tools may reasonably think that the balance shown in their mobile banking app, online, by telephone, or at an ATM, for example, accurately reflects the balance that they have available to conduct a transaction and, therefore, that conducting the transaction will not result in being assessed one or more overdraft fees. But unanticipated overdraft fees are caused by often convoluted settlement processes of financial institutions that occur after the consumer enters into the transaction, the intricacies of which are explained only in fine print, if at all.

Consumers are likely to reasonably expect that a transaction that is authorized at point of sale with sufficient funds will not later incur overdraft fees. Consumers may understand their account balance based on keeping track of their expenditures, or increasingly through the use of mobile and online banking, where debit card transactions are immediately reflected in mobile and online banking balances. Consumers may reasonably assume that when they have sufficient available balance in their account at the time they entered into the transaction, they will not incur overdraft fees for that transaction. But consumers generally cannot reasonably be expected to understand and thereby conduct their transactions to account for the delay between authorization and settlement—a delay that is generally not of the consumers' own making but is the product of payment systems. Nor can consumers control the methods by which the financial institution will settle other transactions—both transactions that precede and that follow the current one—in terms of the balance calculation and ordering processes that the financial institution uses, or the methods by which prior deposits will be taken into account for overdraft fee purposes.[23]

The injury from unanticipated overdraft fees likely is not outweighed by countervailing benefits to consumers or competition. Where a financial institution has authorized a debit card transaction, the institution is obligated to pay the transaction, irrespective of whether an overdraft fee is assessed. Access to overdraft programs therefore is not a countervailing benefit to the

[20] *See, e.g.,* CFPB, Consumer voices on overdraft programs (Nov. 2017), *available at https://files.consumerfinance.gov/f/documents/cfpb_consumer-voices-on-overdraft-programs_report_112017.pdf.*

[21] Depending on the circumstances, assessing overdraft fees may also implicate deceptive or abusive acts or practices, or other unfair acts or practices under CFPA sections 1031, 1036, 12 U.S.C. 5531, 5536.

[22] *See F.T.C.* v. *Wyndham Worldwide Corp.,* 799 F.3d 236, 246 (3d Cir. 2015).

[23] While financial institutions must obtain a consumer's ''opt-in'' before the consumer can be charged overdraft fees on one-time debit card and ATM transactions, 12 CFR 1005.17(b), this does not mean that the consumer intended to make use of those services in these transactions where the consumer believed they had sufficient funds to pay for the transaction without overdrawing their account.

assessment of overdraft fees in such unanticipated circumstances.

Nor does it seem plausible that the ability to generate revenue through unanticipated overdraft fees allows for lower front-end account or maintenance fees that would outweigh the substantial injury in terms of the total costs of the unanticipated overdraft fees charged to consumers. Indeed, in recent months, several large banks have announced plans to entirely eliminate or significantly reduce overdraft fees.[24] In other consumer finance contexts, research has shown that where back-end fees decreased, companies did not increase front-end prices in an equal amount.[25] But even a corresponding front-end increase in pricing would generally not outweigh the substantial injury from unexpected back-end fees.

As for benefits to competition, economic research suggests that shifting the cost of products from front-end prices to back-end fees risks harming competition by making it more difficult to compete on transparent front-end fees and reduces the portion of the overall cost that is subject to competitive price shopping.[26] This is especially the case, where, as here, the fees likely cannot reasonably be anticipated by consumers. Given that back-end fees are likely to be harmful to competition, it may be difficult for institutions to demonstrate countervailing benefits of this practice. A substantial injury that is not reasonably avoidable and that is not outweighed by such countervailing benefits would trigger liability under existing law.

Examples of Potential Unfair Acts or Practices Involving Overdraft Fees That Consumers Would Not Reasonably Anticipate

In light of the complex systems that financial institutions use for overdraft, such as different balance calculations and transaction processing orders, enforcers should scrutinize situations likely to give rise to unanticipated overdraft fees. The following are non-exhaustive examples of such practices that may warrant scrutiny.

Unanticipated overdraft fees can occur on ''authorize positive, settle negative'' or APSN transactions, when financial institutions assess an overdraft fee for a debit card transaction where the consumer had sufficient available balance in their account to cover the transaction at the time the consumer initiated the transaction and the financial institution authorized it, but due to intervening authorizations, settlement of other transactions (including the ordering in which transactions are settled), or other complex processes, the financial institution determined that the consumer's balance was insufficient at the time of settlement.[27] These unanticipated overdraft fees are assessed on consumers who are opted in to overdraft coverage for one-time debit card and ATM transactions, but they likely did not expect overdraft fees for these transactions.

The following table (Table 1) shows an example of unanticipated overdraft fees involving a debit card transaction with an intervening debit transaction. The consumer is charged an overdraft fee even though the consumer's available balance was positive at the time the consumer entered into the debit card transaction.

TABLE 1—UNANTICIPATED OVERDRAFT FEE ASSESSED THROUGH APSN WITH INTERVENING DEBIT TRANSACTION

Description	Transaction	Available balance	Ledger balance
Day 1:			
Opening Balance		$100	$100
Debit card transaction—authorized	−$50	50	100
Day 2:			
Preauthorized ACH debit—posted	−120	−70	−20
Overdraft fee	−34	−104	−54
Day 3:			
Debit card transaction—posted	−50	−104	−104
Overdraft fee	−34	−138	−138

For example, as illustrated above in Table 1, on Day 1, a consumer has $100 in her account available to spend based on her available balance displayed. The consumer enters into a debit card transaction that day for $50. On Day 2, a preauthorized ACH debit that the consumer had authorized previously for $120 is settled against her account. The financial institution charges the consumer an overdraft fee. On Day 3, the debit card transaction from Day 1 settles, but by that point the consumer's account balance has been reduced by the $120 ACH debit settling and the $34 overdraft fee, leaving the balance as negative $54 using ledger balance, or negative $104 using available balance. When the $50 debit card transaction settles against the negative balance, the financial institution charges the consumer another overdraft fee. Consumers may not reasonably expect to be charged this second overdraft fee, based on a debit card transaction that has been authorized with a sufficient account balance. The consumer may reasonably expect that if their account balance shows sufficient funds for the transaction just before entering into the

[24] CFPB, ''Comparing overdraft fees and policies across banks'' (Feb. 10, 2022), *available at https://www.consumerfinance.gov/about-us/blog/comparing-overdraft-fees-and-policies-across-banks/.*

[25] Sumit Agarwal, Souphala Chomsisengphet, Neale Mahoney, & Johannes Stroebel, *Regulating Consumer Financial Products: Evidence from Credit Cards,* Quarterly Journal of Economics, Vol. 130, Issue 1 (Feb. 2015), pp. 111–64, at p. 5 & 42–43, *available at https://academic.oup.com/qje/article/130/1/111/2338025?login=true.*

[26] Xavier Gabaix & David Laibson, *Shrouded Attributes, Consumer Myopia, and Information Suppression in Competitive Markets,* Quarterly Journal of Economics, Vol. 121, Issue 2 (May 2006), pp. 505–40, *available at https://pages.stern.nyu.edu/~xgabaix/papers/shrouded.pdf; see also* Steffen Huck & Brian Wallace, *The impact of price frames on consumer decision making: Experimental evidence* (2015), *available athttps://www.ucl.ac.uk/~uctpbwa/papers/price-framing.pdf;* Agarwal et al., *Regulating Consumer Financial Products, supra* note 25; Sumit Agarwal, Souphala Chomsisengphet, Neale Mahoney, & Johannes Stroebel, *A Simple Framework for Establishing Consumer Benefits from Regulating Hidden Fees,* Journal of Legal Studies, Vol. 43, Issue S2 (June 2014), pp. S239–52, *available at https://nmahoney.people.stanford.edu/sites/g/files/sbiybj23976/files/media/file/mahoney_hidden_fees_jls.pdf.*

[27] *See, e.g.,* CFPB Supervisory Highlights, *supra* note 15; Interagency Overdraft Services Consumer Compliance Discussion, *supra* note Error! Bookmark not defined.; Federal Reserve Board, Consumer Compliance Supervision Bulletin, *supra* note Error! Bookmark not defined.; FDIC, Consumer Compliance Supervisory Highlights, *supra* note Error! Bookmark not defined.

transaction, as reflected in their account balance in their mobile application, online, at an ATM, or by telephone, then that debit card transaction will not incur an overdraft fee. Consumers may not reasonably be able to navigate the complexities of the delay between authorization and settlement of overlapping transactions that are processed on different timelines and impact the balance for each transaction. If consumers are presented with a balance that they can view in real-time, they are reasonable to believe that they can rely on it, rather than have overdraft fees assessed based on the financial institution's use of different balances at different times and intervening processing complexities for fee-decisioning purposes.

Certain financial institution practices can exacerbate the injury from unanticipated overdraft fees from APSN transactions by assessing overdraft fees in excess of the number of transactions for which the account lacked sufficient funds. In these APSN situations, financial institutions assess overdraft fees at the time of settlement based on the consumer's available balance reduced by debit holds, rather than the consumer's ledger balance, leading to consumers being assessed multiple overdraft fees when they may reasonably have expected only one.

The following table (Table 2) shows an example of how financial institutions may process overdraft fees on two transactions. The consumer is charged an additional overdraft fee when the financial institution assesses fees based on available balance, because the financial institution is assessing an overdraft fee on a transaction which the institution has already used in making a fee decision on another transaction. By contrast, the consumer would not have been charged the additional overdraft fee if the financial institution used ledger balance.

TABLE 2—UNANTICIPATED OVERDRAFT FEE ASSESSED THROUGH APSN BY FINANCIAL INSTITUTION USING AVAILABLE BALANCE FOR FEE DECISION

Description	Transaction	Available balance	Ledger balance
Day 1:			
Opening Balance	.....	$100	$100
Debit card transaction—authorized	−$50	50	100
Day 2:			
Preauthorized ACH debit—posted	−60	−10	−40
Overdraft fee (assessed based on available balance)	−34	−44	*6
Day 3:			
Debit card transaction—posted	−50	−44	−44
Overdraft fee	−34	−78	−78

*(But if the financial institution had used ledger balance for fee assessment, the balance would not have been reduced by an overdraft fee.)

For example, as illustrated above in Table 2, on Day 1, a consumer has $100 in her account, which is the amount displayed on her online account. The consumer enters into a debit card transaction that day for $50. On Day 2, a preauthorized ACH debit that the consumer had authorized previously for $60 is settled against her account. Because the debit card transaction from Day 1 has not yet settled, the consumer's ledger balance, prior to posting of the $60 ACH debit, is still $100. But some financial institutions will consider the consumer's balance for purposes of an overdraft fee decision as $50, as already having been reduced by the not-yet-settled debit card transaction from Day 1, and thus the settlement of the $60 ACH debit will take the account negative and incur an overdraft fee. On Day 3, the debit card transaction from Day 1 settles, but by that point the consumer's balance has been reduced by the settlement of the $60 ACH debit plus the overdraft fee for that transaction. If the overdraft fee is $34, the consumer's account has $6 left in ledger balance. The $50 debit card transaction then settles, overdrawing the account and the financial institution charges the consumer an overdraft fee. The consumer would not expect two overdraft fees, since her account balance showed sufficient funds at the time she entered into the debit card transaction to cover either one of them. But in this example, the financial institution charged two overdraft fees, by assessing an overdraft fee on a transaction which the institution has already used in making a fee decision on another transaction. By contrast, a financial institution using ledger balance for the overdraft fee decision would have charged only one overdraft fee.

About Consumer Financial Protection Circulars

Consumer Financial Protection Circulars are issued to all parties with authority to enforce Federal consumer financial law. The CFPB is the principal Federal regulator responsible for administering Federal consumer financial law, *see* 12 U.S.C. 5511, including the Consumer Financial Protection Act's prohibition on unfair, deceptive, and abusive acts or practices, 12 U.S.C. 5536(a)(1)(B), and 18 other ''enumerated consumer laws,'' 12 U.S.C. 5481(12). However, these laws are also enforced by State attorneys general and State regulators, 12 U.S.C. 5552, and prudential regulators including the Federal Deposit Insurance Corporation, the Office of the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, and the National Credit Union Administration. *See, e.g.,* 12 U.S.C. 5516(d), 5581(c)(2) (exclusive enforcement authority for banks and credit unions with $10 billion or less in assets). Some Federal consumer financial laws are also enforceable by other Federal agencies, including the Department of Justice and the Federal Trade Commission, the Farm Credit Administration, the Department of Transportation, and the Department of Agriculture. In addition, some of these laws provide for private enforcement.

Consumer Financial Protection Circulars are intended to promote consistency in approach across the various enforcement agencies and parties, pursuant to the CFPB's statutory objective to ensure Federal consumer financial law is enforced consistently. 12 U.S.C. 5511(b)(4).

Consumer Financial Protection Circulars are also intended to provide transparency to partner agencies regarding the CFPB's intended approach when cooperating in enforcement actions. *See, e.g.,* 12 U.S.C. 5552(b) (consultation with CFPB by State attorneys general and regulators); 12

U.S.C. 5562(a) (joint investigatory work between CFPB and other agencies).

Consumer Financial Protection Circulars are general statements of policy under the Administrative Procedure Act. 5 U.S.C. 553(b). They provide background information about applicable law, articulate considerations relevant to the Bureau's exercise of its authorities, and, in the interest of maintaining consistency, advise other parties with authority to enforce Federal consumer financial law. They do not restrict the Bureau's exercise of its authorities, impose any legal requirements on external parties, or create or confer any rights on external parties that could be enforceable in any administrative or civil proceeding. The CFPB Director is instructing CFPB staff as described herein, and the CFPB will then make final decisions on individual matters based on an assessment of the factual record, applicable law, and factors relevant to prosecutorial discretion.

Rohit Chopra,

Director, Consumer Financial Protection Bureau.

[FR Doc. 2022–23982 Filed 11–4–22; 8:45 am]

BILLING CODE 4810–AM–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Chapter X

Bulletin 2022–06: Unfair Returned Deposited Item Fee Assessment Practices

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Compliance bulletin.

SUMMARY: A Returned Deposited Item is a check that a consumer deposits into their checking account that is returned to the consumer because the check could not be processed against the check originator's account. Blanket policies of charging Returned Deposited Item fees to consumers for all returned transactions irrespective of the circumstances or patterns of behavior on the account are likely unfair under the Consumer Financial Protection Act (CFPA). The Consumer Financial Protection Bureau (Bureau or CFPB) is issuing this bulletin to notify regulated entities how the Bureau intends to exercise its enforcement and supervisory authorities on this issue.

DATES: This bulletin is applicable as of November 7, 2022.

FOR FURTHER INFORMATION CONTACT: Sonya Pass, Senior Legal Counsel, Legal Division, at 202–435–7700. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A Returned Deposited Item is a check that a consumer deposits into their checking account that is returned to the consumer because the check could not be processed against the check originator's account. There are many reasons deposited items can be returned unprocessed. For example, the check originator may not have sufficient funds available in their account to pay the amount stated on the check; the check originator may have directed the issuing depository institution to stop payment; the account referenced on the check may be closed or located in a foreign country; or there may be questionable, erroneous, or missing information on the check, including with respect to the signature, date, account number, or payee name.

Consumers often rely on payments made by check for personal, family, or household purposes. The check may be from another consumer or from a business or entity and may represent a gift, a refund, a payment, or a public benefit. In many circumstances, as discussed below, the check depositor has no control over whether, and likely no reason to anticipate that, the deposited check would be returned. Nor as a general matter can the check depositor verify with the check originator's depository institution prior to depositing a check whether there are sufficient funds in the issuer's account for the check to clear. Yet, many depository institutions have blanket policies of charging fees to the check depositor for Returned Deposited Items for every Returned Deposited Item, irrespective of the circumstances of the particular transaction or patterns of behavior on the account. While certain entities, such as lenders and landlords, may be able to recoup such fees from the check originator, consumers generally cannot.

Under the blanket policies of depository institutions, Returned Deposited Item fees are often in the range of $10–$19. The fees are typically charged in a flat amount on a per-transaction basis. Notably, in the case of checks that are returned for insufficient funds, Returned Deposited Item fees are charged in addition to any non-sufficient funds fees charged by the originating bank to the check originator. Assuming a typical Returned Deposited Item fee of $12 and a non-sufficient funds fee of $35, when the depositor's bank charges a Returned Deposited Item fee to the depositor consumer, and the check originator's bank charges a non-sufficient funds fee to the check originator for the same check, those banks collectively generate $47 in fees from each returned check—$12 to the depositor's bank, $35 to the originator's bank.

II. Violations of the Consumer Financial Protection Act [1]

The Consumer Financial Protection Act (CFPA) prohibits covered persons from engaging in unfair acts or practices.[2] Congress defined an unfair act or practice as one that (A) ''causes or is likely to cause substantial injury to consumers which is not reasonably avoidable,'' and (B) ''such substantial injury is not outweighed by countervailing benefits to consumers or to competition.'' [3]

Blanket policies of charging Returned Deposited Item fees to consumers for all returned transactions irrespective of the circumstances of the transaction or patterns of behavior on the account are likely unfair.

Fees charged for Returned Deposited Items cause substantial injury to consumers. Under the blanket policies of many depository institutions, Returned Deposited Item fees cause monetary injury, in the range of $10–19 for each returned item. Depository institutions that charge Returned Deposited Item fees for returned checks impose concrete monetary harm on a large number of customers.

In many of the instances in which Returned Deposited Item fees are charged, consumers would not be able to reasonably avoid the substantial monetary injury imposed by the fees. An injury is not reasonably avoidable unless consumers are fully informed of the risk and have practical means to avoid it.[4] Under blanket policies of many depository institutions, Returned Deposited Item fees are charged whenever a check is returned because the check originator has insufficient available funds in their account, the check originator instructs the originating depository institution to stop payment, or the check is written against a closed account. But a consumer depositing a check would normally be unaware of and have little to no control over whether a check originator has

[1] As a matter of prosecutorial discretion, the CFPB does not intend to seek monetary relief for potential unfair practices regarding Returned Deposited Item fees assessed prior to November 1, 2023.

[2] 12 U.S.C. 5536(a)(1)(B).

[3] 12 U.S.C. 5531(c)(1).

[4] *See F.T.C.* v. *Neovi, Inc.,* 604 F.3d 1150, 1158 (9th Cir. 2010).

funds in their account, will issue a stop payment instruction, or has closed the account. Nor would a consumer normally be able to verify whether a check will clear with the check originator's depository institution before depositing the check or be able to pass along the cost of the fee to the check originator.

Liability under the prohibition on unfair acts or practices depends on the particular facts and circumstances. The CFPB notes that it is unlikely that an institution will violate the prohibition if the method in which fees are imposed are tailored to only charge consumers who could reasonably avoid the injury. For example, if a depository institution only charges consumers a fee if they repeatedly deposit bad checks from the same originator, or only charges consumers a fee when checks are unsigned, those fees would likely be reasonably avoidable.

Regulation DD, which applies in relevant part to depository institutions except for credit unions,[5] requires depository institutions to disclose fee information on depository accounts to consumers before an account is opened or a service is provided.[6] The returned item fee is among the fees required to be disclosed in the fee schedule when the consumer first opens the account.[7] In applying the CFPA's unfairness prohibition, the Bureau finds persuasive the reasoning of the D.C. Circuit and the Federal Trade Commission (FTC) in *American Financial Services Ass'n* v. *F.T.C.* (*AFSA*).[8] The FTC issued the Credit Practices Rule, which determined that creditor remedies of certain irrevocable wage assignments and non-purchase, non-possessory security interests in household goods are unfair acts or practices. Although the creditor remedies were disclosed and agreed upon in credit contracts, the FTC determined, and the D.C. Circuit upheld, that the provisions were not reasonably avoidable because ''(1) consumers are not, as a practical matter, able to shop and bargain over alternative remedial provisions; and (2) default is ordinarily the product of forces beyond a debtor's control.'' [9] Similar unfairness principles likely apply to account opening disclosures of blanket policies of imposing fees for Returned Deposited Items because, similarly, consumers have limited ability to bargain over specific fee terms in selecting deposit accounts, and consumers are charged these fees in circumstances beyond their control.

The CFPB advises institutions that it may be difficult to show that the injury from blanket policies of charging Returned Deposited Item fees is outweighed by countervailing benefits to consumers or competition. Check processing is a service made broadly available to all depositors of checks, and there is no separate benefit to consumers from having a deposited check returned, as opposed to paid. Benefits to the depository institutions themselves are not necessarily benefits to consumers or competition. Even if they were, the costs to the depository institution of developing and maintaining a reliable check processing system for account holders likely is not attributable to Returned Deposited Item transactions, as those costs are necessary to provide payment services to all check users. Returned Deposited Item fees are also not well-tailored to recoup costs from the consumers actually responsible for the costs to depository institutions of expected losses for the limited circumstances in which the institution cannot recoup funds made available to the depositor on a check that is later returned. Instead, the fee is charged to depositors even where the depository institution incurs no such loss from the returned transaction, and institutions usually do not collect the fee in those limited circumstances where they actually incur a loss (entities only incur a loss because they cannot collect). Depository institutions may argue that consumers may also receive a benefit from a fee to the extent that the fee leads to a decrease in front-end or other costs to the consumer for the product or an increase in the availability or quality of services. However, to the extent the revenue generated by Returned Deposited Item fees charged pursuant to blanket policies causes any discernable consumer benefits in terms of lower front-end costs or better quality or more available services, it is unlikely that a financial institution would be able to show that any such benefits would outweigh the substantial injury to the consumer even in terms of the total amount of such fees paid by the consumer. Indeed, even assuming a 100% pass through of the fee to lower front-end costs for consumers charged the fee, that pass through would not be greater than the total cost of the fees to those consumers.

Deterring consumers from depositing checks in instances where the checks will be returned may benefit consumers and the public interest if the institution's policy and practice are well-tailored to address the issue, do not harm consumers in some other way, minimize losses to the depository institution that would be passed through to consumers, bolster the integrity of the banking system through loss avoidance, and, in the case of fraud, prevent conduct that offends public policy as embodied in statutes and common law. However, deterrence can only be accomplished through the collection of fees in circumstances where the consumer anticipates that a check will be returned but deposits it anyway, such as where a consumer knowingly deposits a counterfeit check. As noted, however, this bulletin is focused on Returned Deposited Item policies that indiscriminately impose fees in circumstances where the consumer does not know the check would be returned. In other words, blanket Returned Deposited Item polices are not targeted to address patterns of behavior indicative of fraud or other circumstances where the consumer reasonably should have anticipated that the check would be returned.[10] With respect to fraud, it is also not apparent that the nature or amount of the fees would result in deterrence beyond other available mechanisms, such as reviewing depositors' accounts, criminal penalties, or more tailored Returned Deposited Item fee policies aimed at consumers who deposit bad checks intentionally or negligently.[11]

As to benefits to competition, economic research suggests that add-on fees may have a distortionary market effect by making it more difficult to compete on transparent front-end prices and reducing the portion of the overall cost that is subject to competitive price shopping.[12] The concern is especially

[5] The National Credit Union Administration has rules governing disclosures for credit unions at 12 CFR 707 *et seq.*

[6] 12 CFR 1030.4.

[7] *See* comment 4(b)(4)–1.iv (listing ''fees associated with checks returned unpaid'' as a type of fee that must be disclosed); Reg DD Sample Form B–4 (describing a fee of $5 for ''Deposited checks returned'').

[8] 767 F.2d 957, 972 (D.C. Cir. 1985).

[9] *Id.* at 976.

[10] As noted above, policies that are tailored to only charge consumers who could reasonably avoid the injury likely would not violate the prohibition on unfairness.

[11] *See F.T.C.* v. *Amazon.com,* No. C14–1038–JCC, 2016 WL 10654030, at *10–11 (W.D. Wash. July 22, 2016) (finding no countervailing benefits where the purported benefits could be achieved without engaging in the conduct that caused substantial injury).

[12] *See* Xavier Gabaix & David Laibson, *Shrouded Attributes, Consumer Myopia, and Information Suppression in Competitive Markets,* Quarterly Journal of Economics, Vol. 121, Issue 2 (May 2006), pp.505–40, *available at https://pages.stern.nyu.edu/~xgabaix/papers/shrouded.pdf; see also* Steffen Huck & Brian Wallace, *The impact of price frames on consumer decision making: Experimental*

Continued

heightened for back-end penalty fees which are often not subject to the competitive process: firms typically have not competed for customers based on penalty fee pricing and consumers do not shop on the basis of fees they do not intend to incur. Indeed, economic research suggests that consumer decision making is impaired by hidden or shrouded pricing regimes.[13] Given these harms to competition, the CFPB advises institutions that there is a substantial risk of violating the prohibition on unfair acts or practices with respect to this practice.

III. Regulatory Matters

This is a general statement of policy under the Administrative Procedure Act. It provides background information about applicable law and articulates considerations relevant to the Bureau's exercise of its authorities. It does not confer any rights of any kind. The Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis for general statements of policy.[14] It also does not impose any new or revise any existing recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring approval by the Office of Management and Budget under the Paperwork Reduction Act of 1995.[15]

Rohit Chopra,

Director, Consumer Financial Protection Bureau.

[FR Doc. 2022–23933 Filed 11–4–22; 8:45 am]

BILLING CODE 4810–AM–P

evidence (2015), *available at https://www.ucl.ac.uk/~uctpbwa/papers/price-framing.pdf;* Sumit Agarwal, Souphala Chomsisengphet, Neale Mahoney, & Johannes Stroebel, *Regulating Consumer Financial Products: Evidence from Credit Cards,* Quarterly Journal of Economics, Vol. 130, Issue 1 (Feb. 2015), pp. 111–64, at p.5 & 42–43, *available at https://academic.oup.com/qje/article/130/1/111/2338025?login=true;* Sumit Agarwal, Souphala Chomsisengphet, Neale Mahoney, & Johannes Stroebel, *A Simple Framework for Establishing Consumer Benefits from Regulating Hidden Fees,* Journal of Legal Studies, Vol. 43, Issue S2 (June 2014), pp.S239–52, *available at https://nmahoney.people.stanford.edu/sites/g/files/sbiybj23976/files/media/file/mahoney_hidden_fees_jls.pdf;* Glenn Ellison, *A Model of Add-On Pricing,* Quarterly Journal of Economics, Vol. 120, Issue 2 (May 2005), pp.585–637, available at *https://economics.mit.edu/files/7605*.

[13] *See* Gabaix & Laibson, *supra* note 12; Huck & Wallace, *supra* note 12; Agarwal *et al., Regulating Consumer Financial Products, supra* note 12; Agarwal *et al., A Simple Framework, supra* note 12; Ellison, *supra* note 12.

[14] 5 U.S.C. 603(a), 604(a).

[15] 44 U.S.C. 3501–3521.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1402; Project Identifier MCAI–2022–01094–R; Amendment 39–22227; AD 2022–22–12]

RIN 2120–AA64

Airworthiness Directives; Bell Textron Inc., Erickson 214 Holdings, LLC, Leonardo S.p.a., and Various Restricted Category Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Bell Textron Inc., Model 204B, 205A, 205A–1, 205B, 210, 212, 412, 412CF, and 412EP helicopters; certain Erickson 214 Holdings, LLC, Model 214B and 214B–1 helicopters; certain Leonardo S.p.a. Model AB412 and AB412 EP helicopters; and certain various restricted category helicopters. This AD was prompted by reports of two in-service failures of forward crosstubes due to fatigue damage and the issuance of newly established life limits. This AD requires determining the total number of landings on certain part-numbered forward crosstubes and incorporating requirements (airworthiness limitations) into existing maintenance records. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective November 22, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 22, 2022.

The FAA must receive comments on this AD by December 22, 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 *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.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1402; 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 mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For service information identified in this final rule, contact Dart Aerospace Ltd. 1270 Aberdeen Street Hawkesbury, ON, K6A 1K7 Canada; telephone 1 613 632 5200; email *support@dartaero.com;* internet dartaerospace.com.
- You may view this service information 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. It is also available at *regulations.gov* under Docket No. FAA–2022–1402.

FOR FURTHER INFORMATION CONTACT: Elizabeth Dowling, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7300; email *9-AVS-NYACO-COS@FAA.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–1402; Project Identifier MCAI–2022–01094–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, 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 final rule 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 *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

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 AD 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 AD, 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 AD. Submissions containing CBI should be sent to Elizabeth Dowling, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7300; email *9-AVS-NYACO-COS@FAA.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada, which is the aviation authority for Canada, issued Transport Canada AD CF–2022–46, dated August 12, 2022 (Transport Canada AD CF–2022–46), to correct an unsafe condition for Bell Textron Inc., Model 204B, 205A–1, 205B, 212, 214B, 214B–1, 412, 412 CF, and 412 EP helicopters, which are modified in accordance with Transport Canada Supplemental Type Certificate (STC) SH01–9 and installed with Dart Aerospace Ltd. high gear forward crosstube part number (P/N) D212–664–101 or P/N D212–664–101B. Transport Canada advises of reports of two in-service failures of Dart Aerospace Ltd. forward crosstube P/N D212–664–101 on Bell Textron Inc., Model 412 helicopters. Transport Canada further advises the forward crosstube fractured during landing, and both failures were due to fatigue damage and involved forward crosstubes which had accumulated more than 20,000 landings.

Additionally, Transport Canada advises if a forward crosstube fails without timely mitigating action from the pilot during landing, the helicopter could contact the ground causing damage to the fuselage and injury to occupants. Transport Canada advises that Dart Aerospace Ltd., issued a revision to the Airworthiness Limitations Section (ALS) of its Instructions for Continued Airworthiness, which establishes a new lift limit for forward crosstubes P/N D212–664–101 and P/N D212–664–101B.

Accordingly, Transport Canada AD CF–2022–46 requires incorporating the newly established airworthiness limitations for forward crosstubes P/N D212–664–101 and P/N D212–664–101B by amending Chapter 4 Airworthiness Limitations of Dart Aerospace Ltd., ICA–D212–664 by inserting Revision 12, dated September 30, 2021. Transport Canada AD CF–2022–46 also requires removing forward crosstubes P/N D212–664–101 and P/N D212–664–101B with more than 20,000 landings from service and allows the use of superseding or later revisions of the ALS that are approved by Transport Canada.

FAA STC No. SR01298NY approves the installation of forward crosstubes P/N D212–664–101 and P/N D212–664–101B on Bell Textron Inc., Model 204B, 205A, 205A–1, 205B, 210, 212, 412, 412CF, and 412EP helicopters; Erickson 214 Holdings, LLC, Model 214B and 214B–1; Leonardo S.p.a. Model AB412 and AB412 EP helicopters; and restricted category Model HH–1K, TH–1F, TH–1L, UH–1A, UH–1B, UH–1E, UH–1F, UH–1H, UH–1L, and UH–1P helicopters. Accordingly, this AD applies to those model helicopters.

You may examine Transport Canada AD CF–2022–46 in the AD docket at *regulations.gov* under Docket No. FAA–2022–1402.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Chapter 4—Airworthiness Limitations (04–00–00), approved March 23, 2022, of Dart Aerospace Ltd., Instructions for Continued Airworthiness, ICA–D212–664, Crosstube Installation, Revision 12, dated September 30, 2021 (Dart ICA–D212–664 Rev 12). This service information specifies life limits for various part-numbered crosstubes. This revision of the service information adds a newly established life limit for forward crosstubes P/N D212–664–101 and P/N D212–664–101B.

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 **ADDRESSES**.

FAA's Determination

These helicopters have been approved by the aviation authority of Canada and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with Canada, Transport Canada, its technical representative, has notified the FAA of the unsafe condition described in its AD. The FAA is issuing this AD after determining that the unsafe condition described previously is likely to exist or develop on other helicopters the same type designs.

AD Requirements

This AD requires determining the total number of landings on forward crosstubes P/N D212–664–101 and P/N D212–664–101B, and if the total number of landings cannot be determined, calculating the total number of landings. For a forward crosstube that has accumulated 20,000 or more total landings or if the total number of landings cannot be calculated, this AD requires removing the forward crosstube from service. This AD also requires incorporating requirements (airworthiness limitations) into existing maintenance records, which are identified in Dart ICA–D212–664 Rev 12, as described previously.

ADs Mandating Airworthiness Limitations

The FAA has previously mandated airworthiness limitations by mandating each airworthiness limitation task (*e.g.,* inspections and replacements (life limits)) as an AD requirement or issuing ADs that require revising the ALS of the existing maintenance manual or instructions for continued airworthiness to incorporate new or revised inspections and life limits. This AD, however, requires operators to incorporate into maintenance records required by 14 CFR 91.417(a)(2) or 135.439(a)(2), as applicable for your rotorcraft, the requirements (airworthiness limitations) identified in the ALS service information, as described previously. The FAA does not intend this as a substantive change. For these ADs, the ALS requirements for operators are the same but are complied with differently. Requiring the incorporation of the new ALS requirements into the existing maintenance records, rather than requiring individual ALS tasks (*e.g.,* repetitive inspections and replacements), requires operators to record AD compliance once after updating the maintenance records, rather than after every time the ALS task is completed.

Differences Between This AD and the Transport Canada AD

Transport Canada AD CF–2022–46 applies to Bell Textron Inc. Model 204B, 205A–1, 205B, 212, 214B, 214B–1, 412, 412 CF, and 412 EP helicopters which are modified in accordance with Transport Canada STC SH01–9 and installed with Dart Aerospace Ltd. high gear forward crosstube P/N D212–664–101 or P/N D212–664–101B; whereas, this AD applies to Bell Textron Inc.,

Model 204B, 205A, 205A–1, 205B, 210, 212, 412, 412CF, and 412EP helicopters; Erickson 214 Holdings, LLC, Model 214B and 214B–1 helicopters; Leonardo S.p.a. Model AB412 and AB412 EP helicopters; and all restricted category Model HH–1K, TH–1F, TH–1L, UH–1A, UH–1B, UH–1E, UH–1F, UH–1H, UH–1L, and UH–1P helicopters, with Dart Aerospace Ltd. high gear forward crosstube P/N D212–664–101 or P/N D212–664–101B installed under (FAA) STC No. SR01298NY.

This AD requires determining the total number of landings on an affected forward crosstube, defines what is considered a ''landing'' for the purposes of this AD, requires a particular method to calculate the total number of landings if it cannot be determined, and requires removing an affected forward crosstube for which the total number of landings cannot be determined from service, whereas, Transport Canada AD CF–2022–46 does not contain that information or those actions. Transport Canada AD CF–2022–46 allows the use of superseding or later revisions of Dart ICA–D212–664 Rev 12 that are approved by Transport Canada, whereas this AD does not because referring to documents that do not exist at the time a final rule is published violates Office of the Federal Register (OFR) regulations regarding approval of materials ''incorporated by reference'' in rules.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule because the forward crosstube is a component of a helicopter's landing gear and is critical to the control of the helicopter during landing. The FAA also has no information pertaining to the number of forward crosstubes that have already met or exceeded the newly established life limit, and fatigue beyond allowable limits of a forward crosstube could lead to instantaneous failure at any time without any previous indications. In light of this, the initial actions required by this AD must be accomplished before further flight. This compliance time is shorter than the time necessary for the public to comment and for publication of the final rule. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forego notice and comment.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without prior notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects up to 594 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 AD.

Determining the total number of landings on an affected forward crosstube takes about 0.5 work-hour for an estimated cost of $43 per helicopter and up to $25,542 for the U.S. fleet. Removing an affected forward crosstube from service and replacing it with an airworthy part takes about 8 work-hours and parts cost about $6,487 for an estimated cost of $7,167 per helicopter. Incorporating requirements (airworthiness limitations) into existing maintenance records takes about 2 work-hours for an estimated cost of $170 per helicopter and up to $100,980 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

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 that this AD:

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

(2) Will not affect intrastate aviation in Alaska.

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:

2022–22–12 Bell Textron Inc., Erickson 214 Holdings, LLC, Leonardo S.p.a., and Various Restricted Category Helicopters: Amendment 39–22227; Docket No. FAA–2022–1402; Project Identifier MCAI–2022–01094–R.

(a) Effective Date

This airworthiness directive (AD) is effective November 22, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the helicopters identified in paragraphs (c)(1) through (4) of this AD with a Dart Aerospace Ltd. high gear forward crosstube part number (P/N) D212–

664–101 or P/N D212–664–101B installed under Supplemental Type Certificate No. SR01298NY:

(1) Bell Textron Inc., Model 204B, 205A, 205A–1, 205B, 210, 212, 412, 412CF, and 412EP helicopters, certificated in any category;

(2) Erickson 214 Holdings, LLC, Model 214B and 214B–1 helicopters, certificated in any category;

(3) Leonardo S.p.a. Model AB412 and AB412 EP helicopters, certificated in any category; and

(4) Various restricted category helicopters:

(i) Model HH–1K helicopters; current type certificate holders include, but are not limited to, Rotorcraft Development Corporation;

(ii) Model TH–1F helicopters; current type certificate holders include, but are not limited to, Robinson Air Crane Inc.; Rotorcraft Development Corporation; and Tamarack Helicopters, Inc.;

(iii) Model TH–1L helicopters; current type certificate holders include, but are not limited to, Bell Textron Inc.; Overseas Aircraft Support, Inc.; and Rotorcraft Development Corporation;

(iv) Model UH–1A helicopters; current type certificate holders include, but are not limited to, Richards Heavylift Helo, Inc.;

(v) Model UH–1B helicopters; current type certificate holders include, but are not limited to, International Helicopters, Inc.; Overseas Aircraft Support, Inc.; Red Tail Flying Services, LLC; Richards Heavylift Helo, Inc.; Rotorcraft Development Corporation; Southwest Florida Aviation International, Inc.; and WSH, LLC (type certificate previously held by San Joaquin Helicopters);

Note 1 to paragraph (c)(4)(v): Helicopters with an SW204 or SW204HP designation are Southwest Florida Aviation International, Inc., Model UH–1B helicopters.

(vi) Model UH–1E helicopters; current type certificate holders include, but are not limited to, Bell Textron Inc.; Overseas Aircraft Support, Inc.; Rotorcraft Development Corporation; Smith Helicopters; and West Coast Fabrications;

(vii) Model UH–1F helicopters; current type certificate holders include, but are not limited to, AST, Inc.; California Department of Forestry; Robinson Air Crane, Inc.; Rotorcraft Development Corporation; and Tamarack Helicopters, Inc.;

(viii) Model UH–1H helicopters; current type certificate holders include, but are not limited to, Arrow Falcon Exporters, Inc.; Global Helicopter Technology, Inc.; Hagglund Helicopters, LLC; JJASPP Engineering Services LLC; Northwest Rotorcraft, LLC; Overseas Aircraft Support, Inc.; Richards Heavylift Helo, Inc.; Rotorcraft Development Corporation; Southwest Florida Aviation International, Inc.; and Tamarack Helicopters, Inc.;

Note 2 to paragraph (c)(4)(viii): Helicopters with an SW205 designation are Southwest Florida Aviation International, Inc., Model UH–1H helicopters.

(ix) Model UH–1L helicopters; current type certificate holders include, but are not limited to, Bell Textron Inc.; Overseas Aircraft Support, Inc.; and Rotorcraft Development Corporation; and

(x) Model UH–1P helicopters; current type certificate holders include, but are not limited to, Robinson Air Crane, Inc.; and Rotorcraft Development Corporation.

(d) Subject

Joint Aircraft System Component (JASC) Code: 3222, Nose/Tail Landing Gear Structure/Axle.

(e) Unsafe Condition

This AD was prompted by reports of two in-service failures of forward crosstubes due to fatigue damage and the issuance of newly established life limits. The FAA is issuing this AD to prevent failure of a forward crosstube, which could result in collapse of the landing gear and subsequent loss of control of the helicopter during landing.

(f) Compliance

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

(g) Requirements

(1) Before further flight after the effective date of this AD, accomplish the actions in paragraph (g)(1)(i) and (ii) of this AD.

(i) Determine the total number of landings on the forward crosstube. For the purposes of this AD, a landing is counted anytime a helicopter contacts the ground regardless of the duration of the landing and regardless of whether the engine is shutdown. If the total number of landings cannot be determined, calculate the total number of landings by multiplying the total hours time-in-service on the forward crosstube by 10.

(ii) For a forward crosstube that has accumulated 20,000 or more total landings or if the total number of landings of a forward crosstube cannot be calculated as required in paragraph (g)(1)(i) of this AD, before further flight, remove the forward crosstube from service.

(2) Within 30 days after the effective date of this AD, incorporate into maintenance records required by 14 CFR 91.417(a)(2) or 135.439(a)(2), as applicable for your helicopter, the requirements (airworthiness limitations) specified in Chapter 4—Airworthiness Limitations (04–00–00), approved March 23, 2022, of Dart Aerospace Ltd., Instructions for Continued Airworthiness, ICA–D212–664, Crosstube Installation, Revision 12, dated September 30, 2021.

(h) Provisions for Alternative Requirements (Airworthiness Limitations)

After the actions required by this paragraph (g)(2) of this AD have been done, no alternative actions and associated thresholds and intervals, including life limits, may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (i)(1) of this AD.

(i) 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 (j) 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.

(j) Related Information

For more information about this AD, contact Elizabeth Dowling, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7300; email *9-AVS-NYACO-COS@FAA.gov.*

(k) 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) Chapter 4—Airworthiness Limitations (04–00–00), approved March 23, 2022, of Dart Aerospace Ltd., Instructions for Continued Airworthiness, ICA–D212–664, Crosstube Installation, Revision 12, dated September 30, 2021.

(ii) [Reserved]

(3) For service information identified in this AD, contact Dart Aerospace Ltd. 1270 Aberdeen Street Hawkesbury, ON, K6A 1K7 Canada; telephone 1 613 632 5200; email *support@dartaero.com;* internet dartaerospace.com.

(4) You may view this service information 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.

(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: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on October 21, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–24342 Filed 11–3–22; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0970; Airspace Docket No. 22–ASW–18]

RIN 2120–AA66

Revocation of Class E Airspace; Stratford, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action removes the Class E airspace at Stratford, TX. This action is due to the cancellation of the instrument procedures at the associated airport, and the airspace no longer being required.

DATES: Effective 0901 UTC, February 23, 2023. 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 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *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: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

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 removes the Class E airspace extending upward from 700 feet above the surface at Stratford Field, Stratford, TX, due to the cancellation of the instrument procedures at this airport, and the airspace no longer being required.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 50590; August 17, 2022) for Docket No. FAA–2022–0970 to remove the Class E airspace at Stratford, TX. 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 7400.11G, dated August 19, 2022, and effective September 15, 2022, 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 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR 71 removes the Class E airspace extending upward from 700 feet above the surface at Stratford Field, Stratford, TX.

This action is the result of the instrument procedures at this airport being cancelled, and the airspace no longer being required.

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 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 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

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

* * * * *

ASW TX E5 Stratford, TX [Remove]

Issued in Fort Worth, Texas, on October 31, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–23996 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0924; Airspace Docket No. 22–ASW–17]

RIN 2120–AA66

Amendment of Class E Airspace; Eagle Lake, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Eagle Lake, TX. This action is due to an airspace review conducted as part of the decommissioning of the Eagle Lake very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program. The geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, February 23, 2023. 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 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *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: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

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 form 700 feet above the surface at Eagle Lake Airport, Eagle Lake, TX, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 50592; August 17, 2022) for Docket No. FAA–2022–0924 to amend the Class E airspace at Eagle Lake, TX. 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 7400.11G, dated August 19, 2022, and effective September 15, 2022, 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 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR 71 amends the Class E airspace extending upward from 700 feet above the surface at Eagle Lake Airport, Eagle Lake, TX, by removing the Eagle Lake VOR/DME and associated extension from the airspace legal description; and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is due to an airspace review conducted as part of the decommissioning of the Eagle Lake VOR, which provided navigation information for the instrument procedures at these airports, as part of the VOR MON Program.

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 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 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

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

* * * * *

ASW TX E5 Eagle Lake, TX [Amended]

Eagle Lake Airport, TX
(Lat. 29°36′00″ N, long. 96°19′19″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Eagle Lake Airport.

Issued in Fort Worth, Texas, on October 31, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–23995 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2020–0755–; Airspace Docket No. 19–AAL–83]

RIN 2120–AA66

Amendment of R–2206 and Establishment of Restricted Areas R–2206B, R–2206C, R–2206D, R–2206E, R–2206F, and R–2206G; Clear, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends restricted area R–2206 by renaming it R–2206A and establishes six new restricted areas R–2206B, R–2206C, R–2206D, R–2206E, R–2206F, and R–2206G, over Clear, AK. The FAA has determined that these actions are necessary to protect aircraft from the hazardous High-Intensity Radiated Field (HIRF) produced by the Long Range Discrimination Radar (LRDR) and segregate non-participating aircraft.

DATES: Effective date 0901 UTC, December 29, 2022.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, 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 amends an existing restricted area and establishes restricted areas over Clear, AK, to protect operators from activities deemed hazardous to nonparticipating aircraft.

History

Notice of Proposed Rulemaking

The FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (86 FR 11194; February 24, 2021), amending R–2206 by renaming it and establishing restricted areas R–2206B, R–2206C, R–2206D, R–2206E, R–2206F, and R–2206G over Clear, AK. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal.

History of R–2206 and Clear Airport

R–2206 was initially established as R–20 on January 1, 1961 (25 FR 12174), over the Clear Air Force Station (AFS) [1] at Clear, AK, to protect the National Airspace System (NAS) while a potential radiation hazard caused by the Ballistic Missile Early Warning System (BMEWS) was assessed by the United States Air Force (USAF). On May 12, 1962, the designation of R–2206 was amended to extend the duration for an indefinite period (27 FR 4553) due to ongoing concern regarding the radiation hazard associated with the BMEWS.

Initially established for private use by the military in support of the BMEWS mission, Clear Airport (PACL) is located less than a ½ Nautical Mile (NM) from the eastern boundary of R–2206. The airport was leased by the Secretary of the Air Force to the State of Alaska on December 20, 1974. The FAA performed an airspace review and issued a letter of ''no objection'' to convert the airport from private to public use on January 20, 1976.[2] Subsequently, the land (1,814 acres) on which PACL is located was declared surplus by the USAF and conveyed to the State of Alaska in the late 1980s. PACL has remained in its original location since its conversion to a public use airport.

The FAA did not object to the proximity of R–2206 to the airport when it was converted to a public use airport because, at the time of conversion, there was no established standard to separate restricted areas and public use airports. The FAA later established that a restricted area must exclude airspace 1,500 feet above ground level (AGL) and below that is within a 3 NM radius of airports available for public use (''1,500AGL/3NM'') in the September 16, 1993, edition of FAA Order JO 7400.2, *Procedures for Handling Airspace Matters*.[3] The FAA therefore considers the original R–2206 as excepted from the subsequently established ''1,500AGL/3NM'' restricted area exclusion in FAA Order JO 7400.2.

Drivers for Missile Defense Agency's (MDA) LRDR

Section 235(a)(1) of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2014 required Missile Defense Agency to deploy a LRDR to protect the United States against long-range ballistic missile threats from the Democratic People's Republic of Korea (North Korea) and to locate the LRDR ''at a location optimized to support the defense of the homeland of the United States.'' Public Law 113–66; 10 U.S.C. 2431 (Dec. 26, 2013). Section 235(b)(1) of the NDAA for FY 2014 also required the Secretary of Defense to ensure the capability ''to deploy additional tracking and discrimination sensor capabilities to support the defense of the homeland of the United States from future long-range ballistic missile threats that emerge from Iran.''

Section 1684 of the NDAA for FY 2016 expressed ''the sense of Congress that additional missile defense sensor discrimination capabilities are needed to enhance the protection of the United States homeland against potential long-range ballistic missiles from Iran that, according to the Department of Defense, could soon be obtained by Iran as a result of its active space launch program.'' Public Law 114–92; 10 U.S.C. 2431 (Jan. 6, 2015). Moreover, Section 1684(d)(1) of the NDAA for FY 2016 established a December 31, 2020, deadline for the deployment of a defensive system.

After a detailed evaluation of cost, schedule, and performance as well as other mission related factors, the Department of Defense (DoD) determined that Clear AFS was the preferred site for the LRDR and designated the USAF as the lead service for LRDR.

[1] On June 15, 2021, Clear AFS was renamed Clear Space Force Station. The renaming was part of ongoing efforts to develop the United States Space Force (USSF). Throughout this document, for continuity with the proposal and clarity, the FAA will use term Clear AFS.

[2] A copy of this letter is in the docket for this rulemaking.

[3] The current version of this Order is accessible at: *https://www.faa.gov/documentLibrary/media/Order/7400.2M_Bsc_w_Chg_1_2_dtd_7_16_20.pdf. See* sub-section 23–1–4, Restricted Area Floor.

Mission of LRDR Program

The mission of the LRDR program is to define, develop, acquire, test, field, and sustain the LRDR as an element of the DoD Ballistic Missile Defense System (BMDS) in support of the Ground-Based Midcourse Defense (GMO) program's Homeland Defense Capability. The LRDR will provide persistent long-range midcourse discrimination, precision tracking, and hit assessment to support the GMO capability against long-range missile threats originating from North Korea and Iran. LRDR contributes to MDA's mission of developing and deploying a layered BMDS to defend the United States from ballistic missile attacks of all ranges in all phases of flight. LRDR's improved discrimination capability increases the defensive capacity of the homeland defense interceptor inventory by enabling the conservation of ground-based interceptors. LRDR also supports additional DoD mission areas such as Space Situational Awareness and Intelligence Data Collection. Changes in operational posture due to the evolving threat, which would result in LRDR deployment with unacceptable levels of HIRF exposure for aviation, necessitate the requirement for additional restricted airspace to support LRDR's critical national defense mission at Clear AFS.

USAF Proposal to the FAA

By memorandum dated September 30, 2019, the USAF submitted a proposal to the FAA to establish two new restricted areas in the vicinity of Clear AFS, to protect the NAS from the HIRF produced by the LRDR. The proposed restricted area requires lateral and vertical limits larger than the current R–2206 to support the deployment of the DoD's LRDR to meet increased warfighter defense and readiness postures. This rule maintains the existing restricted area R–2206 in its current configuration but renames it R–2206A, and supplements this area with six new restricted areas designated R–2206B, R–2206C, R–2206D, R–2206E, R–2206F, and R–2206G. The FAA identified the need for one of the new restricted areas (*i.e.,* R–2206F) that provides an additional 1,100 feet of navigable airspace along Parks Highway to the Northeast of Clear, AK. This additional restricted area allows for a visual route following a known landmark during normal operations. The addition of the new restricted area lead the FAA to re-letter the restricted areas for a more logical sequence (*i.e.,* from low to high on the west side and then from low to high on the east side).

The rule applies the ''1,500AGL/3NM'' restricted area exclusion for PACL for the new restricted areas, with exceptions. The FAA approved a limited deviation from its ''1,500AGL/3NM'' restricted area exclusion standard, published in FAA Order JO 7400.2, paragraph 23–1–4.c., for R–2206D and R–2206E, given the extraordinary nature of the LRDR national defense mission required by Congressional mandate, the limited citing options available to the USAF to achieve its mission, and FAA's ability to identify and implement airspace safety and access mitigations at Clear, AK.

As previously explained, the NDAA for FY 2014 required MDA to deploy a LRDR ''at a location optimized to support the defense of the homeland of the United States.'' Public Law 113–66; 10 U.S.C. 2431 (Dec. 26, 2013). Moreover, MDA was subsequently directed to deploy the system by December 31, 2020. The NDAA for FY 2016 created the LRDR program of record and required ''in a location optimized to support the defense of the homeland of the United States from emerging long-range ballistic missile threats from Iran.'' Public Law 114–328; 10 U.S.C. 2431 (Dec. 23, 2016). To support implementation of this mission, the MDA narrowed the LRDR site selection from 50 possible locations to two locations in Alaska based on evaluative criteria that included, construction and schedule timelines in light of the NDAA mandate, mission assurance, impacts to existing civilian and military infrastructure, and other resource considerations. Of the two remaining sites, only Clear AFS met all of the levied LRDR requirements. The alternative option in Alaska, Eareckson AFS, was ruled out due to remote geographical concerns, which added unacceptable risk to timely and successful deployment as compared to Clear AFS. Moreover, the MDA concluded that the Clear AFS location in Central Alaska offered expanded engagement space necessary to fulfill the LRDR mission. This additional engagement space affords more visibility of hostile threat complexes and greater time to track, discriminate and target lethal incoming objects and results in a much greater probability of successful target intercept. The siting recommendation of Clear AFS was approved in 2016 by the USAF and funding for LRDR at Clear AFS was approved in the NDAA for FY17.[4]

[4] The FAA uploaded a graphical depiction of the restricted areas to the docket for this rulemaking during the NPRM phase.

The FAA emphasizes that any deviations from an FAA Order is reserved for extraordinary circumstances. In this case, the FAA determined that the national defense benefits of a deviation outweigh the costs of any additional airspace safety and access mitigations to manage the safe and efficient operation of the NAS and impacts to PACL. The decision to deviate from FAA Order JO 7400.2 in this rulemaking action is not binding on future determinations by the FAA concerning whether to approve a deviation as each deviation is reviewed on a case-by-case basis. The FAA will review any future requests on their merits, based on the facts and circumstances available at that time and consistent with the FAA's statutory responsibilities.

Activities Within R–2206A–G

The activity to be performed at Clear, AK, within the restricted areas is Ballistic Missile Defense (BMD) of the United States. System testing started in early 2021 and will continue until it is fully integrated into the DoD BMDS. During the system testing phase, the FAA established Title 14 Code of Federal Regulations (CFR) 99.7, special security instructions (SSI), implemented as temporary flight restrictions, as an interim airspace mitigation to protect aviation from the HIRF produced by the LRDR system not covered by R–2206. LRDR is a unique and vital component of the BMDS and will be available continuously both as an early-warning sensor and as an enabler for more effective employment of ground-based interceptors. The LRDR design features high system availability and maintain-while-operate architecture; this ensures that LRDR will be in a continual posture to fight in response to real-word, no-notice events. LRDR also supports additional mission areas including Space Situational Awareness and Intelligence Data Collection.

In routine or normal defensive posture, LRDR will operate at reduced HIRF levels within the restricted areas that provide for the ''1,500AGL/3NM'' restricted area exclusion. This will be accomplished by enforcing main beam elevation limits in the direction of Clear Airport to provide a minimum of 1,500 feet AGL under the portions of restricted areas within 3 NM of the airport. Prescheduled maintenance and calibration activities will also occur during routine or normal posture and would require activation of the additional restricted areas during a few periods per week for a couple of hours at a time. These activities will be scheduled when expected air traffic

around Clear Airport is minimal, with scheduled times openly distributed by Notice to Air Missions (NOTAM) and other outreach mechanisms.

In heightened defensive posture, MDA may require use of all the restricted areas to conduct missile defense or other activities in response to real-world events. During these periods of heightened defensive posture, LRDR will be activated with access to its full field of coverage, which may necessitate activation of all restricted areas; this provides LRDR access to the airspace for defensive actions within 3NM of Clear Airport at and above 400 feet AGL. Besides conducting actual BMDS engagements, LRDR activities that may require temporary activation of all restricted areas include BMDS tests, unique intelligence collection activities such as new foreign space launches, or critical space activities such as collision avoidance involving manned space-flight, satellite break-ups, and satellite deorbits.

Required Coordination Between the FAA, MDA, and USSF

The FAA, MDA, and United States Space Force (USSF) currently have a Letter of Agreement (LOA) in place setting forth the air traffic control (ATC) procedures to use while the SSI implemented as temporary flight restrictions are in place. The LOA establishes authorities, responsibilities, and procedures associated with the coordination of air ambulance flights or other contingencies required for aircraft to fly into and out of the Clear Airport and Healy River Airport (PAHV) during the LRDR operation.

The FAA, MDA, and USSF are currently developing a Letter of Procedure (LOP) that will be effective when the rule goes into effect replacing the LOA now in place for the SSI implemented as temporary flight restrictions. This LOP will remain in place until the LRDR system is fully integrated into the DoD's BMDS. The LOP will address emergency or extraordinary events. The LOP will also address pre-determined NOTAMs to handle the activation and scheduling of the three non-continuous restricted areas (R–2206D–F). The LOP will include procedures for handling national defense no-notice activation from NORAD–USNORTHCOM Command Center, as well as notification times for all other requests, to ensure a NOTAM and notifications to the surrounding areas and aviators can take place with reasonable advance notice prior to activation. Pre-determined actions will provide the framework for rapid adaptation of the special use airspace to handle extraordinary events. The LOP will also address the maintenance of the alert system discussed below. After the LRDR system is fully integrated into the DoD's BMDS, the FAA and the USSF will enter into a new LOP.

Impact on IFR (Instrument Flight Rules) and VFR (Visual Flight Rules) Terminal Ops

In the NPRM, the FAA noted the R–2206 restricted areas would impact IFR routes between Anchorage and Fairbanks, Alaska, including Jet Route J–125, VOR Federal Airway V–436, and Area Navigation (RNAV) Route Q–41. The FAA identified the need for mitigations altering the current airway/route structure to revise the affected airways around the expansion of R–2206. Subsequent to the NPRM, the FAA published a rule for Docket No. FAA–2021–0245 in the **Federal Register** (87 FR 65675, November 1, 2022) amending J–125 and V–436. The rule amended J–125 by removing the route segment between the Anchorage, AK, VHF Omnidirectional Range/Distance Measuring Equipment (VOR/DME) and the Nenana, AK VOR/Tactical Air Navigation (VORTAC) navigational aids because adjacent air traffic service routes J–115, Q–43, and Q–41provided the same enroute capability. The rule also amended V–436 by removing the airway segment between the Talkeetna, AK, VOR/DME and the Nenana, AK, VORTAC navigational aids and replaced it with an airway segment that extends between the Talkeetna VOR/DME and the Fairbanks, AK, VORTAC which moved the airway to transition east of the R–2206 restricted areas. Lastly, Q–41 currently and after the effective date of the rule will remain as published. However, ATC currently and after publication will require radar surveillance in certain segments as a mitigation due to the proximity of the route to the current SSI implemented as temporary flight restrictions and the R–2206 restricted areas.

Anchorage Air Route Traffic Control Center (ARTCC) published that requirement in its Operations Bulletin and briefed all the ARTCC air traffic controllers. With the establishment of the R–2206 restricted areas by this rule, the radar surveillance requirement for aircraft filing and flying the Q–41 route segment affected by the restricted areas will be published in the Anchorage ARTCC's Standard Operating Procedures (SOP) guidance replacing the Operation Bulletin.

As addressed in the NPRM, the FAA reviewed the USAF proposal for impact on arrival and departure flows, Standard Terminal Arrival Route (STAR), Standard Instrument Departure (SID), and departure procedures, and identified a number procedures that needed to be revised to avoid the R–2206 restricted areas. The affected SIDs at Fairbanks International Airport were amended and published in the Flight Information Publication (FLIP) effective August 12, 2021. The affected STARs at Ted Stevens International Airport and the affected instrument approach procedures and obstacle departure procedure at Healy River Airport were amended and are being held to publish in the FLIP effective December 29, 2022. Amendment and publication in the FLIP of the affected SIDs, STARs, instrument approach procedures, and obstacle departure procedure listed in the NPRM ensures the IFR and VFR terminal operations at Fairbanks International Airport, Ted Stevens International Airport, and Healy River Airport are unaffected by the restricted areas.

United States Space Force

The USSF was established on December 20, 2019, when the NDAA for FY 2020 was signed into law. As part of the establishment of the USSF, the using agency unit proposed in the NPRM, 13th Missile Warning Squadron, transitioned from the Air Force Space Command within the USAF to the USSF and was renamed the 13th Space Warning Squadron. The USSF will oversee the LRDR operations at Clear AFS once the system is fully integrated into the DoD's BMDS. Finally, on June 15, 2021, Clear AFS was renamed to Clear Space Force Station (SFS).

Differences From the NPRM

In the NPRM published for Docket No. FAA–2020–0755, the FAA identified an editorial error in describing the proposed altitude floor for restricted area R–2206C. In the preamble of the NPRM, the altitude floor for R–2206C was described incorrectly as 1,100 feet mean sea level (MSL). The correct altitude floor for R–2206C is 1,600 feet MSL. Although the altitude floor for R–2206C was described incorrectly in the preamble of the NPRM, it was described correctly in the proposed regulatory text of the NPRM as 1,600 feet MSL. Therefore, this rule retains the R–2206C designated altitudes listed in the description in the regulatory text as proposed.

Also in the NPRM for Docket No. FAA–2020–0755, editorial errors in describing the proposed altitude floors for restricted areas R–2206B and R–2206D, were identified. In the preamble of the NPRM, the altitude

floors were described incorrectly as 1,100 feet MSL. The correct altitude floor for R–2206B and R–2206D is 1,000 feet MSL. Although the altitude floors for R–2206B and R–2206D were described incorrectly in the preamble of the NPRM, they were described correctly in the proposed regulatory text of the NPRM as 1,000 feet MSL. Therefore, this rule retains the R–2206B and R–2206D designated altitudes listed in the descriptions in the regulatory text as proposed.

Lastly, in the NPRM for Docket No. FAA–2020–0755, the using agency for the restricted area descriptions in the regulatory text was listed as, ''Commander 13th Missile Warning Squadron, Clear, AK.'' However, as a result of the establishment of the USSF and the renaming of the unit to 13th Space Warning Squadron, as noted above, this rule corrects the restricted areas using agency to Commander, 13th Space Warning Squadron, Clear, AK.

Discussion of Comments

The FAA received eleven comments on the NPRM. Ten of the comments were submitted by individuals and one comment was submitted by the Alaska Airmen's Association.

The Alaska Airmen's Association and three other commenters stated that the proposed airspace design may be too complicated based on the FAA's interim approach of establishing Special Security Instructions (SSI) in accordance with 14 CFR 99.7, implemented as a temporary flight restriction, to protect aviation from the HIRF produced during the testing phases of the LRDR. The Alaska Airmen's Association commented that none of the third-party mapping applications are able to display correctly a graphic depiction of the current SSI implemented as temporary flight restrictions identified in the NOTAMs. Commenters also noted that without the ability to precisely determine the status (*i.e.,* active or inactive) of the SSI implemented as temporary flight restrictions, it will likely cause inadvertent and repeated incursions into the temporary flight restrictions.

The FAA acknowledged the concerns about SSI as implemented as temporary flight restrictions and took action to address the issues with the interim approach while developing this final rule. Two NOTAMs were published as an interim approach to protecting aircraft during the LRDR testing phase, one for the continuously active SSI implemented as temporary flight restrictions, which correlate with the designation of R–2206B, C, and G restricted areas and one for the non-continuously active SSI implemented as temporary flight restrictions, which correlate with designation of R–2206D–F restricted areas.

The FAA determined the source of the confusion with these NOTAMs and lack of charted depictions came from the overlapping altitudes of the temporary flight restrictions. The overlapping altitudes of the two SSI implemented as temporary flight restrictions caused errors in the shape files that resulted in the graphical depictions of the flight restricted areas not being displayed on the FAA's Temporary Flight Restriction (TFR) website or third part charting applications. The FAA adjusted the overlapping altitudes of the SSI implemented as temporary flight restrictions and republished the NOTAMs with the changed altitudes on May 7, 2021. As a result, the FAA's TFR website and all third-party charting applications were able to display the SSI implemented as temporary flight restrictions correctly. Pilots have been able to better familiarize themselves with the SSI temporary flight restrictions since May 2021.

The concerns associated with the SSI as implemented as temporary flight restrictions graphical depictions not displaying properly will not carry forward with the establishment of the new restricted areas R–2206A–G pursuant to Part 73. The restricted areas will be depicted correctly on the associated aeronautical charts following the effective date of this rule.

Five individual commenters expressed concerns that the proposed restricted areas (R–2206A–G) would lead to the closure of PACL and remove the ability to navigate under visual flight rules (VFR) via the Parks Highway (Alaska Highway 3) when the restricted areas are active.[5]

The FAA previously considered this issue and addressed the concern in a Letter of Agreement (LOA)[6] between the FAA, MDA, and USSF. The procedures in the LOA requires MDA to halt its activities to allow for flights to access PACL. With the establishment of the restricted areas by this rule, the FAA, MDA, and USSF will establish a Letter of Procedure (LOP) to reflect the restricted areas airspace instead of the SSI implemented as temporary flight restrictions. To further mitigate impacts, the low-altitude restricted areas R–2206D–F will only be utilized for testing between 0200–0400 Tuesday, Thursday, and Saturday to support scheduled calibration. Outside of the scheduled times for testing, the FAA anticipates that the airspace would likely only be activated in the interest of the national defense of the United States as a result of a real world event. When the restricted areas are not active, pilots can land and depart PACL unrestricted.

Also, in response to comments received during the FAA Safety Risk Management Panel (SRMP) requesting increased navigable airspace surrounding Parks Highway, the FAA, MDA, and USAF collaborated on the development of R–2206F and the FAA added R–2206F to the proposal. R–2206F allows VFR navigation via the Parks Highway without impacting the overall design of the restricted areas. Finally, the short activation times for R–2206F will further mitigate and minimize impacts to pilots conducting such VFR operations, navigating via the Parks Highway.

Two individual commenters expressed their concerns that instrument flight rules (IFR) procedures into Healy River Airport (HRR) will be eliminated. The FAA retained the IFR procedures into HRR and kept them available for use, as needed. The FAA also developed an interim procedure, in collaboration with the MDA, which allows for activities occurring within the SSI implemented as temporary flight restrictions to be temporarily halted, as necessary, to enable IFR flights into HRR. Finally, the FAA developed new, permanent HRR approach and departure procedures that will not be affected by the R–2206A–G restricted areas once they are established. The new HRR IFR approach and departure procedures are planned to be published in the FLIP concurrent with the effective date of this rule establishing the R–2206 restricted areas.

The Alaska Airmen's Association expressed concerns that when the LRDR becomes operational, R–2206D–F could go active without warning, for a real world event. They further cited the MDA stating that for reasons of operational security, there can be no prior notification for activating the lower zones.

At the time that the NPRM published, neither the FAA nor MDA had a mechanism in place to notify pilots when R–2206D–F activate outside of prescheduled periods. The communications coverage for real-time notifications by air traffic control near the Clear LRDR and PACL airport was deficient. Anchorage ARTCC has no

[5] The agency notes that one additional individual commenter simply expressed that adopting the proposal would make life a lot harder for pilots conducting VFR operations, with no further explanation.

[6] In the NPRM, the FAA referenced a Letter of Procedure being in place prior to the final rule. However, the proper term is Letter of Agreement.

communications coverage and the local Flight Service Station's communications was intermittent. As such, without other communications measures in place, there was an unacceptable risk for airspace users flying near the LRDR area, entering the low-altitude restricted airspace in R–2206D–F while it was active. Accordingly, to overcome this problem, the FAA, again, in collaboration with the MDA, implemented an actionable and timely notification system that is currently operational. The system includes a dedicated frequency (133.25 VHF) and a visual warning light with daytime and nighttime patterns. The dedicated frequency continually broadcasts a message to aviators on the status of the SSI implemented as temporary flight restrictions currently and will for the restricted areas established by this rule. The transmission is audible from the PACL for aircraft holding short of all runway entry points; the PACL north ramp for helicopter operations by the Bureau of Land Management; while flying northbound from Healy River Airport (PAHV) over the city of Ferry, AK; and while flying southbound from Nenana Airport (PANN) along the Parks Highway. The visual warning light is visible, day and night, while flying southbound from PANN airport between 1,000 feet and 2,600 feet AGL and along the Parks Highway. It is also visible while flying toward PACL between 500 feet and 1,500 feet AGL at 4 NM from headings of 090°, 120°, and 180°; and while flying towards PACL between 500 feet and 1,500 feet AGL at 5.1 NM and 7.3 NM, respectively, from a heading of 360°. The warning light is not visible from the surface; however, aircraft on the ground are encouraged to use the dedicated frequency, 133.25 VHF, for restricted area status updates. Additionally, the Alaska Department of Transportation installed 4 signs on PACL at each of the 3 runway hold short lines and 1 at the north ramp, where helicopters depart, to notify pilots, prior to departure, of the dedicated alerting frequency that is broadcasting the SSI implemented as temporary flight restrictions status currently and the restricted areas established by this rule status as further encouragement.

The Rule

This action amends 14 CFR part 73 by renaming R–2206 to R–2206A and establishing 6 new restricted areas R–2206B, R–2206C, R–2206D, R–2206E, R–2206F, and R–2206G, over the Clear SFS at Clear, AK. The FAA has determined that the action is necessary to protect aircraft from the hazardous HIRF produced by the MDA's LRDR and segregate non-participating aircraft. Full legal descriptions of the restricted areas are contained in ''The Amendment'' section as set forth below.

R–2206A: R–2206 is amended by renaming it R–2206A. There is no change to the boundaries as established under R–2206. The designated altitudes extend upward from the surface to 8,800 feet MSL. R–2206A is active continuously.

R–2206B: R–2206B is established west of PACL, fanning clockwise from the southwest to the northwest, excluding the portion within R–2206A, with the eastern boundary located 3 NM west of PACL. The designated altitudes extend upward from 1,000 feet MSL to, but not including 1,600 feet MSL. R–2206B is active continuously.

R–2206C: R–2206C is established west of PACL, fanning clockwise from the southwest to the northwest, excluding the portion within R–2206A, with the eastern boundary located 3 NM west of PACL. The designated altitudes extend upward from 1,600 feet MSL to 32,000 feet MSL. R–2206C is active continuously.

R–2206D: R–2206D is established northwest of PACL, fanning clockwise from the northwest to north, excluding the portion within R–2206A, with the eastern boundary located ½ NM west of PACL. The designated altitudes extend upward from 1,000 feet MSL to, but not including 1,600 feet MSL. R–2206D activation times are 0200–0400 local time, Tuesday, Thursday, and Saturday; other times by NOTAM.

R–2206E: R–2206E is established north of PACL, fanning clockwise from the northwest to the northeast, excluding the portion within R–2206A, with the eastern boundary located ½ NM west of PACL. The designated altitudes extend upward from 1,600 feet MSL to, but not including 2,100 feet MSL. R–2206E activation times are 0200–0400 local time, Tuesday, Thursday, and Saturday; other times by NOTAM.

R–2206F: R–2206F is established northeast of PACL, enabling VFR aircraft to transition along Alaska Highway 3 (the Parks Highway) with the southern boundary located 3 NM north of PACL. The designated altitudes extend upward from 2,100 feet MSL to 3,200 feet MSL. R–2206F activation times are 0200–0400 local time, Tuesday, Thursday, and Saturday; other times by NOTAM.

R–2206G: R–2206G is established north of PACL, fanning clockwise from the northwest to the northeast, excluding the portions within R–2206A and R–2206F, with the eastern boundary located ½ NM west of PACL. The designated altitudes extend upward from 2,100 feet MSL to 32,000 feet MSL. R–2206G is active continuously.

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 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 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 rulemaking action of renaming restricted area R–2206 to R–2206A and establishing six new restricted areas R–2206B, R–2206C, R–2206D, R–2206E, R–2206F, and R–2206G, over Clear, AK qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). As such, this rulemaking action is not expected to cause or result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this rulemaking action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis, and has determined that no extraordinary circumstances exist warranting preparation of an environmental assessment or environmental impact study.

On May 7, 2021, the MDA, as the lead agency, announced the availability of its

Final Environmental Impact Statement (EIS) for the Long Range Discrimination Radar (LRDR) located at Clear Air Force Station (CAFS), Alaska. 86 FR 24599–24600. The FAA and the Department of the Air Force (DAF) are cooperating agencies to the Final EIS. The MDA's EIS analyzed the operational impacts of the LRDR, including airspace restrictions necessary to ensure that aircraft would not encounter high intensity radiation fields (HIRF) resulting from the LRDR operations that exceed FAA's HIRF certification standards for aircraft electrical and electronic systems. The proposed airspace restrictions include expansion of the existing restricted area (R–2206) at CAFS by adding six new restricted areas. The preferred alternative is to operate the LRDR continuously under the changed operational concept and to implement the associated proposed airspace restrictions as described in the Proposed Action analyzed in the Final EIS.

On June 24, 2021, the MDA as lead agency, with the DAF as a cooperating agency, issued a joint Record of Decision (ROD) to implement changes in operational concept for the LRDR at CAFS, Alaska. 86 FR 33240. The ROD includes modification of the LRDR operational requirements and procedures to reflect continuous operations in response to emerging threats. The action enables the MDA to meet its congressional mandate to fully support the primary mission of the layered Missile Defense System (MDS) to provide continuous and precise tracking and discrimination of long-range missile threats launched against the United States. The FAA is a cooperating agency on the LRDR CAFS EIS because it has special expertise and jurisdiction by law, pursuant to 49 U.S.C. 40101 *et seq.,* for aviation and regulation of air commerce in the interests of aviation safety and efficiency. The MDA requested that the FAA, as a cooperating agency, consider and adopt, in whole or in part, the Final EIS as the required NEPA documentation to support FAA decisions on the establishment of restricted areas. The airspace associated with the proposed action and alternative lies within the jurisdiction of the FAA Anchorage Air Route Traffic Control Center. FAA established 6 new restricted areas and made related changes in airspace management.

On July 6, 2021, the FAA adopted the airspace portion of the MDA's EIS per FAA's policy for Adoption of Other Agencies' NEPA Documents in FAA Order 1050.1F, Paragraph 8–2. On August 23, 2021, the FAA issued a Notice of Availability for its adoption of MDA's Final EIS for LRDR Operations, Clear Air Force Station, Alaska (CAFS), and Record of Decision for FAA actions to accommodate testing and operation of the LRDR at CAFS under the MDA's Modified Operational Concept; *Adoption of the Missile Defense Agency's Final Environmental Impact Statement for Long Range Discrimination Radar (LRDR) Operations, Clear Air Force Station, Alaska (CAFS), and Record of Decision for Federal Aviation Administration Actions to Accommodate Testing and Operation of the LRDR at CAFS under the Missile Defense Agency's Modified Operational Concept,* which addresses the FAA's decision to establish additional restricted areas to protect aviation from HIRF generated during the LRDR testing and operation, implement temporary flight restrictions until the restricted areas are in effect, and make changes to federal airways and instrument flight procedures to accommodate the new restricted areas (86 FR 47195, August 23, 2021).

Lists of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for 14 CFR part 73 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

§ 73.22 [Amended]

■ 2. Section 73.22 is amended as follows:

* * * * *

R–2206 Clear, AK [Removed]

R–2206A Clear, AK [New]

Boundaries. Beginning at lat. 64°19′44″ N, long. 149°15′42″ W; to lat. 64°19′44″ N, long. 149°10′18″ W; thence south, 100 feet west of and parallel to the Alaska Railroad to lat. 64°16′17″ N, long. 149°10′14″ W; to lat. 64°16′17″ N, long. 149°15′42″ W; to the point of beginning.

Designated Altitudes. Surface to 8,800 feet MSL.

Time of designation. Continuous.

Controlling agency. FAA, Anchorage ARTCC.

Using agency. Commander 13th Space Warning Squadron, Clear, AK.

R–2206B Clear, AK [New]

Boundaries. Beginning at lat. 64°20′13″ N, long. 149°13′12″ W; to lat. 64°17′20″ N, long. 149°11′25″ W; to lat. 64°14′31″ N, long. 149°13′43″ W; thence clockwise along a 3.0 NM arc radius centered at lat. 64°17′20″ N, long. 149°11′25″ W; thence to the point of beginning; excluding that portion wholly contained in R–2206A.

Designated Altitudes. 1,000 feet MSL to, but not including 1,600′ MSL.

Time of designation. Continuous.

Controlling agency. FAA, Anchorage ARTCC.

Using agency. Commander 13th Space Warning Squadron, Clear, AK.

R–2206C Clear, AK [New]

Boundaries. Beginning at lat. 64°19′27″ N, long. 149°20′22″ W; thence clockwise along a 4.0 NM arc radius centered at lat. 64°20′22″ N, long. 149°11′25″ W; to lat. 64°23′56″ N, long. 149°15′30″ W; to lat. 64°17′20″ N, long. 149°11′25″ W; to lat. 64°14′10″ N, long. 149°14′01″ W; thence along a 3.0 NM arc radius centered at lat. 64°16′55″ N, long. 149°16′41″ W; to the point of beginning; excluding that portion wholly contained in R–2206A.

Designated Altitudes. 1,600 feet MSL to 32,000 feet MSL.

Time of designation. Continuous.

Controlling agency. FAA, Anchorage ARTCC.

Using agency. Commander 13th Space Warning Squadron, Clear, AK.

R–2206D Clear, AK [New]

Boundaries. Beginning at lat. 64°20′13″ N, long. 149°13′12″ W; thence clockwise along a 3.0 NM arc radius centered at lat. 64°17′20″ N, long. 149°11′25″ W; to lat. 64°18′47″ N, long. 149°05′23″ W; to lat. 64°17′20″ N, long. 149°11′25″ W; thence to point of beginning; excluding that portion wholly contained in R–2206A.

Designated Altitudes. 1,000 feet MSL to but not including 1,600 feet MSL.

Time of designation. 0200–0400 local time, Tuesday, Thursday and Saturday; other times by NOTAM.

Controlling agency. FAA, Anchorage ARTCC.

Using agency. Commander 13th Space Warning Squadron, Clear, AK.

R–2206E Clear, AK [New]

Boundaries. Beginning at lat. 64°23′56″ N, long. 149°15′30″ W; thence clockwise along a 4.0 NM arc radius centered at lat. 64°20′22″ N, long. 149°11′25″ W; to lat. 64°19′29″ N, long. 149°02′27″ W; to lat. 64°17′20″ N, long. 149°11′25″ W; thence to point of beginning; excluding that portion wholly contained in R–2206A.

Designated Altitudes. 1,600 feet MSL to but not including 2,100 feet MSL.

Time of designation. 0200–0400 local time, Tuesday, Thursday and Saturday; other times by NOTAM.

Controlling agency. FAA, Anchorage ARTCC.

Using agency. Commander 13th Space Warning Squadron, Clear, AK.

R–2206F Clear, AK [New]

Boundaries. Beginning at lat. 64°22′07″ N, long. 149°03′09″ W; thence clockwise along the 4.0 NM arc radius centered at lat. 64°20′22″ N, long. 149°11′25″ W; to lat.

64°19′29″ N, long. 149°02′27″ W; to lat. 64°19′19″ N, long. 149°03′07″ W; to lat. 64°19′36″ N, long. 149°03′18″ W; thence north, along a path ½ NM west of Highway 3, Parks Highway; to lat. 64°21′42″ N, long. 149°03′37″ W; to the point of beginning;

Designated Altitudes. 2,100 feet MSL to 3,200 feet MSL.

Time of designation. 0200–0400 local time, Tuesday, Thursday and Saturday; other times by NOTAM.

Controlling agency. FAA, Anchorage ARTCC.

Using agency. Commander 13th Space Warning Squadron, Clear, AK.

R–2206G Clear, AK [New]

Boundaries. Beginning at lat. 64°23′56″ N, long. 149°15′30″ W; thence clockwise along a 4.0 NM arc radius centered at lat. 64°20′22″ N, long. 149°11′25″ W; to lat. 64°19′29″ N, long. 149°02′27″ W; to lat. 64°17′20″ N, long. 149°11′25″ W; thence to point of beginning; excluding; (1) that portion wholly contained in R–2206A; (2) that portion wholly contained in R–2206F.

Designated Altitudes. 2,100 feet MSL to 32,000 feet MSL.

Time of designation. Continuous.

Controlling agency. FAA, Anchorage ARTCC.

Using agency. Commander 13th Space Warning Squadron, Clear, AK.

* * * * *

Issued in Washington, DC, on November 2, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–24242 Filed 11–3–22; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA–555]

Technical Correction to Regulation Regarding Registration Exception for Officials

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule; technical correction.

SUMMARY: This final rule updates a Drug Enforcement Administration regulation involving exemption from registration for law enforcement officials by removing an inapposite cross-reference listing. This action makes no substantive changes to this regulation.

DATES: This rule is effective November 7, 2022

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Controlled Substances Act (CSA) grants the Attorney General authority to promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances; as well as the maintenance and submission of records and reports of registrants; and that are necessary and appropriate for the efficient execution of his statutory functions. 21 U.S.C. 821, 827, 871(b). The Attorney General is further authorized by the CSA to promulgate rules and regulations relating to the registration and control of importers and exporters of controlled substances. 21 U.S.C. 958(f). The Attorney General has delegated this authority to the Administrator of the Drug Enforcement Administration (DEA). 28 CFR 0.100(b).

Technical Correction

Section 1301.24(a) of title 21 of the CFR provides that various law enforcement officials, including certain DEA officers or employees, are exempt from the registration requirement, and no change is being made in that provision.[1]

DEA is amending 21 CFR 1301.24(b) by removing the cross-reference to 21 CFR 1316.03(d). Section 1301.24(b) currently provides, among other things, that any such official exempted under paragraph (a), and acting in the course of his or her official duties, may procure controlled substances during an inspection, in accordance with § 1316.03(d).

Section 1316.03(d) pertains to a DEA inspector entering controlled premises and conducting administrative inspections under the CSA and the regulations. If the DEA inspector collects samples of controlled substances or listed chemicals, § 1316.03(d) provides that the inspector will issue receipts on DEA Form 400 for samples of controlled substances or listed chemicals collected during an inspection. Accordingly, this particular provision would apply only to DEA inspectors conducting administrative inspections, and not to any other law enforcement official that is exempted under 21 CFR 1301.24(a). Section 1316.03(d) remains applicable by its terms to DEA inspectors conducting administrative inspections, and so there is no need to include a cross-reference to this provision in § 1301.24(a). In addition, only DEA officers or employees would have access to such a form. Therefore, DEA has concluded it is best that this inapposite cross-reference to § 1316.03(d) be removed, as this will eliminate any confusion.

[1] See 21 CFR 1301.11(a).

Regulatory Analyses

Administrative Procedure Act

The Administrative Procedure Act (APA) (5 U.S.C. 553) does not require notice and the opportunity for public comment where the agency for good cause finds that notice and public comment are unnecessary, impracticable, or contrary to the public interest under 5 U.S.C. 553(b)(B). This rule contains a technical correction; it imposes no new or substantive requirement on the public or DEA registrants. As such, DEA has determined that notice and the opportunity for public comment on this rule are unnecessary. See 5 U.S.C. 553(b)(B) (relating to notice and comment procedures). ''[W]hen regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary.'' *Gray Panthers Advocacy Committee* v. *Sullivan*, 936 F.2d 1284, 1291 (D.C. Cir. 1991); *see also United States* v. *Cain*, 583 F.3d 408, 420 (6th Cir. 2009) (contrasting legislative rules, which require notice-and-comment procedures, ''with regulations that merely restate or interpret statutory obligations,'' which do not); *Komjathy* v. *Nat. Trans. Safety Bd.*, 832 F.2d 1294, 1296 (D.C. Cir. 1987) (when a rule ''does no more than repeat, virtually verbatim, the statutory grant of authority'' notice-and-comment procedures are not required). Because this is not a substantive rule, and as DEA finds good cause under 5 U.S.C. 553(d)(3) for the above reason, this final rule takes effect upon date of publication in the **Federal Register**.

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

This final rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs 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 is supplemental to, and reaffirms, the principles, structures, and definitions governing regulatory review as established in E.O. 12866. The

Office of Information and Regulatory Affairs (OIRA) has deemed that this is not significant regulatory action under E.O. 12866, and accordingly it has not been reviewed by OIRA.

Executive Order 12988, Civil Justice Reform

This final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This final rule does not have federalism implications warranting the application of E.O. 13132. The final rule does not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or the distribution of power and responsibilities among the various levels of Government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This final rule does not have tribal implications warranting the application of E.O. 13175. This rule does not have substantial direct effects 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.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. As noted in the above discussion regarding applicability of the APA, DEA was not required to publish a general notice of proposed rulemaking prior to this final rule. Consequently, the RFA does not apply.

Unfunded Mandates Reform Act of 1995

DEA has determined and certified pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.,* that this action will not result in any Federal mandate that may 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. Therefore, neither a Small Government Agency Plan nor any other action is required under the provisions of UMRA.

Paperwork Reduction Act of 1995

This action does not involve a collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local Governments, individuals, businesses, or organizations. 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 Office of Management and Budget control number.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. Because this is a rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties, the reporting requirement under 5 U.S.C. 801 does not apply.

List of Subjects in 21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

For the reasons set out above, 21 CFR part 1301 is amended as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.

§ 1301.24 [Amended]

■ 2. Amend § 1301.24(b), by removing ‘‘, in accordance with § 1316.03(d) of this chapter,’’.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 1, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022–24140 Filed 11–4–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0904]

RIN 1625–AA87

Security Zone; Mare Island Dry Dock, Vallejo, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone in the navigable waters near Mare Island Dry Dock, approximately 100 yards from any part of the berthing piers in the Mare Island Strait, Vallejo, CA within the San Francisco Captain of the Port (COTP) zone. The security zone is necessary to protect the harbors, ports, and waterfront facilities during the dry dock period of the USS Frank Cable and associated APL berthing barge. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector San Francisco.

DATES: This rule is effective without actual notice from November 7, 2022 until August 1, 2023. For the purposes of enforcement, actual notice will be used from November 2, 2022 until November 7, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0904 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 LT Anthony Solares, Sector San Francisco, U.S. Coast Guard; telephone 415–399–3585, email *SFWaterways@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

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 it would be impracticable. The event will occur before the completion of a comment period, thereby jeopardizing the security of the harbors, ports, and waterfront facilities during dry dock period of the USS Frank Cable and associated APL berthing barge. We must establish this security zone by November 2, 2022.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date would be contrary to the public interest because immediate action is needed to provide for the security of the harbors, ports, and waterfront facilities, protection of high-ranking government officials, and mitigation of potential subversive acts.

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 Captain of the Port Sector San Francisco (COTP) has determined that the USS Frank Cable and APL berthing barge will attend Mare Island Dry Dock for an extended period of time and a fixed security zone is necessary for the duration of the dry dock period. This area is located adjacent to U.S. navigable waters in the San Francisco COTP zone. This rule is needed to ensure the safety of the USS Frank Cable and APL berthing barge crew.

IV. Discussion of the Rule

This rule establishes a security zone from midnight on November 2, 2022 until midnight on August 1, 2023. The security zone will cover all navigable waters of the Mare Island Strait, from surface to bottom, within 100 yards from any part of the berthing piers in the Mare Island Strait. The duration of the zone is intended to protect the harbors, ports, and waterfront facilities during the dry dock period of the USS Frank Cable. No vessel or person will be permitted to enter the security zone except for authorized support vessels, aircraft, and support personnel, or other vessels authorized by the COTP or a designated representative.

A designated representative means a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel designated by or assisting the Captain of the Port Sector San Francisco (COTP) in the enforcement of the security zone. The security zone is closed to all vessel traffic, except as may be permitted by the COTP or a designated representative.

To seek permission to enter, contact the COTP or the COTP's designated representative by VHF Marine Radio channel 16 or through the 24-hour Command Center at telephone (415) 399–3547. Those in the security zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

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 size, location, and duration of the security zone. Additionally, vessel traffic can pass safely around the area, and this rule allows to ask permission to enter 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 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 security 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 security zone established for the duration of the USS Frank Cable dry dock period in the navigable waters near Mare Island Dry Dock, approximately 100 yards from any part of the berthing piers in the Mare Island Strait, Vallejo, It is categorically excluded from further review under paragraph L60 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.T11–116 to read as follows:

§ 165.T11–116 Security Zone; Mare Island Dry Dock, Vallejo, CA.

(a) *Location.* The following area is a security zone: all navigable waters of Mare Island Strait, Vallejo, CA within 100 yards of Mare Island Dry Dock berthing piers.

(b) *Definitions.* As used in this section, a *designated representative* means 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 Sector San Francisco (COTP) in the enforcement of the security zone.

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

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

(3) To seek permission to enter, contact the COTP or the COTP's designated representative by VHF Marine Radio channel 16 or through the 24-hour Command Center at telephone (415) 399–3547. Those in the security zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from midnight on November 2, 2022 through midnight on August 1, 2023.

Dated: November 1, 2022.

Taylor Q. Lam,

Captain, U.S. Coast Guard, Captain of the Port Sector San Francisco.

[FR Doc. 2022–24200 Filed 11–4–22; 8:45 am]

BILLING CODE 9110–04–P

Proposed Rules

Federal Register
Vol. 87, No. 214
Monday, November 7, 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 AGRICULTURE

Agricultural Marketing Service

7 CFR Part 993

[Doc. No. AMS–SC–22–0053; SC22–993–1 PR]

Dried Prunes Produced in California; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, Department of Agriculture (USDA).

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a recommendation from the Prune Marketing Committee (Committee) to increase the assessment rate established for the 2022–23 crop year and subsequent fiscal years. The proposed assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Comments must be received by December 7, 2022.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule. Comments must be submitted to the Docket Clerk electronically by Email: *MarketingOrderComment@usda.gov* or via the internet at: *https://www.regulations.gov.* Comments should reference the document number and the date and page number of this issue of the **Federal Register**. Comments submitted in response to this proposed rule will be included in the record and will be made available to the public and can be viewed at: *https://www.regulations.gov.* Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Jeffery Rymer, Marketing Specialist, or Gary Olson, Regional Director, Western Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487–5901, or Email: *Jefferym.Rymer@usda.gov* or *GaryD.Olson@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, proposes to amend regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposed rule is issued under Marketing Order No. 993, as amended (7 CFR part 993), regulating the handling of dried prunes grown in California. Part 993 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and is comprised of producers and handlers of dried prunes operating within the area of production, and a public member.

The Agricultural Marketing Service (AMS) is issuing this proposed rule in conformance with Executive Orders 12866 and 13563. 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).

Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This proposed rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have tribal implications. AMS has determined that this proposed rule is unlikely to have substantial direct effects 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.

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the Order now in effect, California prune handlers are subject to assessments. Funds to administer the Order are derived from such assessments. It is intended that the assessment rate would be applicable to all assessable dried prunes for the 2022–23 crop year, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with Department of Agriculture (USDA) a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This proposed rule would increase the assessment rate from $0.28 per ton of salable dried prunes, the rate that was established for the 2020–21 and subsequent crop years, to $0.33 per ton of salable dried prunes for the 2022–23 and subsequent crop years.

The Order authorizes the Committee, with the approval of AMS, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the Committee are familiar with the Committee's needs and with the costs of goods and services in their local area and are able to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting, and all directly affected persons have an opportunity to participate and provide input.

For the 2021–22 and subsequent crop years, the Committee recommended, and AMS approved, an assessment rate that would continue in effect from fiscal

year to fiscal year unless modified, suspended, or terminated by AMS upon recommendation and information submitted by the Committee or other information available to AMS.

The Committee met on June 28, 2022, and unanimously recommended 2022–23 crop year expenditures of $26,700 and an assessment rate of $0.33 per ton of salable dried prunes handled for the 2022–23 and subsequent crop years. In comparison, last year's budgeted expenditures were $26,212. The proposed assessment rate of $0.33 per ton is $0.05 higher than the rate currently in effect. The Committee recommended increasing the assessment rate due to a lower than normal crop size produced in the 2021–22 crop year and a projected lower crop size again for the 2022–23 crop year. The Committee projects handler receipts of 75,000 tons of assessable dried prunes from the 2022–23 crop year, which is the same level that was projected for the 2021–22 crop year.

The major expenditures recommended by the Committee for the 2022–23 crop year include $14,935 for personnel costs, $11,125 for operating expenses, and $640 for contingencies. Budgeted expenditures for the 2021–22 crop year were $14,025, $12,000, and $187, respectively.

Dried prunes harvested in 2022 will be marketed over the course of the 2022–23 crop year, which begins on August 1, 2022. The crop year is a 12-month period that begins on August 1 of each year and ends on July 31 of the following year. The expected 75,000 tons of assessable dried prunes from the 2022–23 crop would generate $24,750 (75,000 tons salable dried prunes multiplied by $0.33 assessment rate) in assessment revenue at the proposed assessment rate. The $1,950 balance of funds needed to cover budgeted expenditures would come from funds carried over from the previous crop year. The 2022–23 crop year assessment rate increase should be appropriate to ensure the Committee has sufficient revenue to fund its recommended 2022–23 crop year budgeted expenditures.

The Committee derived the recommended assessment rate by considering anticipated crop year expenses, actual prune tonnage received by handlers during the 2021–2022 crop year, an estimated 2022–23 crop of 75,000 tons of salable dried prunes, and the anticipated funds that will be carried over into the new crop year. Income derived from handler assessments ($24,750),and the balance carried over from the previous crop year ($1,950) are expected to be adequate to cover budgeted expenses ($26,700).

The proposed assessment rate would continue in effect indefinitely unless modified, suspended, or terminated by AMS upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate would be in effect for an indefinite period, the Committee would continue to meet prior to or during each crop year to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or AMS. Committee meetings are open to the public and interested persons may express their views at these meetings. AMS would evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Committee's 2022–23 budget and those for subsequent crop years would be reviewed and, as appropriate, approved by AMS.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 600 producers of dried prunes in the production area and 27 handlers subject to regulation under the Order. Small agricultural producers of prunes are defined by the Small Business Administration (SBA) as those having annual receipts of less than $3,000,000, and small agricultural service firms are defined as those whose annual receipts are less than $30,000,000 (13 CFR 121.201).

According to the National Agricultural Statistics Service (NASS), the average producer price for California dried prunes for the 2021–22 crop was $2,000 per ton. NASS further reported 2021–22 crop year production for California dried prunes was 74,000 tons. The estimated total 2021–22 crop year value of California dried punes is $148,000,000 (74,000 tons times $2,000 per ton equals $148,000,000). Dividing the estimated total crop value by the estimated number of producers (600) yields an estimated average receipt per producer of $246,667 ($148,000,000 divided by 600), so the majority of producers would have annual receipts less than the $3,000,000 SBA small agricultural producer threshold for prunes.

In addition, according to AMS Market News data, the reported average terminal market price for 2021 for California dried prunes was $38.93 per 28-pound carton. Dividing the average carton price by the 28-pound carton size yields an estimated price per pound of $1.39 ($38.93 average price per 28-pound carton divided by 28 pounds). The handler price for prunes is $2,780 per ton ($1.39 per pound multiplied by 2,000 pounds per ton equals $2,780 per ton). Multiplying the 2021–22 California dried prune estimated production of 74,000 tons by the estimated average price per ton of $2,780 equals $205,720,000.

Dividing this figure by the 27 regulated handlers yields estimated average annual handler receipts of $7,619,259 ($205,720,000 divided by 27 handlers), which is, below the SBA threshold for small agricultural service firms. Therefore, using the above data, the majority of producers and handlers of California dried prunes may be classified as small entities.

This proposal would increase the assessment rate collected from handlers for the 2022–23 and subsequent crop years from $0.28 to $0.33 per ton of salable dried prunes. The Committee unanimously recommended 2022–23 crop year expenditures of $26,700 and an assessment rate of $0.33 per ton of salable dried prunes. The proposed assessment rate of $0.33 is $.05 higher than the current rate. The Committee expects the industry to handle 75,000 tons of dried prunes during the 2022–23 crop year. Thus, the $0.33 per ton of salable dried prunes should provide $24,750 in assessment income (75,000 tons multiplied by $0.33). The Committee also expects $1,950 to be carried over into the 2022–23 crop year, which begins August 1, 2022. Income derived from handler assessments, along with funds carried over from the previous crop year, should be adequate to meet budgeted expenditures for the 2022–23 crop year.

The major expenditures recommended by the Committee for the 2022–23 crop year include $14,935 for personnel costs, $11,125 for operating expenses, and $640 for contingency

reserve. Budgeted expenses for these items during the 2021–22 crop year were $14,025, $12,000, and $187, respectively. The Committee deliberated the proposed budget categories and decreased their budget for office supplies and expenses to account for the 2022–23 crop year being a non-election year, therefore requiring less office supplies. Overall, the 2022–23 crop year budget of $26,700 is $488 more than the $26,212 budgeted for the 2021–22 crop year.

The Committee recommended increasing the assessment rate due to a lower than normal crop size produced in the 2021–22 crop year and a projected lower crop size again for the 2022–23 crop year. At the current assessment rate, assessment income would equal $21,000 (75,000 tons multiplied $0.28), an amount along with the carry over funds from the previous year sufficient to cover the Committee's anticipated 2022–23 expenditures of $26,700.

Prior to arriving at this budget and the proposed assessment rate, the Committee considered information from various sources including the Committee's Executive, Marketing, Inspection, and Research subcommittees. Alternate expenditure levels were discussed by these groups, based upon the relative value of various projects to the dried prune industry and the expected dried prune production. The assessment rate of $0.33 per ton of salable dried prunes was derived by considering anticipated expenses, the projected volume of assessable dried prunes, the current monetary balance expected to be carried into the upcoming crop year, and additional pertinent factors.

A review of NASS information indicates that the average producer price for the 2021–22 crop year was $2,000 per ton, and the estimated quantity of assessable dried prunes harvested in the 2021–22 crop year was 74,000 tons, which would yield total producer revenue $148,000,000 ($2,000 per ton multiplied by 74,000 tons). Therefore, utilizing the assessment rate of $0.33 per ton, assessment revenue for the 2021–22 crop year, as a percentage of total producer revenue, would be approximately 1.65 percent ($0.33 multiplied by 74,000 tons divided by $148,000,000 multiplied by 100).

This proposed action would increase the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to producers. However, these costs would be offset by the benefits derived by the operation of the Order.

The Committee's meetings were widely publicized throughout the production area. The dried prune industry and all interested persons are invited to attend the meetings and participate in Committee deliberations on all issues. Like all Committee meetings, the June 28, 2022, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit comments on this proposed rule, including the regulatory and information collection impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0178, Vegetable and Specialty Crops. No changes in those requirements would be necessary as a result of this proposed rule. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would not impose any additional reporting or recordkeeping requirements on either small or large California dried prune handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

AMS has not identified any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *https://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 30-day comment period is provided to allow interested persons to respond to this proposed rule. All written comments timely received will be considered before a final determination is made on this rule.

List of Subjects in 7 CFR Part 993

Marketing agreements, Plum, Prunes, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service proposes to amend 7 CFR part 993 as follows:

PART 993—DRIED PRUNES PRODUCED IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 993 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 993.347 is revised to read as follows:

§ 993.347 Assessment rate.

On and after August 1, 2022, an assessment rate of $0.33 per ton of salable dried prunes is established for California dried prunes.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2022–24172 Filed 11–4–22; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1222

[Doc. No. AMS–SC–22–0050]

Harmonized Tariff Schedule Numbers for the Paper and Paper-Based Packaging Products

AGENCY: Agricultural Marketing Service, Department of Agriculture (USDA).

ACTION: Proposed rule.

SUMMARY: This proposal invites comments on updates to the Harmonized Tariff Schedule (HTS) numbers for paper and paper-based packaging products in the Paper and Paper-Based Packaging Promotion, Research, and Information Order (Order). In addition, this action proposes new language that allows assessment collection to continue even if HTS numbers change in the future. The Paper and Packaging Board (Board) administers the Order with oversight by the U.S. Department of Agriculture (USDA).

DATES: Comments must be received by December 7, 2022.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule. All comments must be submitted through the Federal e-rulemaking portal at *https://www.regulations.gov* and should reference the document number and the date and page number of this issue of the **Federal Register**. All comments submitted in response to this proposed

rule will be included in the rulemaking record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting comments will be made public on the internet at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Marlene Betts, Marketing Specialist, or Alexandra Caryl, Branch Chief, Mid-Atlantic Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Room 1406–S, Stop 0244, Washington, DC 20250–0244; Telephone: (202) 720–5057; or Email: *Marlene.Betts@usda.gov* or *Alexandra.Caryl@usda.gov.*

SUPPLEMENTARY INFORMATION: This proposal is issued under the Order (7 CFR part 1222). The Order is authorized under the Commodity Promotion, Research, and Information Act of 1996 (1996 Act) (7 U.S.C. 7411–7425).

Executive Orders 12866 and 13563

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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

Executive Order 13175

This action has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. Agricultural Marketing Service (AMS) has assessed the impact of this proposed rule on Indian tribes and determined that this rulemaking would not have tribal implications that require consultation under Executive Order 13175. AMS hosts a quarterly teleconference with tribal leaders where matters of mutual interest regarding the marketing of agricultural products are discussed. Information about the proposed changes to the regulations will be shared during an upcoming quarterly call, and tribal leaders will be informed about the proposed revisions to the regulation and the opportunity to submit comments. AMS will work with the USDA Office of Tribal Relations to ensure meaningful consultation is provided as needed with regards to this change to the Order.

Executive Order 12988

This proposal has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. Section 524 of the 1996 Act (7 U.S.C. 7423) provides that it shall not affect or preempt any other Federal or State law authorizing promotion or research relating to an agricultural commodity.

Under section 519 of the 1996 Act (7 U.S.C. 7418), a person subject to an order may file a written petition with USDA stating that an order, any provision of an order, or any obligation imposed in connection with an order, is not established in accordance with the law, and request a modification of an order or an exemption from an order. Any petition filed challenging an order, any provision of an order, or any obligation imposed in connection with an order, shall be filed within two years after the effective date of an order, provision, or obligation subject to challenge in the petition. The petitioner will have the opportunity for a hearing on the petition. Thereafter, USDA will issue a ruling on the petition. The 1996 Act provides that the district court of the United States for any district in which the petitioner resides or conducts business shall have the jurisdiction to review a final ruling on the petition if the petitioner files a complaint for that purpose not later than 20 days after the date of the entry of USDA's final ruling.

Background

The Paper and Paper-Based Packaging Promotion, Research, and Information Order (Order) took effect in January 2014 (79 FR 3696), and assessment collection began in March 2014 for paper and paper-based packaging. The program is funded by assessments on manufacturers and importers of 100,000 short tons or more of paper and paper-based packaging per year. The assessments are used for projects to promote paper and paper-based packaging. This proposed rule invites comments on updates to the Harmonized Tariff Schedule (HTS) numbers for paper and paper-based packaging products. This action also proposes the addition of verbiage that allows the collection of assessments to continue even if HTS numbers change in the future. Updates to the HTS numbers and the additional verbiage are necessary to ensure that importers are being assessed appropriately.

This change would ensure that importers are being assessed on the same products as domestic manufacturers. The proposed changes were recommended by the Board at its meeting on June 21, 2022. The Board was unanimously in favor of this recommendation. AMS agrees to propose the updates to the HTS numbers.

Update HTS Numbers

Sections 1222.46(p) of the Order allows for the Board to recommend amendments to the Order as the Board considers appropriate. The Board reviewed the current HTS numbers after noting that several changes made by the U.S. International Trade Commission (USITC) are not reflected in the Order's current HTS numbers. Therefore, this action proposes to update the Order's HTS numbers, bringing them in-line with the most current HTS numbers as provided by the USITC.[1] In addition, this action proposes additional verbiage that allows the collection of assessments to continue even if HTS numbers change in the future.

Section 1222.52(e) would be updated to include language that would allow the Board to continue to collect assessments in the event the USITC makes future changes to any HTS number by merely replacing a previous number. In addition, the list of HTS numbers in the table for assessments on importers of paper and paper-based packaging have all been reviewed and updated in the Order to coincide with the most current HTS numbers as provided by USITC.

Initial Regulatory Flexibility Act Analysis

In accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this action on small entities that would be affected by this rule. The purpose of the RFA is to fit regulatory action to scale of businesses subject to such action so that small businesses will not be disproportionately burdened. The Small Business Administration defines small agricultural service firms as those having annual receipts of no more than $30 million (13 CFR part 121). Manufacturers and importers would be considered agricultural service firms.

According to the Board, there are approximately 50 manufacturers in the United States that produce the types of paper and paper-based packaging covered under the Order. Using an average price of $1,165 per short ton,[2]

[1] *https://hts.usitc.gov/current* Chapter 48.

[2] No domestic market pricing information for paper and paper-based packaging was publicly

Continued

a manufacturer who produces less than about 25,760 short tons of paper and paper-based packaging per year would be considered a small entity. The Board estimates that no manufacturers produced less than 25,760 short tons in 2021; thus, no domestic manufacturers would be considered small businesses.

Based on U.S. Customs and Border Protection (Customs) data, there were 3,020 importers of paper and paper-based packaging in 2021. Of these, 34 importers, or 1 percent, had annual receipts of more than $30 million of paper and paper-based packaging. Thus, most importers would be considered small entities.

The proposed rule would update the Order's HTS numbers, bringing them in-line with the most current HTS numbers as provided by the USITC. In addition, this action proposes additional verbiage that allows the Board to continue to collect assessments even if HTS numbers change in the future.

This rulemaking does not impose additional recordkeeping requirements on manufacturers and importers of paper and paper-based packaging. There are no Federal rules that duplicate, overlap, or conflict with this proposed rule. In accordance with OMB regulations (5 CFR part 1320) that implements the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the information collection and recordkeeping requirements that are imposed by the Order have been previously approved under OMB control number 0581–0093. This rulemaking does not result in a change to the information collection and recordkeeping requirements previously approved.

Regarding outreach efforts, the Board discussed this action during Board meetings in 2022. The Board members unanimously approved the changes to the HTS numbers to bring them in accordance with the USITC numbers and ensure that assessments on domestic manufacturers are the same as assessments on imports. In addition, all of the Board's meetings are open to the public and interested persons are invited to participate and express their views.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities or citizen access to Government information and services, and for other purposes.

We have performed this initial RFA analysis regarding the impact of the proposed action on small entities and we invite comments concerning the potential effects of this action.

USDA has determined that this proposed rule is consistent with and would effectuate the purpose of the 1996 Act.

A 30-day comment period is provided to allow interested persons to respond to this proposal. All written comments received in response to this proposed rule by the date specified will be considered prior to finalizing this action.

List of Subjects in 7 CFR Part 1222

Administrative practice and procedure, Advertising, Labeling, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service proposed to amend 7 CFR part 1222 as follows:

PART 1222—PAPER AND PAPER–BASED PACKAGING PROMOTION, RESEARCH, AND INFORMATION ORDER

■ 1. The authority citation for 7 CFR part 1222 continues to read as follows:

Authority: 7 U.S.C. 7411–7425; 7 U.S.C. 7401.

■ 2. In § 1222.52, revise paragraph (e) to read as follows:

§ 1222.52 Assessment.

* * * * *

(e) Each importer of paper and paper-based packaging shall pay through Customs to the Board an assessment on the paper and paper-based packaging imported into the United States identified in the Harmonized Tariff Schedule of the United States (HTSUS) number listed in the following table. In the event that any HTSUS number subject to assessment is changed and such change is merely a replacement of a previous number and has no impact on the description of the paper and paper-based packaging involved, assessments will continue to be collected based on the new number.

Paper and paper-based packaging	Assessment $/kg
4802.54.1000	$0.000386
4802.54.3100	0.000386
4802.54.5000	0.000386
4802.54.6100	0.000386
4802.55.1000	0.000386
4802.55.2000	0.000386
4802.55.4000	0.000386
4802.55.6000	0.000386
4802.55.7020	0.000386
4802.55.7040	0.000386
4802.56.1000	0.000386
4802.56.2000	0.000386
4802.56.4000	0.000386
4802.56.6000	0.000386
4802.56.7020	0.000386
4802.56.7050	0.000386
4802.56.7090	0.000386
4802.57.1000	0.000386
4802.57.2000	0.000386
4802.57.4000	0.000386
4802.57.4020	0.000386
4802.57.4040	0.000386
4802.57.4090	0.000386
4802.58.1000	0.000386
4802.58.2020	0.000386
4802.58.2040	0.000386
4802.58.2080	0.000386
4802.58.5000	0.000386
4802.58.6020	0.000386
4802.58.6040	0.000386
4802.61.1000	0.000386
4802.61.2000	0.000386
4802.61.3110	0.000386
4802.61.3135	0.000386
4802.61.3191	0.000386
4802.61.5000	0.000386
4802.61.6020	0.000386
4802.61.6040	0.000386
4802.62.1000	0.000386
4802.62.2000	0.000386
4802.62.3000	0.000386
4802.62.5000	0.000386
4802.62.6120	0.000386
4802.62.6140	0.000386
4802.69.1000	0.000386
4802.69.2000	0.000386
4802.69.3000	0.000386
4804.11.0000	0.000386
4804.19.0000	0.000386
4804.21.0000	0.000386
4804.29.0000	0.000386
4804.31.4020	0.000386
4804.31.4040	0.000386
4804.31.6000	0.000386
4804.39.4020	0.000386
4804.39.4049	0.000386
4804.39.6020	0.000386
4804.39.6040	0.000386
4804.41.2000	0.000386
4804.41.4000	0.000386
4804.42.0010	0.000386
4804.42.0020	0.000386
4804.42.0030	0.000386
4804.42.0040	0.000386
4804.42.0050	0.000386
4804.49.0000	0.000386
4804.51.0000	0.000386
4804.52.0010	0.000386
4804.52.0020	0.000386
4804.52.0030	0.000386
4804.52.0040	0.000386
4804.52.0050	0.000386
4804.59.0000	0.000386
4805.11.0000	0.000386
4805.12.1000	0.000386
4805.12.2000	0.000386
4805.19.1000	0.000386
4805.19.2000	0.000386
4805.24.5000	0.000386
4805.24.7000	0.000386
4805.24.9000	0.000386
4805.25.0000	0.000386
4805.91.1010	0.000386
4805.91.9000	0.000386

available; instead, average prices were estimated using export data from the U.S. Census Bureau.

Paper and paper-based packaging	Assessment $/kg
4805.92.4010	0.000386
4805.92.4030	0.000386
4805.93.4010	0.000386
4805.93.4030	0.000386
4805.93.4050	0.000386
4805.93.4060	0.000386
4807.00.9100	0.000386
4807.00.9400	0.000386
4810.13.1120	0.000386
4810.13.1140	0.000386
4810.13.1900	0.000386
4810.13.2010	0.000386
4810.13.2090	0.000386
4810.13.5000	0.000386
4810.13.6000	0.000386
4810.13.7020	0.000386
4810.13.7040	0.000386
4810.14.1120	0.000386
4810.14.1140	0.000386
4810.14.1900	0.000386
4810.14.2010	0.000386
4810.14.2090	0.000386
4810.14.5000	0.000386
4810.14.6000	0.000386
4810.14.7020	0.000386
4810.14.7040	0.000386
4810.19.1100	0.000386
4810.19.1900	0.000386
4810.19.2010	0.000386
4810.19.2090	0.000386
4810.22.1000	0.000386
4810.22.5044	0.000386
4810.22.5080	0.000386
4810.22.6000	0.000386
4810.22.7020	0.000386
4810.22.7040	0.000386
4810.29.1025	0.000386
4810.29.1035	0.000386
4810.29.5000	0.000386
4810.29.6000	0.000386
4810.29.7020	0.000386
4810.29.7025	0.000386
4810.29.7035	0.000386
4810.31.1020	0.000386
4810.31.1040	0.000386
4810.31.3000	0.000386
4810.31.6500	0.000386
4810.32.1020	0.000386
4810.32.1040	0.000386
4810.32.1060	0.000386
4810.32.3000	0.000386
4810.32.6500	0.000386
4810.39.1200	0.000386
4810.39.1400	0.000386
4810.39.3000	0.000386
4810.39.6500	0.000386
4810.92.1225	0.000386
4810.92.1235	0.000386
4810.92.6525	0.000386
4810.92.6535	0.000386
4810.99.1050	0.000386
4810.99.6500	0.000386
4811.51.2010	0.000386
4811.51.2020	0.000386
4811.51.2030	0.000386
4811.59.4020	0.000386
4811.90.8030	0.000386

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Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2022–24108 Filed 11–4–22; 8:45 am]

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SMALL BUSINESS ADMINISTRATION

13 CFR Part 120

RIN 3245–AH92

Small Business Lending Company (SBLC) Moratorium Rescission and Removal of the Requirement for a Loan Authorization

AGENCY: U.S. Small Business Administration.

ACTION: Proposed rule.

SUMMARY: The U.S. Small Business Administration (SBA or Agency) is proposing to lift the moratorium on licensing new Small Business Lending Companies (SBLCs) and add a new type of entity called a Mission-Based SBLC. SBA is also proposing to remove the requirement for a Loan Authorization.

DATES: SBA must receive comments on this proposed rule on or before January 6, 2023.

ADDRESSES: You may submit comments, identified by RIN 3245–AH92, through the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

SBA will post all comments on *http://www.regulations.gov.* If you wish to submit confidential business information (CBI) as defined in the User Notice at *http://www.regulations.gov,* please submit the information via email to *Dianna.Seaborn@sba.gov.* Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review the information and make the final determination whether it will publish the information.

FOR FURTHER INFORMATION CONTACT: Dianna Seaborn, Director, Office of Financial Assistance, Office of Capital Access, Small Business Administration, at (202) 205–3645 or *Dianna.Seaborn@sba.gov.* The phone number above may also be reached by individuals who are deaf or hard of hearing, or who have speech disabilities, through the Federal Communications Commission's TTY-Based Telecommunications Relay Service teletype service at 711.

SUPPLEMENTARY INFORMATION:

I. Background Information

The mission of SBA is to ''aid, counsel, assist, and protect . . . the interests of small business concerns in order to preserve free competitive enterprise . . . and to maintain and strengthen the overall economy of our nation.'' 15 U.S.C. 631(a). SBA accomplishes this mission, in part, through programs that bridge the financing gap in the private market. One such program is the 7(a) Loan Program authorized by section 7(a) of the Small Business Act (15 U.S.C. 636(a)), which supports our nation's economy by providing SBA-guaranteed loans to small businesses that lack adequate access to capital on reasonable terms and conditions.

Section 7(a)(17) of the Small Business Act states that SBA shall authorize lending institutions and other entities, in addition to banks, to make 7(a) loans. To this end, SBA has authorized Small Business Lending Companies (SBLCs) as defined in 13 CFR 120.10 to participate in the 7(a) Loan Program. SBLCs are non-depository lending institutions authorized by SBA only to make loans pursuant to section 7(a) of the Small Business Act and loans to Intermediaries in SBA's Microloan program. Under current regulations, SBLCs may not be affiliated with another SBA Lender, including 7(a) Lenders or Certified Development Companies (CDCs) that participate in SBA's CDC/504 Loan Program. SBLCs are subject to all regulations pertaining to 7(a) loans and Loan Program Requirements (as defined in 13 CFR 120.10) regarding origination, servicing, and liquidation. Unlike the majority of 7(a) Lenders, which are Federally-regulated depository institutions, SBLCs are regulated, supervised, and examined solely by SBA. As SBA-regulated entities, SBLCs are subject to specific regulations regarding formation, capitalization, and enforcement actions.

On August 17, 1981, SBA published a Proposed Rule (46 FR 41523) to, among other things, impose a moratorium on licensing new SBLCs, because the Agency did not have adequate resources to effectively service and supervise additional SBLCs. Subsequently, on January 4, 1982, SBA published a Final Rule (47 FR 9) repealing its authority to approve additional SBLCs as participating lenders. Since then, the number of SBLC Licenses has remained unchanged at 14. To become an SBLC under current regulations, an entity must acquire one of the existing 14 SBLC Licenses from an entity that is willing to sell its SBLC License and exit the 7(a) Loan Program.

On February 18, 2011, SBA created the Community Advantage (CA) Pilot Program to provide 7(a) loans in underserved markets through mission-oriented lenders focused on economic development (76 FR 9626). SBA waived the moratorium on the licensing of new SBLCs to allow organizations that met the definition of an SBLC but that did not have an SBLC License to participate in the CA Pilot Program as CA Lenders. The CA Pilot Program was recently extended until September 30, 2024 (87 FR 19165).

SBA is also proposing to remove the requirement for a Loan Authorization. Both the 7(a) Loan Program and the 504 Loan Program currently require a Loan Authorization providing the terms and conditions under which SBA will make or guarantee business loans. Currently, under delegated processing methods, 7(a) Lenders and CDCs (SBA Lenders) must review a lengthy template that covers every potential loan requirement and lending scenario to select the requirements that pertain to the individual loan application. The SBA Lender then creates the Authorization, signs it, and uploads it into SBA's electronic transmission (E-Tran) system as a digital record. Under non-delegated processing methods, SBA's loan guaranty processing centers (SBA Centers) prepare the Authorization for the SBA Lender to sign and upload into E-Tran. Separately, the terms and conditions of each loan are also submitted into E-Tran by the SBA Lender through the submission of the loan application data and conditions. This dual entry of information is a duplication of effort and creates an opportunity for a mismatch of information between the two sources of the loan terms and conditions. SBA Lenders have provided feedback that the current process to capture the loan terms and conditions through the use of the Authorization is cumbersome, outdated, and is not necessary because the information can be captured through the submission of the terms and conditions into E-Tran through the normal course of submitting the loan application data and conditions. SBA proposes to eliminate the requirement to create a separate Authorization and to instead rely on the use of the terms and conditions of the loan application as submitted by the SBA Lender into E-Tran. These terms and conditions will reflect the agreement between the SBA and the SBA Lender providing the terms and conditions under which SBA will guarantee a business loan, subject to the Lender's compliance with all applicable Loan Program Requirements. SBA obligates funds to support the guaranty at the time SBA issues the SBA Loan Number. Currently, the Authorization is the written agreement that spells out the terms and conditions, which the SBA Lender is required to sign. The proposed change incorporates the terms and conditions in the E-Tran system, and SBA will continue to obligate funds to support the guaranty based on the terms and conditions in E-Tran. SBA's guaranty is conditioned upon the SBA Lender complying with Loan Program Requirements.

II. Section-by-Section Analysis

SBLC Moratorium Recission

Section 120.10—Definitions

SBA has determined that certain markets where there are capital market gaps continue to struggle to obtain financing on non-predatory terms. Therefore, SBA is proposing to lift the moratorium on licensing new Small Business Lending Companies (SBLC) and create a new type of Mission-Based SBLC to help bridge this financing gap.

SBA is proposing to add a new definition for Mission-Based SBLC. SBA proposes to define a Mission-Based SBLC as a specific type of SBLC that is a nonprofit organization whose purpose is to fill an identified capital market gap. Similar to regular SBLCs, SBA will license these Mission-Based SBLCs for the sole purpose of making 7(a) loans.

Mission-Based SBLCs will allow SBA to better meet the needs of underserved communities. Mission-Based SBLCs will increase opportunities for access to capital in precisely targeted capital market gaps as described more fully below in proposed revisions to section 120.470. SBA is proposing for Mission-Based SBLCs to be nonprofit entities because nonprofit lending organizations often specifically target the capital market gaps SBA intends to fill, yet nonprofits may be unable to meet SBA's current requirements for SBLCs, which are typically for-profit. Adding Mission-Based SBLCs to the possible types of 7(a) Lenders will also allow CA Lenders an opportunity to apply to permanently participate in the 7(a) Loan Program as a Mission-Based SBLC while continuing to meet the needs of underserved communities. When SBA authorizes an additional Mission-Based SBLC License to a CA Lender, the CA Lender will transition from making 7(a) loans in a temporary pilot program to instead making 7(a) loans under a permanent license in the permanent 7(a) loan program.

Within this definition, SBA proposes to state that it will accept applications for new Mission-Based SBLCs from time to time as published in the **Federal Register**. SBA plans to issue **Federal Register** Notices when application periods for new Mission-Based SBLC Licenses will open, with information regarding the number of applications that will be accepted, the time period applications will be open, and/or the number of Licenses that will be issued. As with current SBLC Licenses and the CA Pilot Program, SBA's ability to accept new program participants is tied to market conditions and SBA's capacity to supervise and oversee additional lenders. Rather than authorizing a certain number of lenders at the outset and then imposing a moratorium and foreclosing opportunities for new lenders, SBA intends to build in the flexibility for SBA to issue **Federal Register** Notices to open and close application periods. This will allow SBA to respond more quickly to needs in underserved markets based on its oversight capacity and provide notice to the public so potential lenders may begin to prepare applications.

To accomplish the goal of expanding capital opportunities for underserved businesses and allowing Mission-Based SBLCs and regular SBLCs to increase the availability of 7(a) loans to small businesses, SBA must remove the moratorium on licensing new SBLCs. Current section 120.10 definition of Small Business Lending Company (SBLC) states that SBA has imposed a moratorium on licensing new SBLCs since January 1982, and the number of licensed SBLCs has remained at 14 ever since. SBA proposes revising this definition to remove the statement that SBA has imposed a moratorium on licensing new SBLCs. Not only will this allow SBA to license Mission-Based SBLCs, but it will allow SBA to increase the number of regular SBLCs as well. As with SBA's proposed definition of Mission-Based SBLCs above, SBA proposes to accept applications for SBLC Licenses from time to time as published in the **Federal Register**. For the same reasons described above, this will allow SBA the flexibility to respond to market conditions and oversight capacity while providing the public notice to allow interested parties to prepare applications. Based on current oversight capacity, and as described in the cost-benefit analysis below, SBA anticipates that it has the ability to license and supervise three new additional SBLCs. SBA anticipates that current CA Lenders in good standing may apply and will be immediately approved as Mission-Based SBLCs, which will not increase the number of

entities supervised and overseen by SBA.

Section 120.466—SBA Supervised Lender Application

Current section 120.466, paragraph (a)(6), states that in connection with any application to become an SBLC, the applicant must include a letter agreement from the existing SBLC stating that the SBLC is seeking to transfer its lending authority. SBA is proposing to revise this section because the lifting of the moratorium on new SBLC Licenses will no longer require that an applicant show that an existing lender is transferring its authority. However, as SBA is proposing to accept applications for new SBLCs from time to time in section 120.10, there may be periods when new SBLC Licenses are not being issued and existing Licenses will be acquired and transferred. Therefore, SBA is proposing to revise this section to state that an applicant to become an SBLC must show a letter agreement from an existing SBLC if it is acquiring an existing License.

Section 120.470—What are SBA's additional requirements for SBLCs?

SBA is proposing to revise section 120.470 to reference and include additional requirements for its proposed new type of SBLC, Mission-Based SBLCs. As a type of SBLC, except where otherwise explicitly mentioned in regulations, all requirements imposed on SBLCs and SBA Supervised Lenders will apply to Mission-Based SBLCs as well.

For the reasons discussed above, Mission-Based SBLCs must be nonprofit organizations. SBA is proposing to revise paragraph (b) to reflect this requirement for a Mission-Based SBLC's business structure. Regular SBLCs may continue to be for-profit or nonprofit corporations, limited liability companies, or limited partnerships.

To ensure that Mission-Based SBLCs fill identified capital market gaps and provide targeted financial assistance to underserved communities, SBA has determined that it is necessary to impose additional restrictions on Mission-Based SBLCs. To this end, SBA is proposing to add a new paragraph (h) to describe the requirements Mission-Based SBLCs must meet.

Proposed subparagraph (h)(1) discusses the requirements for a Mission-Based SBLC related to the identified capital market gap the lender will fill. SBA proposes to require that a Mission-Based SBLC must make a certain percentage of the total number of loans in its identified capital market gap. This is similar to the requirement in the existing CA Pilot Program, where CA Lenders must make at least 60% of their total loans to certain communities or businesses. To ensure that the needs of the identified capital market gap are being met while keeping in mind each Mission-Based SBLC's individual risk tolerance, SBA has determined that it will not impose a specific percentage-based requirement on all Mission-Based SBLCs in regulation. Instead, the minimum acceptable percentage of loans made to an identified capital market gap will be individualized based on the Mission-Based SBLC's target market, risk tolerance, financing needs, or other factors identified by the lender in their proposed business plan upon application.

The proposed regulation states that when an entity applies to become a Mission-Based SBLC, it will include in its business plan an identified capital market gap that it proposes to fill and the percentage of its total loans that it proposes to make in this market. An identified capital market gap may include a geographic area, startup businesses, business sector (such as certain NAICS codes), demographic (such as veteran-owned businesses), or other underserved market as described in the business plan. SBA will determine, in its sole discretion, whether the proposed capital market gap is acceptable and the percentage of loans made in that market on the basis of whether SBA agrees there is a need in the target market. For example, SBA may determine that 7(a) loans are widely available in a large metropolitan area by examining historical loan data and the number of active lenders in the area and be less likely to approve an applicant to become a Mission-Based SBLC without a strong showing that there is a capital market gap and a thorough business plan to meet that gap. In another example, SBA's historical data indicates that there are comparatively fewer 7(a) Lenders and 7(a) loans made in certain rural areas, and an applicant to become a Mission-Based SBLC may be more likely to show that such areas have a capital market gap that can be filled by the lender.

Proposed subparagraph (h)(2) states that SBA will determine in its sole discretion a Mission-Based SBLC's minimum acceptable percentage of total loans that it must make in its identified capital market gap, maximum loan size, geographic area of operation, and capitalization. SBA will make this determination on the basis of the applicant's proposed identified capital market gap, proposed capitalization, business plan, experience of staff, or lending history, among other things included in the application. SBA believes that such determinations are necessary when authorizing Mission-Based SBLCs to ensure that the needs of identified capital market gaps are addressed, allow flexibility for individualization of lenders' operations, and ensure limits on SBA's risk exposure. For example, an experienced and well-capitalized applicant to become a Mission-Based SBLC may propose an identified capital market gap in a comparatively expensive business sector, therefore, SBA may accept a larger than average maximum loan size. Alternatively, a Lender with comparatively little experience may propose to operate in a relatively inexpensive geographic area of operation, and SBA may determine that a lower maximum loan size is necessary. Additionally, a nonprofit organization that is not as well capitalized but that targets a highly underserved area may be licensed as a Mission-Based SBLC but SBA may determine that a lower maximum loan size is necessary. SBA intends to allow Mission-Based SBLCs to request higher loan amounts and expansions to geographic areas as their lending history, capitalization, and other factors indicate the risk is acceptable. Allowing individualization for Mission-Based SBLCs will allow SBA and lenders flexibility to more precisely target underserved communities.

Section 120.471—What are the minimum capital requirements for SBLCs?

Current section 120.471, subparagraph (a)(1) addresses minimum capital requirements for SBLCs and states that beginning on January 4, 2024, each SBLC that makes or acquires a 7(a) loan must maintain, at a minimum, unencumbered paid-in capital and paid-in surplus of at least $5,000,000, or 10 percent of the aggregate of its share of all outstanding loans, whichever is greater. SBA proposes to revise this paragraph by adding a new subparagraph (4) that will state that, a Mission-Based SBLC must maintain a minimum amount of capital at the discretion of the Administrator in consultation with SBA's Associate Administrator for SBA's Office of Capital Access (AA/OCA), to ensure sufficient risk protection for SBA and lenders while not burdening smaller lenders with large capital requirements. This proposal will allow SBA to license Mission-Based SBLCs that are nonprofit mission-oriented lenders that target capital market gaps identified by SBA when these entities would otherwise not

be able to meet SBA's minimum capital requirements.

Section 120.820—CDC Affiliation

Current section 120.820 limits the entities with which CDCs may be affiliated. SBA proposes to add a new subparagraph (g), which states notwithstanding subparagraphs (b), (c), and (e), a CDC may be affiliated with a Mission-Based SBLC. This revision will allow CDCs to form the required entity whose sole purpose is to make 7(a) loans as a Mission-Based SBLC that targets capital market gaps identified by SBA. This revision is consistent with the CA Pilot Program, which allows CDCs to be affiliated with CA Lenders, and allows such CA Lenders to apply to become permanent participants in the 7(a) Loan Program as Mission-Based SBLCs.

Removal of Requirement for Loan Authorization

Section 120.10—Definitions

SBA is proposing to remove the definition for Authorization. For the reasons stated above, SBA will continue to rely on the SBA Form 750, which is a written agreement executed by all participating lenders requiring that those same lenders comply with all statutes and regulations. For loan accounting purposes, lenders will continue, as they do today, to electronically submit their request for a loan guaranty authorization from the Agency's loan accounting system of record—E-Tran.

SBA is proposing to amend the definition of Loan Instruments to remove the word Authorization. The amended definition will state that Loan Instruments are the note, instruments of hypothecation, and all other agreements and documents related to a loan.

SBA is proposing to amend the definition of Loan Program Requirements or SBA Loan Program Requirements to remove the word Authorization. The amended definition will state that Loan Program Requirements or SBA Loan Program Requirements are requirements imposed upon Lenders, CDCs, or Intermediaries by statute; SBA and applicable government-wide regulations; any agreement the Lender, CDC, or Intermediary has executed with SBA or to which the Lender or CDC is subject; SBA Standard Operating Procedures (SOPs); **Federal Register** notices; and official SBA notices and forms applicable to the 7(a) Loan Program, 504 Loan Program or Microloan Program; as such requirements are issued and revised by SBA from time to time. For CDCs, this term also includes requirements imposed by Debentures, as that term is defined in § 120.802. For Intermediaries, this term also includes requirements imposed by promissory notes, collateral documents, and grant agreements.

Section 120.120—What are eligible uses of proceeds?

Current section 120.120 states that a small business must use an SBA business loan for sound business purposes, and the uses of proceeds are prescribed in each loan's Authorization. The section goes on to describe the various ways in which a borrower may use SBA loan proceeds. SBA proposes to amend this section to remove the sentence that states ''The uses of proceeds are prescribed in each loan's Authorization.'' SBA already captures the uses of proceeds of the SBA-guaranteed loan through the loan application data and conditions the SBA Lender enters into ETRAN; therefore, it is not necessary to include the information in a separate Authorization.

Section 120.192—Approval or Denial

Current section 120.192 states that Applicants receive notice of approval or denial by the Lender, CDC, Intermediary, or SBA, as appropriate. Notice of denial will include the reasons. If a loan is approved, an Authorization will be issued. SBA proposes to amend section 120.192 to remove the sentence that states ''If a loan is approved, an Authorization will be issued.'' SBA's current practice is to review an Authorization and issue an SBA Loan Number when the Authorization is considered satisfactory to SBA. SBA considers the issuance of the loan number to indicate loan approval by SBA. The proposed rule to no longer require an Authorization will only slightly modify the current process. Under the proposed rule, SBA will indicate loan approval by issuing a loan number.

Section 120.220—Fees That Lender Pays SBA

Section 120.220 states the requirements for the fees that 7(a) Loan Program Lenders pay SBA. The preamble of section 120.220 states in part ''Acceptance of the guaranty fee by SBA does not waive any right of SBA arising from a Lender's negligence, misconduct or violation of any provision of these regulations, the guaranty agreement, or the loan authorization.'' For the reasons stated above, SBA proposes to remove the reference to the loan Authorization so that the sentence states ''Acceptance of the guaranty fee by SBA does not waive any right of SBA arising from a Lender's negligence, misconduct or violation of any provision of these regulations, or the guaranty agreement.''

Current section 120.220(e) states in part ''Acceptance of the guarantee fee by SBA shall not waive any right of SBA arising from the [7(a)] Lender's misconduct or violation of any provision of this part, the guarantee agreement, the Authorization, or other loan documents.'' For the reasons stated above, SBA proposes to remove the reference to the loan Authorization so that the revised section 120.220(e) will state ''Acceptance of the guarantee fee by SBA shall not waive any right of SBA arising from the [7(a)] Lender's misconduct or violation of any provision of this part, the guarantee agreement, or other loan documents.''

Section 120.801—How a 504 Project Is Financed

Current section 120.801(a) applies to the 504 Loan Program and states ''One or more small businesses may apply for 504 financing through a CDC serving the area where the 504 Project is located. SBA issues an Authorization if it agrees to guarantee part of the funding for a Project.'' For the reasons stated above, SBA proposes to remove the sentence that references the Authorization.

Section 120.842—ALP Express Loans

Current section 120.842(b)(4) states the requirements for submission of loan documents for 504 Loan Program ALP Express loans and states in part ''If approved, SBA will notify the ALP CDC of the loan number assigned to the loan and provide the CDC with a signed copy of the Loan Authorization.'' SBA's current practice is to review an Authorization and issue a loan number when the Authorization is considered satisfactory to SBA. Under the proposed rule, SBA will indicate loan approval by issuing a loan number. Therefore, SBA proposes to remove the reference to the Loan Authorization so the sentence will state ''If approved, SBA will notify the ALP CDC of the loan number assigned to the loan.''

Current section 120.842(b)(5) states the requirements for loan and debenture closing for 504 Loan Program ALP Express loans and states ''After receiving notification of the loan number and a signed copy of the Loan Authorization from SBA, the ALP CDC is responsible for properly undertaking all actions necessary to close the ALP Express Loan and Debenture in accordance with the expedited loan closing procedures applicable to a Priority CDC and with § 120.960.'' For

the reasons stated above, SBA proposes to remove the reference to the loan Authorization so that section 120.842(b)(5) will state ''After receiving notification of the loan number, the ALP CDC is responsible for properly undertaking all actions necessary to close the ALP Express Loan and Debenture in accordance with the expedited loan closing procedures applicable to a Priority CDC and with § 120.960.''

Section 120.921—Terms of Third Party Loans

Current section 120.921(a) states the requirements for the loan maturity of the 504 Loan Program Third Party Lender loan. Section 120.921(a) states ''A Third Party Loan must have a term of at least 7 years when the 504 loan is for a term of 10 years and 10 years when the 504 loan is for 20 years. If there is more than one Third Party Loan, an overall loan maturity must be calculated, taking into account the maturities and amounts of each loan. If there is a balloon payment, it must be justified in the loan report and clearly identified in the Loan Authorization.'' For the reasons stated above, SBA proposes to remove the last sentence in section 120.921(a) in its entirety so that it states ''A Third Party Loan must have a term of at least 7 years when the 504 loan is for a term of 10 years and 10 years when the 504 loan is for 20 years. If there is more than one Third Party Loan, an overall loan maturity must be calculated, taking into account the maturities and amounts of each loan.''

Section 120.960—Responsibility for Closing

Current section 120.960(c)(1) states that SBA may, within its sole discretion, decline to close a 504 Loan Program Debenture; direct the transfer of the 504 loan to another CDC; or cancel its guarantee of the Debenture, prior to sale, if the CDC has failed to comply materially with any requirement imposed by statute, regulation, SOP, policy and procedural notice, any agreement the CDC has executed with SBA, or the terms of a Debenture or loan authorization. For the reasons stated above, SBA proposes to remove the reference to the loan Authorization.

Section 120.971—Allowable Fees Paid by Borrower

Section 120.971 states the requirements for the allowable fees that a 504 Loan Program Certified Development Company (CDC) may charge the Borrower in connection with a 504 loan and Debenture. Section 120.971(a)(1) describes the Processing fee and states ''The CDC may charge up to 1.5 percent of the net Debenture proceeds to process the financing. Two-thirds of this fee will be considered earned and may be collected by the CDC when the Authorization for the Debenture is issued by SBA. The portion of the processing fee paid by the Borrower may be reimbursed from the Debenture proceeds;'' For the reasons stated above, SBA proposes to remove the reference to the Authorization for the Debenture and to instead refer to the issuance of the loan number so that the amended section 120.971(a)(1) will state ''The CDC may charge up to 1.5 percent of the net Debenture proceeds to process the financing. Two-thirds of this fee will be considered earned and may be collected by the CDC when the loan number is issued by SBA. The portion of the processing fee paid by the Borrower may be reimbursed from the Debenture proceeds;''

Compliance With Executive Orders 12866, 12988, 13132, and 13563, the Paperwork Reduction Act (44 U.S.C., Ch. 35), the Congressional Review Act (5 U.S.C. 801–808), and the Regulatory Flexibility Act (5 U.S.C. 601–612)

Executive Order 12866

The Office of Management and Budget anticipates that this rule will be a ''significant regulatory action'' under Executive Order 12866. SBA has drafted a Regulatory Impact Analysis for the public's information in the next section. Each section begins with a core question.

A. Regulatory Objective of the Proposal

Is there a need for this regulatory action?

1. SBLC Moratorium Recission

Access to capital is one of the primary factors indicating whether a small business will startup, grow, and survive. However, many small businesses experience significant challenges securing the financing they need to sustain their businesses. In a 2019 report on minority-owned firms, financial challenges due to lack of credit availability was cited by 51% of Black-owned businesses, 40% of Hispanic-owned businesses, 36% of Asian-owned businesses, and 30% of White-owned businesses.[1] Further, according to a 2020 report on small business employer firms, nearly half of recent credit applicants experienced funding gaps,[2] and only 51% of applicants received the full amount of financing sought.[3]

SBA's existing loan programs serve an important role in credit markets for small businesses by providing financing to businesses that do not have credit available elsewhere from conventional sources on reasonable terms. However, there are still gaps in capital for underserved communities that require policies targeted to meeting their needs. The proposed revisions will increase lending activity in identified capital market gaps, resulting in the expansion of business opportunities and the creation of more jobs in underserved communities.

SBA's CA Pilot Program, which currently expires September 30, 2024, was specifically created to increase access to capital to small businesses located in underserved markets. SBA has learned that CA Lenders are able to routinely make at least 60 percent of their loans to small businesses located in underserved markets; therefore, SBA is onboarding more lenders to participate in 7(a) lending to increase the number of mission-based lenders that use the program. Licensing new SBLCs and Mission-Based SBLCs will provide a path for successful CA Lenders to become participants in the 7(a) Loan Program long-term. In addition, many non-traditional lenders participated in SBA's Paycheck Protection Program (PPP), which provided billions of dollars to small businesses during the economic upheaval caused by the COVID–19 pandemic. Based on the success of the PPP, removing the moratorium on licensing new SBLCs and Mission-Based SBLCs opens opportunities for more non-traditional lenders to participate in the 7(a) Loan Program, providing additional sources of capital to America's small businesses and targeting gaps in the credit market.

2. Removal of the Requirement for a Loan Authorization

SBA's current policy of requiring a separate Loan Authorization document that contains the loan terms and conditions in addition to the loan terms and conditions that the SBA Lender also submits to SBA with its guaranty application is cumbersome, outdated, and duplicative. SBA is proposing to revise its regulations to eliminate the

[1] Federal Reserve Bank of Atlanta, ''Small Business Credit Survey Report on Minority-Owned Firms,'' December 2019, page 3 at 20191211-ced-minority-owned-firms-report.pdf (*fedsmallbusiness.org*).

[2] Federal Reserve Banks of Atlanta, Boston, Chicago, Cleveland, Dallas, Kansas City, Minneapolis, New York, Philadelphia, St. Louis, San Francisco ''Small Business Credit Survey 2020 Report on Employer Firms,'' page ii at 2020-sbcs-employer-firms-report (*fedsmallbusiness.org*).

[3] Ibid, page ii.

duplication of effort and opportunity for a mismatch of information between the two sources of the loan terms and conditions.

B. Benefits and Costs of the Rule

What are the potential benefits and costs of this regulatory action?

1. SBLC Moratorium Rescission

SBA anticipates minor additional costs or impact on the subsidy to operate the 7(a) Loan Program in the first 5 years under these proposed regulations resulting from an anticipated modest increase in 7(a) loan activity due to additional SBLCs, as newly established SBLCs take up to five years to reach the current lending activity sustained by established SBLC license holders. SBA has confirmed that there will be no subsidy impact in FY 2024.

The existing 14 licensed SBLCs each approve an average of 125 loans per year. SBA anticipates new SBLCs will require a ramp-up period over the course of their first several years after they are licensed to reach this level of 7(a) lending activity. Over the course of the past four fiscal years, the majority of new 7(a) lenders have made between 1 and 26 7(a) loans in their first year of activity, with the average number of loans from each new 7(a) lender of less than three loans in their first year of 7(a) loan activity. Over the fiscal years 2018 through 2021, there were three new SBLC's that acquired SBLC Licenses, and those new SBLCs approved a total of 40 7(a) loans in their first years of operation, for an average of approximately 13 7(a) loans for each SBLC in their first year. Based on loan volume for other new 7(a) lenders between FY 2018 and FY 2021, SBA anticipates new SBLCs, including Mission-Based SBLCs, to make approximately eight 7(a) loans in their first year after they become fully operational because of the targeted markets of Mission-based SBLCs. The three new SBLCs have the potential to increase 7(a) lending by the approximately 425 loans per year over the next four years.[4]

The rate and capacity at which SBA will authorize new SBLC Licenses is dependent on SBA having adequate staffing and funding to conduct oversight activities and initial screening of applications. Based on current staffing levels, SBA has the capacity to authorize three new SBLC Licenses in total, which does not include the conversion of existing CA Lenders to Mission-Based SBLCs. SBA's Office of Credit Risk Management (OCRM), which supervises and examines SBA Lenders, will require one new GS–13/14 Risk Management Analyst full-time equivalent employee for every seven new SBLC Licenses issued. For purposes of the cost estimates, the costs associated with each Risk Management Analyst position is based on the Federal wage scale for the Washington, DC area for a GS 14, Step 10, at $164,102 per year, with an additional cost of 100 percent (an additional $164,102 per year) added for overhead and benefits costs to yield an annual risk management staffing cost to the Agency of approximately $328,204 for every seven new SBLC Licenses issued.

SBA anticipates that all CA Lenders in good standing participating in the CA Pilot Program may apply to become Mission-Based SBLCs. When SBA authorizes an additional Mission-Based SBLC License to a CA Lender, the CA Lender will transition from making 7(a) loans in a temporary pilot program to instead making 7(a) loans under a permanent license in the regular 7(a) program. This means a CA Lender transitioning to a Mission-Based SBLC will not increase the total number of entities overseen and supervised by SBA or the cost to SBA.

SBA is authorized[5] to charge a fee for conducting oversight activities, including safety and soundness examinations of SBA-Supervised Lenders. All entities applying to participate as an SBLC (including a Mission-Based SBLC) will undergo an initial safety and soundness examination at the time of application. SBA estimates the fee for completing the initial safety and soundness examination will be a minimum of $10,000 per applicant. The fees charged by SBA for conducting oversight activities support the contractors necessary to work with SBA staff on the oversight and examination activities. Additional full-time employees will be necessary dependent upon the number of additional SBA-Supervised non-regulated entities onboarded.

The fees imposed on the new SBLCs, including Mission-Based SBLCs, will be consistent with the oversight fees for the 7(a) Loan Program published annually by OCRM.[6] SBA conducts safety and soundness exams on SBLCs at least once every two years. Additionally, SBA conducts targeted reviews of loan files in between regularly scheduled safety and soundness exams. The total biennial cost of these risk-based reviews is currently $50,000 to $150,000 per institution, with review costs correlated to the size of the SBLC's loan portfolio. For FY 2022, the annual fee for monitoring and Other Lender Oversight Activities for SBA Supervised Lenders, which includes SBLCs, is $161.16 for every $1 million in 7(a) guaranteed dollars a 7(a) Lender has outstanding. For FY 2022, the additional fee for Delegated Authority Lenders is approximately $13.11 for every $1 million in 7(a) guaranteed dollars a delegated Lender has outstanding. This fee covers the costs of Delegated Authority Reviews and is assessed annually based on each delegated 7(a) Lender's portion of the total dollar amount of 7(a) guarantees in the SBA loan portfolio for all delegated 7(a) Lenders as of the end of the prior fiscal year. For this calculation, 7(a) guaranteed dollars does not include loans originated under PPP.

SBA also charges 7(a) Lenders fees for monitoring, including the quarterly off-site/monitoring reviews conducted through the Loan and Lender Monitoring System (L/LMS). SBA's oversight fees include costs related to Other Lender Oversight Activities (*e.g.,* technical assistance and analytics, a portion of OCRM salaries for 7(a) Lender oversight activities, supervision and enforcement activities, and similar costs to support SBA's lender oversight program). These oversight fees are based on SBA's costs. The fees for monitoring (*e.g.,* L/LMS and subscription services), Other Lender Oversight Activities, and Delegated Authority Reviews are assessed annually based on each 7(a) Lender's portion of the total dollar amount of 7(a) guarantees in SBA's portfolio or, as applicable, the relevant portfolio segment the activity covers. Oversight fees are assessed on a per-loan basis and range from $161 to $174 per loan based on whether the lender is a non-delegated or holds delegated lender authority.

Lifting the moratorium on licensing new SBLCs and authorizing Mission-Based SBLCs will benefit the approximately 51% of small employer firms that do not have their financing needs met,[7] either because they did not receive all the financing for which they applied, or because they did not apply

[4] This estimate is from the average number of 7(a) loans each year based on the 1,694 new 7(a) loans approved by all new SBA 7(a) Lenders in the four-year period of fiscal year 2018 through fiscal year 2022

[5] See section 23(a) of the Small Business Act. 15 U.S.C. 650(a), 15 U.S.C. 634(b)(6), (7), (14), and 13 CFR 120.1070.

[6] SBA Information Notice 5000–828947, FY 2022 Updated Fee Schedule for SBA Oversight of 7(a) Lenders, March 3, 2022. (*https://www.sba.gov/document/information-notice-5000-828947-fy-2022-updated-fee-schedule-sba-oversight-7a-lenders*).

[7] Ibid, page 11.

due to a variety of reasons, including the belief they would be turned down.

The proposed revisions may have a negative impact to the 14 existing SBLCs by destabilizing the value of their licenses due to increased competition and issuance of new SBLC Licenses. The value of SBLC Licenses may periodically fluctuate based on whether SBA is or is not accepting applications for new SBLCs and entities interested in the program must acquire existing SBLC License.

C. What alternatives have been considered?

1. SBLC Moratorium Rescission

SBA considered leaving the regulations unchanged and relying upon the CA Pilot Loan Program to address the needs of access to capital in underserved markets; however, the low historic loan volume and lack of any CA loan activity in some rural and underserved geographic areas makes this an unviable alternative.

SBA also considered requiring mission-based lenders to meet the $5 million capitalization requirements currently in place for all SBLC license holders; however, SBA determined many of these lending entities would be unable to qualify for SBA's program based on such a requirement.

2. Removal of the Requirement for a Loan Authorization

SBA considered leaving the requirements for the Loan Authorization intact. SBA does not have quantitative data on the effects of removing or retaining the requirements for the Loan Authorization. However, SBA Lenders struggle under the burden of the existing lengthy Loan Authorization requirement, and they have and continue to request relief from this requirement. In the interest of reducing duplicative effort and making better use of existing technology and processes, SBA determined it is in the interest of SBA and SBA Lenders to revise the requirement for a Loan Authorization as proposed.

SBA also considered facilitating electronic entry of the Loan Authorization for the subject SBA loans. However, electronic entry of the Loan Authorization form would not address the duplicative effort resulting from subsequent entry in E-Tran. This, therefore, would also not be a viable alternative.

Executive Order 12988

This action meets applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have preemptive effect or retroactive effect.

Executive Order 13132

This rule does not have federalism implications as defined in Executive Order 13132. It 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, as specified in the Executive Order. As such it does not warrant the preparation of a Federalism Assessment.

Executive Order 13563

A description of the need for this regulatory action and benefits and costs associated with this action, including possible distributional impacts that relate to Executive Order 13563, are included above in the Regulatory Impact Analysis under Executive Order 12866.

Paperwork Reduction Act, 44 U.S.C. Ch. 35

The portions of the proposed rule on the SBLC moratorium rescission would require SBA Form 2498, ''SBA Supervised Lender Assessment Plan,'' to be revised to edit the requirement that an applicant to become an SBLC must include a letter from an existing SBLC evidencing intent to transfer lending authority to conform with revisions to 13 CFR 120.466. The portion of this rule on removing the requirement for a Loan Authorization is not subject to the Paperwork Reduction Act because the Loan Authorization is not an information collection. Removal of the Loan Authorization may require revision to OMB-approved forms, and such revisions will be submitted to OMB in accordance with the requirements of the PRA when the rule is finalized.

Congressional Review Act, 5 U.S.C. Ch. 8

Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, also known as the Congressional Review Act or CRA, 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. SBA will submit 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. A major rule under the CRA cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs anticipatesanticipates that this rule is not a ''major rule'' as defined by 5 U.S.C. 804(2). Therefore, this rule is not subject to the 60-day restriction.

Regulatory Flexibility Act, 5 U.S.C. 601–612

When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires the agency to ''prepare and make available for public comment an initial regulatory analysis'' which will ''describe the impact of the proposed rule on small entities.'' SBA does not anticipate the rulemaking will have a significant impact to the approximately existing 2,897 7(a) Lenders participating in the 7(a) Loan Program.

Of the 182 new 7(a) Lenders onboarded since FY 2018, only four were new SBLCs that acquired an SBLC License after receiving SBA's approval for the SBLC License transfer. SBA does not require SBLCs to provide SBA with the financial statements of the SBLC parent company, if applicable, or affiliates; therefore, SBA is not able to determine whether the SBLCs are small businesses in accordance with SBA size standards. SBA anticipates approving three SBLCs, including Mission-Based SBLCs, in the full first year after this proposed rule becomes effective.

Because some SBLC applicants may be considered small businesses per size standards in 13 CFR 121.201,[8] SBA must address the cost of preparing and submitting an SBLC application to SBA. The 2021 annual revenues (including revenues of any Parent Company) for the 13 active SBLCs (one inactive SBLC is in the process of transferring their license and their 2021 revenues were not available) range from a low of $5.1 million to a high of $910.8 million, with average annual revenues of $81.3 million. These revenues are well above the SBA small business size standard of $41.5 million in annual revenues for the North American Industry Classification System (NAICS) industry 522298, ''All Other Nondepository Credit Intermediation'' average revenue threshold to be considered a ''small business'', which includes revenue from affiliates such as parent companies. SBA does not require an SBLC to be a small business in order to participate as a 7(a)

[8] Based on the Size Standard for NAICS Code 522298, All Other Nondepository Credit Intermediation, of $41.5 million gross revenues averaged over the last five years—13 CFR 121.201 *https://www.ecfr.gov/current/title-13/chapter-I/part-121/subpart-A/subject-group-ECFRf12a11421b08a31/section-121.201.*

Lender, therefore SBA does not review the SBLC applicant for size when evaluating an SBLC application. SBA also does not collect financial information on any SBLC affiliates, which would be necessary to make a size determination for an SBLC; therefore, it is not feasible for SBA to determine if any of the SBLCs are small businesses.

Based on SBA's experience with similar data collections, an organization applying to become an SBA Supervised Lender would typically employ the services of a financial manager, an accountant, an attorney, and an administrative assistant when preparing a complete application for submission to SBA. SBA also anticipates a minor increase of additional 7(a) loan approvals each year based on the approximately three new SBLC and Mission-Based SBLC lenders per year.

The cost estimate for an SBLC applicant to complete an SBA SBLC application is based on the estimated time to complete the application multiplied by the median hourly wage by job position wages published by the U.S. Department of Labor's Bureau of Labor Statistics for 2021 [9] and increased by 100% to account for overhead benefit costs. The cost breakdown is as follows: Financial Manager (30 hours times an hourly rate of $63.32 plus overhead and benefit costs of $63.32 per hour = $3,799.20); plus Accountant (10 hours times an hourly rate of $37.14, plus overhead and benefit costs of $37.14 per hour = $742.80); plus Lawyers (5 hours times an hourly rate of $61.54, plus overhead and benefit costs of $61.54 per hour = $615.40); plus Administrative Assistant (5 hours times an hourly rate of $19.08, plus overhead and benefit costs of $19.08 per hour = $190.80); for a total anticipated cost to complete the SBLC application for each SBLC applicant of $5,348. As stated elsewhere, SBA estimates the fee for completing the initial safety and soundness examination will be a minimum of $10,000 per applicant, which would increase the cost burden for each of the three SBLC applicants to $15,348.

SBA believes the one-time estimated cost burden of $15,348 does not represent a significant economic impact to a potential SBLC applicant in comparison to the average annual revenue of existing SBLCs of $81.3 million per SBLC.

For the above reasons, SBA certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. SBA specifically requests comments on whether the number of hours estimated to prepare a complete application is appropriate.

[9] *https://www.bls.gov/oes/current/oes_nat.htm.*

List of Subjects in 13 CFR Part 120

Community development, Loan programs-business, Reporting and recordkeeping requirements, Small businesses.

For the reasons stated in the preamble, SBA proposes to amend 13 CFR part 120 as follows:

PART 120—BUSINESS LOANS

■ 1. The authority citation for 13 CFR part 120 continues to read as follows:

Authority: 15 U.S.C. 634(b)(6), (b)(7), (b)(14), (h), and note, 636(a), (h) and (m), and note, 636m, 650, 657t, and note, 657u, and note, 687(f), 696(3), and (7), and note, 697, 697a and e, and note; Pub. L. 116–260, 134 Stat. 1182.

■ 2. Amend § 120.10 by:

■ a. Removing the definition for ''Authorization'';

■ b. Revising the definitions for ''Loan Instruments'' and ''Loan Program Requirements or SBA Loan Program requirements'';

■ c. Adding a definition for ''Mission-Based Small Business Lending Company (MISSION–BASED SBLC)'' in alphabetical order; and

■ d. Revising the definition for ''Small Business Lending Company (SBLC)''.

The revisions and addition read as follows:

§ 120.10 Definitions

* * * * *

Loan Instruments are the note, instruments of hypothecation, and all other agreements and documents related to a loan.

Loan Program Requirements or SBA Loan Program Requirements are requirements imposed upon Lenders, CDCs, or Intermediaries by statute; SBA and applicable government-wide regulations; any agreement the Lender, CDC, or Intermediary has executed with SBA or to which the Lender or CDC is subject; SBA Standard Operating Procedures (SOPs); **Federal Register** notices; and official SBA notices and forms applicable to the 7(a) Loan Program, 504 Loan Program or Microloan Program, as such requirements are issued and revised by SBA from time to time. For CDCs, this term also includes requirements imposed by Debentures, as that term is defined in § 120.802. For Intermediaries, this term also includes requirements imposed by promissory notes, collateral documents, and grant agreements.

* * * * *

Mission-Based Small Business Lending Company (Mission-Based SBLC) is a type of SBLC that is a nonprofit lending institution licensed and authorized by SBA only to make loans pursuant to section 7(a) of the Small Business Act to fill an identified capital market gap. SBA accepts applications for Mission-Based SBLCs from time to time as published in the **Federal Register**.

* * * * *

Small Business Lending Company (SBLC) is a non-depository lending institution that is SBA-licensed and is authorized by SBA to only make loans pursuant to section 7(a) of the Small Business Act and loans to Intermediaries in SBA's Microloan program. SBA accepts applications for SBLCs from time to time as published in the **Federal Register**.

* * * * *

§ 120.120 [Amended]

■ 3. Amend § 120.120 introductory paragraph by removing the last sentence.

§ 120.192 [Amended]

■ 4. Amend § 120.192 by removing the last sentence.

■ 5. Amend § 120.220 by revising the last sentence of the introductory paragraph and the last sentence of paragraph (e) to read as follows:

§ 120.220 Fees that Lender pays SBA.

* * * Acceptance of the guaranty fee by SBA does not waive any right of SBA arising from a Lender's negligence, misconduct or violation of any provision of these regulations or the guaranty agreement.

* * * * *

(e) * * * Acceptance of the guarantee fee by SBA shall not waive any right of SBA arising from the Lender's misconduct or violation of any provision of this part, the guarantee agreement or other loan documents.

* * * * *

■ 6. Amend § 120.466 by revising paragraph (a)(6) to read as follows:

§ 120.466 SBA Supervised Lender application.

* * * * *

(a) * * *

(6) In connection with any application to acquire an existing SBLC License, the applicant must include a letter agreement signed by an authorized official of the SBLC whose License is to be acquired certifying that the SBLC is seeking to transfer its SBA lending authority to the applicant;

* * * * *

■ 7. Amend § 120.470 by revising the introductory paragraph and paragraph (b) and by adding a paragraph (h) to read as follows:

§ 120.470 What are SBA's additional requirements for SBLCs?

In addition to complying with SBA's requirements for SBA Lenders and SBA Supervised Lenders, an SBLC (including a Mission-Based SBLC) must meet the requirements contained in this regulation and the SBLC regulations that follow.

* * * * *

(b) * * * An SBLC must be a corporation (profit or nonprofit) or a limited liability company or limited partnership, except for a Mission-Based SBLC, which must be a nonprofit corporation.

* * * * *

(h) *Mission-Based SBLCs.* (1) A Mission-Based SBLC must make a certain percentage of the total number of its loans in an identified capital market gap. An entity applying to become a Mission-Based SBLC must identify in its business plan the capital market gap it will target and the percentage of its total loans it proposes to make in that market. The identified capital market gap may include a geographic area, startup businesses, business sector, demographic, or other underserved market. An identified capital market gap and the percentage of loans made in that market is accepted by SBA, in SBA's sole discretion, based on whether SBA agrees there is a need in the targeted market and whether the applicant can meet that need.

(2) SBA determines, in its sole discretion, a Mission-Based SBLC's minimum acceptable lender capitalization, percentage of total loans that it will make in its identified capital market gap, maximum loan size, and geographic area of operation. SBA may make these determinations on the basis of the Mission-Based SBLC's proposed lender capitalization, proposed identified capital market gap, Loan Loss Reserve Account, business plan, experience of staff, or lending history, among other things.

■ 8. Amend § 120.471 by adding paragraph (a)(4) to read as follows:

§ 120.471 What are the minimum capital requirements for SBLCs?

(a) * * *

(4) A Mission-Based SBLC must maintain a minimum amount of capital as determined at the discretion of the Administrator in consultation with SBA's Associate Administrator for the Office of Capital Access (AA/OCA). The capital requirement will ensure sufficient risk protection for SBA and lenders while not burdening smaller lenders with large capital requirements.

* * * * *

■ 9. Amend § 120.801 by revising the last sentence of paragraph (a) to read as follows:

§ 120.801 How a 504 Project is financed.

(a) * * * SBA issues a loan number if it agrees to guarantee part of the funding for a Project.

* * * * *

■ 10. Amend § 120.820 by adding paragraph (g) to read as follows:

§ 120.820 CDC Affiliation.

* * * * *

(g) Notwithstanding paragraphs (b), (c), and (e) of this section, a CDC may be affiliated with a Mission-Based SBLC.

■ 11. Amend § 120.842 by revising the last sentence of paragraph (b)(4) and paragraph (b)(5) to read as follows:

§ 120.842 ALP Express Loans.

* * * * *

(b) * * *

(4) * * * If approved, SBA will notify the ALP CDC of the loan number assigned to the loan.

(5) * * * After receiving notification of the loan number from SBA, the ALP CDC is responsible for properly undertaking all actions necessary to close the ALP Express Loan and Debenture in accordance with the expedited loan closing procedures applicable to a Priority CDC and with § 120.960, and in compliance with all applicable Loan Program Requirements.

* * * * *

§ 120.921 [Amended]

■ 12. Amend § 120.921 by removing the last sentence in paragraph (a).

■ 13. Amend § 120.960 by revising paragraph (c)(1) to read as follows:

§ 120.960 Responsibility for closing.

* * * * *

(c) * * *

(1) The CDC has failed to comply materially with any Loan Program Requirement as defined in § 120.10;

* * * * *

■ 14. Amend § 120.971 by revising paragraph (a)(1) to read as follows:

§ 120.971 Allowable fees paid by Borrower.

(a) * * *

(1) *Processing fee.* The CDC may charge up to 1.5 percent of the net Debenture proceeds to process the financing. Two-thirds of this fee will be considered earned and may be collected by the CDC when the loan number is issued by SBA. The portion of the processing fee paid by the Borrower may be reimbursed from the Debenture proceeds;

* * * * *

Isabella Casillas Guzman,

Administrator.

[FR Doc. 2022–23597 Filed 11–4–22; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1404; Project Identifier MCAI–2022–01044–A]

RIN 2120–AA64

Airworthiness Directives; Pilatus Aircraft Ltd. Airplanes

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 Pilatus Aircraft Ltd. (Pilatus) Model PC–12/47E airplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as corrosion of the actuator attachment lug areas underneath the anti-rotation pads of the main landing gear (MLG) and nose landing gear (NLG). This proposed AD would require replacing certain MLG and NLG electro-mechanical actuators. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by December 22, 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 *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.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1404; 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 MCAI, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aviation Safety Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4059; email: *doug.rudolph@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–2022–1404; Project Identifier MCAI–2022–01044–A'' 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 *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 Doug Rudolph, Aviation Safety Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, MO 64106. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2022–0158, dated August 4, 2022 (referred to after this as ''the MCAI''), to correct an unsafe condition on certain serial-numbered Pilatus Model PC–12/47E airplanes.

The MCAI was prompted by occurrences of corrosion on the MLG and NLG actuator attachment lugs, underneath the anti-rotation pads of Pilatus Model PC–12/47E airplanes. The MCAI states that investigations revealed that extending or retracting the affected landing gear results in fretting between the anti-rotation pads and the actuator attachment lugs. This decreases the effectivity of surface protection, allows corrosion to develop on the attachment lug areas underneath the anti-rotation pads, and leads to cracking and failure of the attachment lugs.

This condition, if not addressed, could result in loss of functionality of the MLG and NLG, which could result in damage to the airplane and injury to the occupants. The MCAI requires inspecting, and if required, replacing affected MLG and NLG electro-mechanical actuators with serviceable actuators and prohibits the installation of an affected actuator unless it has been reworked to become a serviceable actuator.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–1404.

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information described above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require replacing affected MLG and NLG actuators with serviceable actuators (either improved part number actuators or reworked (inspection and modification) actuators) and prohibits the installation of an affected actuator unless it has been reworked (inspection and modification) to become a serviceable actuator.

Differences Between This Proposed AD and the MCAI

The MCAI bases the compliance time for the replacement of affected MLG and NLG electro-mechanical actuators on the corrosion environment of the airplane. FAA regulations do not require operators to track operations in different environmental conditions and thus there is no way to determine whether an airplane is in the category of moderate to severe or mild corrosion environment. Therefore, this proposed AD would establish the compliance time for the replacement as within 3 months after the effective date of the final rule, regardless of the airplane's operating environment.

The MCAI and the proposed AD affect the same serial-numbered Model PC–12/47E airplanes, but the MCAI limits the requirement for replacement to certain serial-numbered PC–12/47E airplanes with an affected electro-mechanical landing gear installed and prohibits installation of the affected landing gear on all airplanes in the applicability. Pilatus has notified the FAA that all the airplanes in the applicability should be part of the proposed replacement requirements and installation prohibition. EASA is considering a revision to the MCAI based on this information. Because of this, the proposed AD would require the replacement on all serial-numbered Model PC–12/47E airplanes in the applicability of the proposed AD.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 440 airplanes of U.S. registry.

The FAA estimates that the costs of one of the two actions below would be required to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Rework (inspection and modification) *.	5 work-hours × $85 per hour = $425.	$1,245 (if needed)	$1,670 (for rework of all three actuators).	$734,800
Replacement *	3 work-hours × $85 per hour = $255.	$4,750 (Actuator P/N 959.56.01.852, nose landing gear) and $11,100. (for 2 actuators—Actuator P/N 659.56.01.853, main landing gear).	$16,105 (for replacement of all three actuators).	7,086,200

* Only the rework (inspection and modification) or the replacement would be required by this proposed AD. Both actions would not be required.

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:

Pilatus Aircraft Ltd.: Docket No. FAA–2022–1404; Project Identifier MCAI–2022–01044–A.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 22, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pilatus Aircraft Ltd. Model PC–12/47E airplanes, serial number (S/N) 1300 and S/Ns 1451 and higher, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 3211, Main Landing Gear Attach Section; and JASC Code 3221, Nose/Tail Landing Gear Attach Section.

(e) Unsafe Condition

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as corrosion leading to cracks on the actuator attachment lug areas underneath the anti-rotation pads of the main landing gear (MLG) and nose landing gear (NLG). The FAA is issuing this AD to address this condition. The unsafe condition, if not addressed, could result in loss of functionality of the MLG and NLG, which could result in damage to the airplane and injury to the occupants.

(f) Definitions

For the purposes of this AD, the following definitions apply:

(1) Affected parts are defined as MLG electro-mechanical actuators having part number (P/N) 959.56.01.823 or P/N 959.56.01.845 and NLG electro-mechanical actuators having P/N 959.56.01.824 or P/N 959.56.01.844.

(2) Serviceable parts are defined as one of the following:

(i) MLG electro-mechanical actuators having P/N 959.56.01.823 or P/N 959.56.01.845 and NLG electro-mechanical actuators having P/N 959.56.01.824 or P/N 959.56.01.844 that have been reworked (inspection and modification) in accordance with the instructions in Pilatus PC–12 Service Bulletin No. 32–030, dated June 27, 2022; and Tamagawa Seiki Co., Ltd., Service Bulletin No. SB21–0001, dated March 31, 2022; or

(ii) MLG electro-mechanical actuators having P/N 959.56.01.853 and NLG electro-mechanical actuators having P/N 959.56.01.852.

(g) Compliance

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

(h) Actions

(1) Within 3 months after the effective date of this AD, replace each affected part as defined in paragraph (f)(1) of this AD with a serviceable part as defined in either paragraph (f)(2)(i) or (ii) of this AD.

(2) As of the effective date of this AD, do not install an affected part as defined in paragraph (f)(1) of this AD on any airplane unless it has been reworked (inspection and modification) and made a serviceable part as defined in paragraph (f)(2)(i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in § 39.19. In accordance with § 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, mail it to the address identified in paragraph (j)(2) of this AD or email to: *9-AVS-AIR-730-AMOC@faa.gov*. If mailing information, also submit information by email.

(j) Additional Information

(1) Refer to European Union Aviation Safety Agency (EASA) AD 2022–0158, dated August 4, 2022, for related information. This EASA AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–1404.

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

(3) For Pilatus and Tamagawa Seiki Co., Ltd. service information that is not incorporated by reference in this AD, contact Pilatus Aircraft Limited, Customer Support General Aviation, CH–6371 Stans, Switzerland; phone: +41 848 24 7 365; email: *techsupport.ch@pilatus-aircraft.com;* website: *pilatus-aircraft.com.*

(k) Material Incorporated by Reference

None.

Issued on October 25, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–23567 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–1347; Airspace Docket No. 22–ASO–25]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Morganton, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace extending upward from 700 feet above the surface for Foothills Regional Airport, Morganton, NC, by updating the airport's name and geographic coordinates. Additionally, the geographic coordinates of Fiddlers NDB would be updated. Also, Grace Hospital would be removed from the descriptor, as all instrument approaches into the hospital have been canceled. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Comments must be received on or before December 22, 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 20590–0001; Telephone: (800) 647–5527, or (202) 366–9826. You must identify the Docket No. FAA–2022–1347; Airspace Docket No. 22–ASO–25 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order JO 7400.11G Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *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 would amend airspace in Morganton, NC, to support IFR operations in the area.

Comments Invited

Interested persons are invited to comment on 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 (Docket No. FAA–2022–1347 and Airspace Docket No. 22–ASO–25) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for the address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Persons 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–2022–1347; Airspace Docket No. 22–ASO–25.'' The postcard will be dated/time-stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this document may be changed in light of the 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 the **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 between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays, at the office of the Eastern Service Center, Federal Aviation Administration, Room 350,1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to 14 CFR part 71 to amend Class E airspace extending upward from 700 feet above the surface for Foothills

Regional Airport (formerly Morganton-Lenoir Airport), Morganton, NC, by updating the airport's name and geographic coordinates. This action would also update the Fiddlers NDB geographic coordinates to coincide with the FAA's database and remove Grace Hospital from the descriptor, as instrument approaches no longer exist for the hospital. Also, reference to Hickory, NC, Class E airspace would be removed, as the airspace is shared.

Class E airspace designations are published in Paragraph 6005 of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, 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.

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 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.

Lists 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 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 Federal Aviation Administration Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

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

* * * * *

ASO NC E5 Morganton, NC [Amended]

Foothills Regional Airport, NC
(Lat. 35°49′13″ N, long. 81°36′41″ W)
Fiddlers NDB
(Lat. 35°42′61″ N, long. 81°40′28″ W)

That airspace extending upward from 700 feet or more above the surface within a 9.5-mile radius of the Foothills Regional Airport and within 2.5 miles each side of the 205° bearing from Fiddlers NDB, extending from the 9.5-mile radius to 7 miles southwest of the NDB.

Issued in College Park, Georgia, on October 28, 2022.

Andreese C. Davis,

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

[FR Doc. 2022–24018 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–1351; Airspace Docket No. 22–ASW–22]

RIN 2120–AA66

Proposed Revocation of Class E Airspace; Marfa, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to remove the Class E airspace at Marfa, TX. The FAA is proposing this action due to the closure of the airport.

DATES: Comments must be received on or before December 22, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–1351/Airspace Docket No. 22–ASW–22, at the beginning of your comments. You may also submit comments through the internet at *www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *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: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

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 would remove the Class E airspace extending upward from 700 feet above the surface at Alta Vista Ranch Airport, Marfa, TX, due to the closure of the airport.

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 and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–1351/Airspace Docket No. 22–ASW–22.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. 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 *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *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 the **ADDRESSES** section for the 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 Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G 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 by removing the Class E airspace extending upward from 700 feet above the surface at Alta Vista Ranch Airport, Marfa, TX.

This action is the result of the closure of the airport.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, 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.

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 will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would 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 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, 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 14 CFR 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 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

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

* * * * *

ASW TX E5 Marfa, Alta Vista Ranch Airport, TX [Remove]

Issued in Fort Worth, Texas, on October 31, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–23993 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–13–P

LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 385

[Docket No. 21–CRB–0001–PR (2023–2027)]

Determination of Rates and Terms for Making and Distributing Phonorecords (Phonorecords IV)

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Proposed rule.

SUMMARY: The Copyright Royalty Judges publish for comment and objection proposed regulations that set rates and terms applicable during the period from January 1, 2023, through December 31, 2027, for the section 115 statutory license for making and distributing phonorecords of nondramatic musical works.

DATES: Comments and objections, if any, are due no later than December 7, 2022.

ADDRESSES: You may send comments, identified by docket number 21–CRB–0001–PR (2023–2027), online through eCRB at *https://app.crb.gov.*

Instructions: To send your comment through eCRB, if you don't have a user account, you will first need to register for an account and wait for your

registration to be approved. Approval of user accounts is only available during business hours. Once you have an approved account, you can only sign in and file your comment after setting up multi-factor authentication, which can be done at any time of day. All comments must include the Copyright Royalty Board name and the docket number for this proposed rule. All properly filed comments will appear without change in eCRB at *https://app.crb.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to eCRB at *https://app.crb.gov* and perform a case search for docket 21–CRB–0001–PR (2023–2027).

FOR FURTHER INFORMATION CONTACT: Anita Brown, CRB Program Specialist, at 202–707–7658 or *crb@loc.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 115 of the Copyright Act, title 17 of the United States Code, requires a copyright owner of a nondramatic musical work to grant a license (also known as the ''mechanical'' compulsory license) to any person who wants to make and distribute phonorecords of that work, under circumstances set forth in the statute and regulations. In addition to the production or distribution of physical phonorecords (compact discs, vinyl, cassette tapes, and the like), section 115 applies to digital transmissions of phonorecords, including permanent digital downloads and ringtones.

Chapter 8 of the Copyright Act authorizes the Copyright Royalty Judges (Judges) to conduct proceedings every five years to determine the rates and terms for the section 115 license. 17 U.S.C. 801(b)(1), 804(b)(4). Accordingly, the Judges commenced the current proceeding in January 2021, by publishing notice of the commencement and a request that interested parties submit petitions to participate. *See* 86 FR 25 (Jan. 5, 2021).

The Judges received petitions to participate in the current proceeding from Amazon.com Services LLC, Apple Inc., Copyright Owners (joint petitioners Nashville Songwriters Association International (NSAI) and National Music Publishers Association (NMPA)), Google LLC, George Johnson, Joint Record Company Participants (filed by Recording Industry Association of America, Inc. for joint petitioners Sony Music Entertainment, UMG Recordings, Inc., and Warner Music Group Corp.), Pandora Media, LLC, David Powell, SoundCloud Operations Inc.,[1] Spotify USA Inc., and Brian Zisk.

The Judges gave notice to all participants of the three-month negotiation period required by 17 U.S.C. 803(b)(3) and directed that, if the participants were unable to negotiate a settlement, they should submit Written Direct Statements no later than September 10, 2021.[2] The Judges extended the deadline to October 13, 2021. *Order Granting Joint Motion to Modify the Case Scheduling Order* (eCRB No. 25555) (Aug. 3, 2021). The Judges received Written Direct Statements from participants Amazon.com Services LLC, Apple Inc., Copyright Owners (Nashville Songwriters Association International (NSAI) and National Music Publishers Association (NMPA)), Google LLC, George Johnson, Pandora Media, LLC, and Spotify USA Inc.

On August 31, 2022, the Judges received a motion stating that several participants, (Settling Parties),[3] had reached a partial settlement regarding the rates and terms under Section 115 of the Copyright Act, namely, for Licensed Activity (as defined in 37 CFR part 385, subpart A)[4] presently addressed in subparts C & D of 37 CFR part 385 together with certain regulations of general application (*e.g.,* definitions and late fee provisions) applicable to the subpart C & D Configurations presently addressed in 37 CFR part 385, subpart A, for the 2023–2027 rate period[5] and seeking approval of that partial settlement. *See Motion to Adopt Settlement of Statutory Royalty Rates and Terms for Subpart C and D Configurations,* Docket No. 21–CRB–0001–PR (2023–2027) at 1 (Motion). The movants state that ''the settlement [ ] represents the consensus of both licensees and licensors representing the vast majority of the market for rights under Section 115 for Subpart C & D Configurations.''[6] Motion at 3.

On September 26, 2022, the Judges issued ''Order 63 to File Certification or Provide Settlement Agreements'' (Order 63), which ordered the Settling Parties to certify that the Motion and the Proposed Regulations annexed to the Motion represent the full agreement of the Settling Parties, *i.e.,* that there are no other related agreements and no other clauses. Order 63 further ordered that if such other agreements or clauses exist, the Settling Parties shall file them.

On September 26, 2022, the Settling Parties filed a ''Joint Response to George Johnson's Motion to Compel Production of Settlement and CRB Order 63'' (Joint Response). Portions of the Joint Response, which were submitted as Restricted, are responsive to Order 63. On October 6, 2022, the Settling Parties filed a ''Joint Submission of Settling Participants Regarding Settlement Agreement'' (Joint Submission) which removed the Restricted designation to the ''Settlement Agreement'' attached as Exhibit A to the Joint Submission. However, the Joint Response and the Joint Submission do not completely and adequately respond to Order 63.

On October 3, 2022, Google and NMPA filed ''Google and NMPA's Joint Notice of Lodging'' (Joint Notice of Lodging), which indicated that those two parties found Order 63 unclear regarding what is meant by ''related agreements.'' Google and NMPA offered that they broadly construed Order 63's reference to ''related agreements'' to include certain letter agreements executed between Google, on the one hand, and certain music publishers and the NMPA, on the other hand, on or around the execution date of the settlement agreement. Google and NMPA indicated they will ''lodge'' such letter agreements concurrently with their Joint Notice of Lodging.[7] Google and NMPA also indicated that they do not believe that the letter agreements are substantively related to the parties' settlement agreement, and that the letter agreements simply concern Google's allocation practices to avoid double

[1] SoundCloud Operations Inc. withdrew from the proceeding on May 21, 2021.

[2] Several parties negotiated a proposed partial settlement in May 2021. The Judges accordingly published for comment the parties' proposed changes (to subparts A and B of 37 CFR part 385). *See* 87 FR 33093 (June 1, 2022).

[3] The participants who filed the motion are the National Music Publishers' Association (''NMPA'') and Nashville Songwriters Association International (''NSAI,'' and collectively with NMPA, the ''Copyright Owners''), on the one hand, and Amazon.com Services LLC, Apple Inc., Google LLC, Pandora Media, LLC, and Spotify USA Inc. Motion at 1.

[4] ''*Licensed Activity* . . . as the term is used in subparts C and D of this part, means delivery of musical works, under voluntary or statutory license, via Digital Phonorecord Deliveries in connection with Interactive Eligible Streams, Eligible Limited Downloads, Limited Offerings, mixed Bundles, and Locker Services.'' 37 CFR 385.2.

[5] The motion refers to the rate period as ''the full time period addressed by the Proceeding''. Motion at 1.

[6] The movants indicate that participant George Johnson does not agree to the settlement and that participants David Powell and Brian Zisk should be dismissed because they did not file a Written Direct Statement. Motion at 3 and n. 1. Mr. Johnson filed an opposition to the motion (eCRB. No. 27239) on September 6 which the Judges consider relevant to this proposed rule.

[7] On October 7, 2022, Google and NMPA submitted ''Google and NMPA's Joint Notice of Public Lodging'' which included public versions of letter agreements.

payments arising from certain direct agreements.

On October 17, 2022, the Judges issued ''Order 64 to File Settlement Agreements and Provide Certification'' (Order 64), which clarified the scope of Order 63 and ordered the Settling Parties to:

(1) *file* (not ''lodge'') any supplemental written agreements between Service Participants, on the one hand, and Copyright Owners and/or their affiliates, including copyright owners that they represented in this proceeding, on the other hand, that represent consideration for, or are contractually related to, the Settlement referenced in the Motion.

(2) file a detailed description of any supplemental oral agreements between Service Participants, on the one hand, and Copyright Owners and/or their affiliates, including copyright owners that they represented in this proceeding, on the other hand, that represent consideration for, or are contractually related to the Settlement referenced in the Motion, through a certification or certifications from individuals with direct knowledge of any such supplemental oral agreements.

(3) file a certification or certifications from a person or persons with first-hand knowledge stating that there are no other agreements, written or oral, beyond the Settlement, the Settlement Agreement and the filed supplemental written or oral agreements responsive to this order.

(4) explain in a supplemental brief why the remaining restricted portions of the Joint Response, apart from Exhibit A, from which the Restricted designation has been removed, would, if disclosed, interfere with the ability of the Producer to obtain like information in the future.

On October 26, 2022, the Settling Parties filed a ''Joint Response to Order 64'' (Joint Response 2).

In response to item #1 above, Joint Response 2 noted that the October 6, 2022, Joint Submission removed the Restricted designation to the ''Settlement Agreement'' and attached it within Exhibit A to Joint Response 2. In Joint Response 2, Google and NMPA also filed the aforementioned letter agreements as Exhibit B to Joint Submission 2.[8] Joint Response 2 also included the Settling Parties' representation that other than the Settlement Agreement itself, there are no other agreements responsive to Order 64.

In response to item #2 above, Joint Response 2 stated that there are no supplemental oral agreements responsive to Order 64.

In response to item #3 above, Joint Response 2 included Exhibits C–1 through C–7, certifications from a representative of each Party with first-hand knowledge of the Settlement Agreement and negotiations, which collectively attest that there are no other agreements, written or oral, responsive to Order 64 beyond the agreements provided as part of Joint Response 2.

In response to item #4 above, Joint Response 2 noted that the Settling Parties do not believe that there is any reason why any restricted portions of the Joint Response need to remain restricted. Therefore, the Settling Parties filed, concurrently with Joint Response 2, a revised version of the Joint Response that removes all redactions, entitled ''[Revised to Remove Redactions] Joint Response to George Johnson's Motion to Compel Production of Settlement and CRB Order 63.'' (Revised Joint Response).

The Settling Parties offered that through Joint Response 2, and the related submissions referenced therein, the Judges have all materials necessary to publish the proposed rates and terms for public comment. The Settling Parties noted the necessary public comment and objection period, as well as potential consequences to the industry if rates and terms are not effective in time to be operationalized for the beginning of 2023, and therefore request that the Judges publish the proposed rates and terms for public comment as soon as possible.[9] Proposed regulations implementing the settlement are attached to Joint Response 2.

Section 801(b)(7)(A) of the Copyright Act authorizes the Judges to adopt rates and terms negotiated by ''some or all of the participants in a proceeding at any time during the proceeding'' provided they are submitted to the Judges for approval. This section states that the Judges shall (1) provide an opportunity to comment on the agreement to non-participants who would be bound by the terms, rates, or other determination set by the agreement; and (2) provide an opportunity to comment and to object to participants in the proceeding who would be bound by the terms, rates, or other determination set by the agreement. *See* section 801(b)(7)(A). The Judges may decline to adopt the agreement as a basis for statutory terms and rates for participants not party to the agreement if any *participant* objects and the Judges conclude that the agreement does not provide a reasonable basis for setting statutory terms or rates. *Id.*

Having reviewed Joint Response 2, its attachments, and the related submissions referenced therein, the Judges find that Joint Response 2, Exhibit A, sub-exhibit A (referenced therein as the ''Settlement Agreement'' and ''Proposed Regulations'') includes ''the agreement'' for purposes of Section 801(b)(7)(A). The portions of Joint Response 2 Exhibit A, sub-exhibit A referred to as ''Settlement Agreement'' and ''Proposed Regulations'' may be found on pages 9–17 of 89 and 19–34 of 89 of Joint Response 2, *(eCRB No. 27290).* The regulatory amendments that adoption of the proposed settlement would entail are reflected in the Proposed Regulations portion of this document.[10]

If the Judges adopt rates and terms reached pursuant to a negotiated settlement, those rates and terms are binding on all copyright owners of musical works and those using the musical works in the activities described in the proposed regulations.

The Judges solicit comments and objections from participants on whether they should adopt the proposed regulations as statutory rates and terms relating to the making and distribution of phonorecords of nondramatic musical works.

Comments and objections regarding the rates and terms must be submitted no later than December 7, 2022.

List of Subjects in 37 CFR Part 385

Copyright, Phonorecords, Recordings.

Proposed Regulations

For the reasons set forth in the preamble, the Copyright Royalty Judges propose to amend 37 CFR part 385 as follows:

PART 385—RATES AND TERMS FOR USE OF NONDRAMATIC MUSICAL WORKS IN THE MAKING AND DISTRIBUTING OF PHYSICAL AND DIGITAL PHONORECORDS

■ 1. The authority citation for part 385 continues to read as follows:

Authority: 17 U.S.C. 115, 801(b)(1), 804(b)(4).

■ 2. Revise subpart A to read as follows:

[8] Joint Response 2 reiterated Google and NMPA's view that the letter agreements are not substantively related to the parties' settlement agreement, and that the letter agreements simply concern Google's allocation practices to avoid double payments arising from certain direct agreements

[9] The Judges are aware of the participants' and the public's interest in timely implementation of rates and terms, and note that the submission of partial agreements and related materials as restricted has been a source of unfortunate delay in consideration of the proposed settlement of statutory royalty rates and terms for subpart C and D configurations.

[10] The docket for this proceeding, including documents referenced in this document, may be accessed via the Electronic filing system eCRB at *https://app.crb.gov* and perform a case search for docket 21–CRB–0001–PR (2023–2027).

Subpart A—Regulations of General Application

Subpart A—Regulations of General Application

§ 385.1 General.

(a) *Scope.* This part establishes rates and terms of royalty payments for the use of nondramatic musical works in making and distributing of physical and digital phonorecords in accordance with the provisions of 17 U.S.C. 115. This subpart contains regulations of general application to the making and distributing of phonorecords subject to the section 115 license.

(b) *Legal compliance.* Licensees relying on the compulsory license detailed in 17 U.S.C. 115 shall comply with the requirements of that section, the rates and terms of this part, and any other applicable regulations. This part describes rates and terms for the compulsory license only.

(c) *Interpretation.* This part is intended only to set rates and terms for situations in which the exclusive rights of a Copyright Owner are implicated and a compulsory license pursuant to 17 U.S.C. 115 is obtained. Neither this part nor the act of obtaining a license under 17 U.S.C. 115 is intended to express or imply any conclusion as to the circumstances in which a user must obtain a compulsory license pursuant to 17 U.S.C. 115.

(d) *Relationship to voluntary agreements.* The rates and terms of any license agreements entered into by Copyright Owners and Licensees relating to use of musical works within the scope of those license agreements shall apply in lieu of the rates and terms of this part.

§ 385.2 Definitions.

Unless otherwise specified, capitalized terms in this part shall have the same meaning given to them in 17 U.S.C. 115(e). For the purposes of this part, the following definitions apply:

Accounting Period means the monthly period specified in 17 U.S.C. 115(c)(2)(I) and in 17 U.S.C. 115(d)(4)(A)(i), and any related regulations, as applicable.

Active Subscriber means an End User of a Bundled Subscription Offering who has made at least one Play during the Accounting Period.

Affiliate means an entity controlling, controlled by, or under common control with another entity, except that an affiliate of a Sound Recording Company shall not include a Copyright Owner to the extent it is engaging in business as to musical works.

Artificial Accounts are accounts that are disabled or terminated for having engaged in User Manipulation or other fraudulent activity and for which any subscription revenues are refunded or otherwise not received by the Service Provider.

Bundle means a combination of a Subscription Offering providing Eligible Interactive Streams and/or Eligible Limited Downloads and one or more other products or services having more than token value, purchased by End Users in a single transaction (*e.g.,* where End Users make a single payment without separate pricing for the Subscription Offering component).

Bundled Subscription Offering means a Subscription Offering providing Eligible Interactive Streams and/or Eligible Limited Downloads included within a Bundle.

Copyright Owner(s) are nondramatic musical works copyright owners who are entitled to royalty payments made under this part pursuant to the compulsory license under 17 U.S.C. 115.

Digital Phonorecord Delivery has the same meaning as in 17 U.S.C. 115(e)(10).

Eligible Interactive Stream means a Stream that is an Interactive Stream as defined in 17 U.S.C. 115(e)(13).

Eligible Limited Download means a Limited Download as defined in 17 U.S.C. 115(e)(16) that is only accessible for listening for—

(1) An amount of time not to exceed one month from the time of the transmission (unless the Licensee, in lieu of retransmitting the same sound recording as another Eligible Limited Download, separately, and upon specific request of the End User made through a live network connection, reauthorizes use for another time period not to exceed one month), or in the case of a subscription plan, a period of time following the end of the applicable subscription no longer than a subscription renewal period or three months, whichever is shorter; or

(2) A number of times not to exceed 12 (unless the Licensee, in lieu of retransmitting the same sound recording as another Eligible Limited Download, separately, and upon specific request of the End User made through a live network connection, reauthorizes use of another series of 12 or fewer plays), or in the case of a subscription transmission, 12 times after the end of the applicable subscription.

End User means each unique person that:

(1) Pays a subscription fee for an Offering during the relevant Accounting Period; or

(2) Makes at least one Play during the relevant Accounting Period.

Family Plan means a discounted Subscription Offering to be shared by up to six members of the same family or household for a single subscription price.

Free Trial Offering means a subscription to a Service Provider's transmissions of sound recordings embodying musical works when—

(1) Neither the Service Provider, the Sound Recording Company, the Copyright Owner, nor any person or entity acting on behalf of or in lieu of any of them receives any monetary consideration for the Offering;

(2) The usage does not exceed 45 days per subscriber per one-year period, which days may be nonconsecutive;

(3) In connection with the Offering, the Service Provider complies with the recordkeeping requirements in § 385.4 or superseding Copyright Office recordkeeping requirements;

(4) The Free Trial Offering is made available to the End User free of any charge; and

(5) The Service Provider offers the End User periodically during the trial an opportunity to subscribe to, and/or auto-renews the End User into, a non-Free Trial Offering of the Service Provider.

GAAP means U.S. Generally Accepted Accounting Principles in effect at the relevant time, except that if the U.S. Securities and Exchange Commission permits or requires entities with securities that are publicly traded in the U.S. to employ International Financial Reporting Standards in lieu of Generally Accepted Accounting Principles, then that entity may employ International Financial Reporting Standards as ''GAAP'' for purposes of this subpart.

Licensee means any entity availing itself of the compulsory license under 17 U.S.C. 115 to use copyrighted musical works in the making or distributing of physical or digital phonorecords.

Licensed Activity as the term is used in subparts C and D of this part, means Covered Activity, under voluntary or statutory license, in the form of Eligible Interactive Streams, Eligible Limited Downloads, and Restricted Downloads.

Locker Service means an Offering providing digital access to sound recordings of musical works in the form of Eligible Interactive Streams, Permanent Downloads, Restricted Downloads or Ringtones where the Service Provider has reasonably

determined that the End User has purchased or is otherwise in possession of the subject phonorecords of the applicable sound recording prior to the End User's first request to use the sound recording via the Locker Service. The term Locker Service does not mean any part of a Service Provider's products otherwise meeting this definition, but as to which the Service Provider has not obtained a section 115 license.

Mixed Service Bundle means an Offering providing Licensed Activity consisting of Eligible Interactive Streams or Eligible Limited Downloads that meets all of the following criteria:

(1) The Offering is made available to End Users only in combination (*i.e.,* the Offering is not available on a standalone basis) with one or more products or services (including services subject to other subparts) of more than token value as part of one transaction for which End Users make a payment without receiving pricing for the Offering separate from the product(s) or service(s) with which it is made available.

(2) The Offering is made available by a Service Provider that also offers End Users a separate, standalone Subscription Offering.

(3) The Offering offers End Users less functionality relative to that separate, standalone Subscription Offering. Such lesser functionality may include, but is not limited to, limitations on the ability of End Users to choose to listen to specific sound recordings on request or a limited catalog of sound recordings.

(4) Where an Offering could qualify or be considered as either a Bundled Subscription Offering or a Mixed Service Bundle, such Offering shall be deemed a Mixed Service Bundle for the purpose of calculating and paying royalties under subpart C of this part.

Music Bundle means two or more of physical phonorecords, Permanent Downloads or Ringtones delivered as part of one transaction (*e.g.,* download plus ringtone, CD plus downloads). In the case of Music Bundles containing one or more physical phonorecords, the Service Provider must sell the physical phonorecord component of the Music Bundle under a single catalog number, and the musical works embodied in the Digital Phonorecord Delivery configurations in the Music Bundle must be the same as, or a subset of, the musical works embodied in the physical phonorecords; provided that when the Music Bundle contains a set of Digital Phonorecord Deliveries sold by the same Sound Recording Company under substantially the same title as the physical phonorecord (*e.g.,* a corresponding digital album), the Service Provider may include in the same bundle up to 5 sound recordings of musical works that are included in the stand-alone version of the set of digital phonorecord deliveries but not included on the physical phonorecord. In addition, the Service Provider must permanently part with possession of the physical phonorecord or phonorecords it sells as part of the Music Bundle. In the case of Music Bundles composed solely of digital phonorecord deliveries, the number of digital phonorecord deliveries in either configuration cannot exceed 20, and the musical works embodied in each configuration in the Music Bundle must be the same as, or a subset of, the musical works embodied in the configuration containing the most musical works.

Offering means a Service Provider's engagement in Licensed Activity covered by subparts C and D of this part.

Paid Locker Service means a Locker Service for which the End User pays a fee to the Service Provider.

Performance Royalty means the license fee payable for the right to perform publicly musical works in any of the forms covered by subparts C and D this part.

Permanent Download has the same meaning as in 17 U.S.C. 115(e)(24).

Play means an Eligible Interactive Stream, or a play of an Eligible Limited Download, lasting 30 seconds or more and, if a track lasts in its entirety under 30 seconds, an Eligible Interactive Stream or a play of an Eligible Limited Download of the entire duration of the track. A Play excludes an Eligible Interactive Stream or a play of an Eligible Limited Download caused by User Manipulation.

Promotional Offering means a digital transmission of a sound recording, in the form of an Eligible Interactive Stream or an Eligible Limited Download, embodying a musical work, the primary purpose of which is to promote the sale or other paid use of that sound recording or to promote the artist performing on that sound recording and not to promote or suggest promotion or endorsement of any other good or service and

(1) A Sound Recording Company is lawfully distributing the sound recording through established retail channels or, if the sound recording is not yet released, the Sound Recording Company has a good faith intention to lawfully distribute the sound recording or a different version of the sound recording embodying the same musical work;

(2) The Service Provider is in compliance with the recordkeeping requirements of § 385.4 or superseding Copyright Office recordkeeping requirements;

(3) For Eligible Interactive Streams of segments of sound recordings not exceeding 90 seconds, the Sound Recording Company delivers or authorizes delivery of the segments for promotional purposes and neither the Service Provider nor the Sound Recording Company creates or uses a segment of a sound recording in violation of 17 U.S.C. 106(2) or 115(a)(2);

(4) The Promotional Offering is made available to an End User free of any charge; and

(5) The Service Provider provides to the End User at the same time as the Promotional Offering Stream an opportunity to purchase the sound recording or the Service Provider periodically offers End Users the opportunity to subscribe to a paid Offering of the Service Provider.

Purchased Content Locker Service means a Locker Service made available to End User purchasers of Permanent Downloads, Ringtones, or physical phonorecords at no incremental charge above the otherwise applicable purchase price of the Permanent Downloads, Ringtones, or physical phonorecords acquired from a qualifying seller. With a Purchased Content Locker Service, an End User may receive one or more additional phonorecords of the purchased sound recordings of musical works in the form of Permanent Downloads or Ringtones at the time of purchase, or subsequently have digital access to the purchased sound recordings of musical works in the form of Eligible Interactive Streams, additional Permanent Downloads, Restricted Downloads, or Ringtones.

(1) A qualifying seller for purposes of this definition is the entity operating the Service Provider, including Affiliates, predecessors, or successors in interest, or—

(i) In the case of Permanent Downloads or Ringtones, a seller having a legitimate connection to the locker service provider pursuant to one or more written agreements (including that the Purchased Content Locker Service and Permanent Downloads or Ringtones are offered through the same third party); or

(ii) In the case of physical phonorecords,

(A) The seller of the physical phonorecord has an agreement with the Purchased Content Locker Service provider establishing an integrated offer that creates a consumer experience commensurate with having the same Service Provider both sell the physical

phonorecord and offer the integrated locker service; or

(B) The Service Provider has an agreement with the entity offering the Purchased Content Locker Service establishing an integrated offer that creates a consumer experience commensurate with having the same Service Provider both sell the physical phonorecord and offer the integrated locker service.

(2) [Reserved]

Relevant Page means an electronic display (for example, a web page or screen) from which a Service Provider's Offering consisting of Eligible Interactive Streams or Eligible Limited Downloads is directly available to End Users, but only when the Offering and content directly relating to the Offering (*e.g.,* an image of the artist, information about the artist or album, reviews, credits, and music player controls) comprises 75% or more of the space on that display, excluding any space occupied by advertising. An Offering is directly available to End Users from a page if End Users can receive sound recordings of musical works (in most cases this will be the page on which the Eligible Limited Download or Eligible Interactive Stream takes place).

Restricted Download means a Digital Phonorecord Delivery in a form that cannot be retained and replayed on a permanent basis. The term Restricted Download includes an Eligible Limited Download.

Ringtone means a phonorecord of a part of a musical work distributed as a Digital Phonorecord Delivery in a format to be made resident on a telecommunications device for use to announce the reception of an incoming telephone call or other communication or message or to alert the receiver to the fact that there is a communication or message.

Service Provider means that entity governed by subparts C and D of this part, which might or might not be the Licensee, that with respect to the section 115 license

(1) Contracts with or has a direct relationship with End Users or otherwise controls the content made available to End Users;

(2) Is able to report fully on Service Provider Revenue from the provision of musical works embodied in phonorecords to the public, and to the extent applicable, verify Service Provider Revenue through an audit; and

(3) Is able to report fully on its usage of musical works, or procure such reporting and, to the extent applicable, verify usage through an audit.

Service Provider Revenue. (1) Subject to paragraphs (2) through (5) of this definition and subject to GAAP, Service Provider Revenue shall mean, for each Offering subject to subpart C of this part:

(i) All revenue from End Users recognized by a Service Provider for the provision of the Offering;

(ii) All revenue recognized by a Service Provider by way of sponsorship and commissions as a result of the inclusion of third-party ''in-stream'' or ''in-download'' advertising as part of the Offering, *i.e.,* advertising placed immediately at the start or end of, or during the actual delivery of, a musical work, by way of Eligible Interactive Streams or Eligible Limited Downloads; and

(iii) All revenue recognized by the Service Provider, including by way of sponsorship and commissions, as a result of the placement of third-party advertising on a Relevant Page of the Service Provider or on any page that directly follows a Relevant Page leading up to and including the Eligible Limited Download or Eligible Interactive Stream of a musical work; provided that, in case more than one Offering is available to End Users from a Relevant Page, any advertising revenue shall be allocated between or among the Service Providers on the basis of the relative amounts of the page they occupy.

(2) Service Provider Revenue shall:

(i) Include revenue recognized by the Service Provider, or by any associate, Affiliate, agent, or representative of the Service Provider in lieu of its being recognized by the Service Provider; and

(ii) Include the value of any barter or other nonmonetary consideration; and

(iii) Except as expressly detailed in this part, not be subject to any other deduction or set-off other than refunds to End Users for Offerings that the End Users were unable to use because of technical faults in the Offering or other bona fide refunds or credits issued to End Users in the ordinary course of business.

(3) Service Provider Revenue shall exclude revenue derived by the Service Provider solely in connection with activities other than Offering(s), whereas advertising or sponsorship revenue derived in connection with any Offering(s) shall be treated as provided in paragraphs (1), (2), and (4) of this definition.

(4) For purposes of paragraph (1) of this definition, advertising or sponsorship revenue shall be reduced by the actual cost of obtaining that revenue, not to exceed 15%.

(5) In instances in which a Service Provider provides a Bundled Subscription Offering to End Users, the revenue from End Users deemed to be recognized by the Service Provider for the Offering for the purpose of paragraph (1) of this definition of Service Provider Revenue shall be as follows:

(i) For Bundled Subscription Offerings where both each component of the Bundle is a product or service of the Service Provider (including Affiliates) and the Service Provider (including Affiliates) makes the Bundle available to End Users directly, then the revenue from End Users deemed to be recognized by the Service Provider for the purpose of paragraph (1) of this definition shall be the aggregate of the retail price paid for the Bundle (*i.e.,* all components for one retail price) multiplied by a fraction where the numerator is the standalone retail price of the Subscription Offering component in the Bundle and the denominator is the sum of the standalone retail prices of each of the components in the Bundle (*e.g.* if a Service Provider sells the Subscription Offering component on a standalone basis for $10/month and a separate product and/or service on a standalone basis for $5/month, then the fraction shall be $10 divided by $15, *i.e.* ⅔, resulting in Service Provider Revenue of $8,000 if the aggregate of the retail price paid for the Bundle is $12,000).

(ii) For Bundled Subscription Offerings where either one or more components of the Bundle are not products or services of the Service Provider (including Affiliates) or the Service Provider (including Affiliates) does not make the Bundle available to End Users directly, then the revenue from End Users deemed to be recognized by the Service Provider for the purpose of paragraph (1) of this definition shall be the revenue recognized by the Service Provider from the Bundle multiplied by a fraction where the numerator is the standalone retail price of the Subscription Offering component in the Bundle and the denominator is the sum of the standalone retail prices of each of the components of the Bundle. Notwithstanding the preceding sentence, where the Service Provider does not recognize revenue for one or more components of the Bundle, then the standalone price(s) of the component(s) for which revenue is not recognized shall not be included in the calculation of the denominator of the fraction described in this sub-paragraph (*e.g.,* where a Bundle of three services, each with a standalone price of $20/month, sells for $50/month, and the Service Provider recognizes $30,000 of revenue from the provision of only two of those services, one of which is a Subscription Offering, then the fraction

shall be $20 divided by $40, *i.e.* ½, resulting in Service Provider Revenue of $15,000).

(iii) For the calculations in paragraphs (5)(i) and (ii) of this definition, in the event that there is no standalone published price for a component of the Bundle, then the Service Provider shall use the average standalone published price for End Users for the most closely comparable product or service in the U.S. or, if more than one comparable exists, the average of standalone prices for comparables. If no reasonably comparable product or service exists in the U.S., then the Service Provider may use another good faith, reasonable measure of the market value of the component.

Sound Recording Company means a person or entity that:

(1) Is a copyright owner of a sound recording embodying a musical work;

(2) In the case of a sound recording of a musical work fixed before February 15, 1972, has rights to the sound recording, under chapter 14 of title 17, United States Code, that are equivalent to the rights of a copyright owner of a sound recording of a musical work under title 17, United States Code;

(3) Is an exclusive Licensee of the rights to reproduce and distribute a sound recording of a musical work; or

(4) Performs the functions of marketing and authorizing the distribution of a sound recording of a musical work under its own label, under the authority of a person identified in paragraphs (1) through (3) of this definition.

Standalone Limited Offering means a Subscription Offering providing Eligible Interactive Streams or Eligible Limited Downloads for which—

(1) An End User cannot choose to listen to a particular sound recording (*i.e.,* the Service Provider does not provide Eligible Interactive Streams of individual recordings that are on-demand, and Eligible Limited Downloads are rendered only as part of programs rather than as individual recordings that are on-demand); or

(2) The particular sound recordings available to the End User over a period of time are substantially limited relative to Service Providers in the marketplace providing access to a comprehensive catalog of recordings (*e.g.,* a product limited to a particular genre or permitting Eligible Interactive Streams only from a monthly playlist consisting of a limited set of recordings).

Standalone Non-Portable Subscription Offering—Mixed means a Subscription Offering through which an End User can listen to sound recordings either in the form of Eligible Interactive Streams or Eligible Limited Downloads but only from a non-portable device to which those Eligible Interactive Streams or Eligible Limited Downloads are originally transmitted.

Standalone Non-Portable Subscription Offering—Streaming Only means a Subscription Offering through which an End User can listen to sound recordings only in the form of Eligible Interactive Streams and only from a non-portable device to which those Eligible Interactive Streams are originally transmitted while the device has a live network connection.

Standalone Portable Subscription Offering means a Subscription Offering through which an End User can listen to sound recordings in the form of Eligible Interactive Streams or Eligible Limited Downloads from a portable device.

Stream means the digital transmission of a sound recording of a musical work to an End User—

(1) To allow the End User to listen to the sound recording, while maintaining a live network connection to the transmitting service, substantially at the time of transmission, except to the extent that the sound recording remains accessible for future listening from a Streaming Cache Reproduction;

(2) Using technology that is designed such that the sound recording does not remain accessible for future listening, except to the extent that the sound recording remains accessible for future listening from a Streaming Cache Reproduction; and

(3) That is subject to licensing as a public performance of the musical work.

Streaming Cache Reproduction means a reproduction of a sound recording embodying a musical work made on a computer or other receiving device by a Service Provider solely for the purpose of permitting an End User who has previously received a Stream of that sound recording to play the sound recording again from local storage on the computer or other device rather than by means of a transmission; provided that the End User is only able to do so while maintaining a live network connection to the Service Provider, and the reproduction is encrypted or otherwise protected consistent with prevailing industry standards to prevent it from being played in any other manner or on any device other than the computer or other device on which it was originally made.

Student Plan means a discounted Subscription Offering available on a limited basis to students.

Subscription Offering means an Offering for which End Users are required to pay a fee to have access to the Offering for defined subscription periods of 3 years or less (in contrast to, for example, a service where the basic charge to users is a payment per download or per play), whether the End User makes payment for access to the Offering on a standalone basis or as part of a Bundle.

TCC means the total amount expensed by a Service Provider or any of its Affiliates in accordance with GAAP for rights to make Eligible Interactive Streams or Eligible Limited Downloads of a musical work embodied in a sound recording through the Service Provider for the Accounting Period, which amount shall equal the Applicable Consideration for those rights at the time the Applicable Consideration is properly recognized as an expense under GAAP. As used in this definition, ''Applicable Consideration'' means anything of value given for the identified rights to undertake the Licensed Activity, including, without limitation, ownership equity, monetary advances, barter or any other monetary and/or nonmonetary consideration, whether that consideration is conveyed via a single agreement, multiple agreements and/or agreements that do not themselves authorize the Licensed Activity but nevertheless provide consideration for the identified rights to undertake the Licensed Activity, and including any value given to an Affiliate of a Sound Recording Company for the rights to undertake the Licensed Activity. Value given to a Copyright Owner of musical works that is controlling, controlled by, or under common control with a Sound Recording Company for rights to undertake the Licensed Activity shall not be considered value given to the Sound Recording Company. Notwithstanding the foregoing, Applicable Consideration shall not include in-kind promotional consideration given to a Sound Recording Company (or Affiliate thereof) that is used to promote the sale or paid use of sound recordings embodying musical works or the paid use of music services through which sound recordings embodying musical works are available where the in-kind promotional consideration is given in connection with a use that qualifies for licensing under 17 U.S.C. 115.

User Manipulation means any behavior that artificially distorts the number of Plays, including, but not limited to, the use of manual (*e.g.,* click farms) or automated (*e.g.,* bots) means.

§ 385.3 Late payments.

A Licensee shall pay a late fee of 1.5% per month, or the highest lawful rate,

whichever is lower, for any payment owed to a Copyright Owner and remaining unpaid after the due date established in 17 U.S.C. 115(c)(2)(I) or 17 U.S.C. 115(d)(4)(A)(i), as applicable and detailed in part 210 of this title. Late fees shall accrue from the due date until the Copyright Owner receives payment.

§ 385.4 Recordkeeping for promotional or free trial non-royalty-bearing uses.

(a) *Effect of Copyright Office recordkeeping regulations.* Unless and until the Copyright Office promulgates superseding regulations concerning recordkeeping for promotional or free trial non-royalty-bearing uses subject to this part, the recordkeeping provisions in this section shall apply to Service Providers.

(b) *General.* A Service Provider transmitting a sound recording embodying a musical work subject to 17 U.S.C. 115 and subparts C and D of this part and claiming a Promotional Offering or Free Trial Offering zero royalty rate shall keep complete and accurate contemporaneous written records of making or authorizing Eligible Interactive Streams or Eligible Limited Downloads, including the sound recordings and musical works involved, the artists, the release dates of the sound recordings, a brief statement of the promotional activities authorized, the identity of the Offering or Offerings for which the zero-rate is authorized (including the internet address if applicable), and the beginning and end date of each zero rate Offering.

(c) *Retention of records.* A Service Provider claiming zero rates shall maintain the records required by this section for no less time than the Service Provider maintains records of royalty-bearing uses involving the same types of Offerings in the ordinary course of business, but in no event for fewer than five years from the conclusion of the zero rate Offerings to which they pertain.

(d) *Availability of records.* If the Mechanical Licensing Collective requests information concerning zero rate Offerings, the Service Provider shall respond to the request within an agreed, reasonable time.

■ 3. Revise subpart C, consisting of §§ 385.20 and 385.21, to read as follows:

Subpart C—Eligible Interactive Streaming, Eligible Limited Downloads, Standalone Limited Offerings, Mixed Service Bundles, Bundled Subscription Offerings, Locker Services, and Other Delivery Configurations

§ 385.20 Scope.

This subpart establishes rates and terms of royalty payments for Eligible Interactive Streams and Eligible Limited Downloads of musical works, and other reproductions or distributions of musical works through Standalone Limited Offerings, Mixed Service Bundles, Bundled Subscription Offerings, Paid Locker Services, and Purchased Content Locker Services provided through subscription and nonsubscription digital music Service Providers in accordance with the provisions of 17 U.S.C. 115, exclusive of Offerings subject to subpart D of this part.

§ 385.21 Royalty rates and calculations.

(a) *Applicable royalty.* Licensees that engage in Licensed Activity covered by this subpart pursuant to 17 U.S.C. 115 shall pay royalties therefor that are calculated as provided in this section.

(b) *Rate calculation.* Royalty payments for Licensed Activity in this subpart shall be calculated as provided in this paragraph (b). If a Service Provider makes available different Offerings, royalties must be calculated separately with respect to each Offering taking into consideration Service Provider Revenue, TCC, subscribers, Plays, expenses, and Performance Royalties associated with each Offering. A Service Provider shall not be required to subject the same portion of Service Provider Revenue, TCC, subscribers, Plays, expenses, or Performance Royalties to the calculation of royalties for more than one Offering in an Accounting Period.

(1) *Step 1: Calculate the all-in royalty for the Offering.* For each Accounting Period, the all-in royalty for each Offering in this subpart with the exception of Mixed Service Bundles shall be the greater of {a} the applicable percent of Service Provider Revenue, as set forth in Table 1 to this paragraph (b)(1), and {b} the result of the TCC Prong Calculation for the respective type of Offering as set forth in Table 2 to this paragraph (b)(1). For Mixed Service Bundles, the all-in royalty shall be the result of the TCC Prong Calculation as set forth in table 2.

TABLE 1 TO PARAGRAPH (b)(1)

Royalty year	2023	2024	2025	2026	2027
Percent of Service Provider Revenue	15.1	15.2	15.25	15.3	15.35

TABLE 2 TO PARAGRAPH (b)(1)

Type of offering	TCC prong calculation
Standalone Non-Portable Subscription Offering—Streaming Only	The lesser of (i) 26.2% of TCC for the Accounting Period or (ii) the aggregate amount of 60 cents per subscriber for the Accounting Period.
Standalone Non-Portable Subscription Offering—Mixed	The lesser of (i) 26.2% of TCC for the Accounting Period or (ii) the aggregate amount of 60 cents per subscriber for the Accounting Period.
Standalone Portable Subscription Offering	The lesser of (i) 26.2% of TCC for the Accounting Period or (ii) the aggregate amount of $1.10 per subscriber for the Accounting Period.
Free nonsubscription/ad-supported services free of any charge to the End User.	26.2% of TCC for the Accounting Period.
Bundled Subscription Offering	24.5% of TCC for the Accounting Period.
Mixed Service Bundle	26.2% of TCC for the Accounting Period.
Purchased Content Locker Service	26.2% of TCC for the Accounting Period.
Standalone Limited Offering	26.2% of TCC for the Accounting Period.
Paid Locker Service	26.2% of TCC for the Accounting Period.

(2) *Step 2: Subtract applicable Performance Royalties.* From the amount determined in step 1 in paragraph (b)(1) of this section, for each Offering of the Service Provider, subtract the total amount of Performance Royalties that the Service Provider has expensed or will expense pursuant to public performance licenses in connection with uses of musical works through that Offering during the Accounting Period that constitute Licensed Activity. Although this amount may be the total of the Service Provider's payments for that Offering for the Accounting Period, it will be less than the total of the performance royalties if the Service Provider is also engaging in public performance of musical works that does not constitute Licensed Activity. In the case in which the Service Provider is also engaging in the public performance of musical works that does not constitute Licensed Activity, the amount to be subtracted for Performance Royalties shall be the amount allocable to Licensed Activity uses through the relevant Offering as determined in relation to all uses of musical works for which the Service Provider pays performance royalties for the Accounting Period. The Service Provider shall make this allocation on the basis of Plays of musical works, provided that if the Service Provider is not capable of tracking Play information, including because of bona fide limitations of the available technology for Offerings of that nature or of devices useable with the Offering, the allocation may instead be accomplished in a manner consistent with the methodology used for making royalty payment allocations for the use of individual sound recordings, and further provided that, if the Service Provider is also not capable of utilizing a manner consistent with a methodology used for making royalty payment allocations for the use of individual sound recordings, the Service Provider may use an alternative, good faith methodology that is reasonable, identifiable, and implemented consistently.

(3) *Step 3: Determine the payable royalty pool.* The payable royalty pool is the amount payable for the reproduction and distribution of all musical works used by the Service Provider by virtue of its Licensed Activity for a particular Offering during the Accounting Period. This amount is the greater of:

(i) The result determined in step 2 in paragraph (b)(2) of this section; and

(ii) The royalty floor (if any) resulting from the calculations described in paragraph (d) of this section.

(4) *Step 4: Calculate the per-work royalty allocation.* This is the amount payable for the reproduction and distribution of each musical work used by the Service Provider by virtue of its Licensed Activity through a particular Offering during the Accounting Period. To determine this amount, the result determined in step 3 in paragraph (b)(3) of this section must be allocated to each musical work used through the Offering. The allocation shall be accomplished by the Mechanical Licensing Collective by dividing the payable royalty pool determined in step 3 for the Offering by the total number of Plays of all musical works through the Offering during the Accounting Period (other than Plays subject to subpart D of this part) to yield a per-Play allocation, and multiplying that result by the number of Plays of each musical work (other than Plays subject to subpart D of this part) through the Offering during the Accounting Period. For purposes of determining the per-work royalty allocation in all calculations under step 4 in this paragraph (b)(4) only (*i.e.,* after the payable royalty pool has been determined), for sound recordings of musical works with a playing time of over 5 minutes, each Play shall be counted as provided in paragraph (c) of this section. Notwithstanding the foregoing, if the Service Provider is not capable of tracking Play information because of bona fide limitations of the available technology for Offerings of that nature or of devices useable with the Offering, the per-work royalty allocation may instead be accomplished in a manner consistent with the methodology used for making royalty payment allocations for the use of individual sound recordings.

(c) *Overtime adjustment.* For purposes of the calculations in step 4 in paragraph (b)(4) of this section only, for sound recordings of musical works with a playing time of over 5 minutes, adjust the number of Plays as follows.

(1) 5:01 to 6:00 minutes—Each Play = 1.2 Plays.

(2) 6:01 to 7:00 minutes—Each Play = 1.4 Plays.

(3) 7:01 to 8:00 minutes—Each Play = 1.6 Plays.

(4) 8:01 to 9:00 minutes—Each Play = 1.8 Plays.

(5) 9:01 to 10:00 minutes—Each Play = 2.0 Plays.

(6) For playing times of greater than 10 minutes, continue to add 0.2 Plays for each additional minute or fraction thereof.

(d) *Royalty floors for specific types of Offerings.* The following royalty floors for use in step 3 in paragraph (b)(3) of this section shall apply to the respective types of Offerings:

(1) *Standalone non-portable Subscription Offerings—streaming only.* Except as provided in paragraphs (d)(4) and (6) of this section with respect to Standalone Limited Offerings, in the case of a Subscription Offering through which an End User can listen to sound recordings only in the form of Eligible Interactive Streams and only from a non-portable device to which those Eligible Interactive Streams are originally transmitted while the device has a live network connection, the royalty floor for use in step 3 in paragraph (b)(3) of this section is the aggregate amount of 18 cents per subscriber per Accounting Period.

(2) *Standalone non-portable Subscription Offerings—mixed.* Except as provided in paragraphs (d)(4) and (6) of this section with respect to Standalone Limited Offerings, in the case of a Subscription Offering through which an End User can listen to sound recordings either in the form of Eligible Interactive Streams or Eligible Limited Downloads but only from a non-portable device to which those Eligible Interactive Streams or Eligible Limited Downloads are originally transmitted, the royalty floor for use in step 3 in paragraph (b)(3) of this section is the aggregate amount of 36 cents per subscriber per Accounting Period.

(3) *Standalone portable Subscription Offerings.* Except as provided in paragraphs (d)(4) and (6) of this section with respect to Standalone Limited Offerings, in the case of a Subscription Offering through which an End User can listen to sound recordings in the form of Eligible Interactive Streams or Eligible Limited Downloads from a portable device, the royalty floor for use in step 3 in paragraph (b)(3) of this section is the aggregate amount of 60 cents per subscriber per Accounting Period.

(4) *Bundled Subscription Offerings.* In the case of a Bundled Subscription Offering, the royalty floor for use in step 3 in paragraph (b)(3) of this section is the aggregate amount of 33 cents per Accounting Period for each Active Subscriber. Notwithstanding the foregoing, solely where the Licensed Activity provided as part of a Bundled Subscription Offering would qualify as a Standalone Limited Offering if offered on a standalone basis, the royalty floor for use in step 3 in paragraph (b)(3) of this section is the aggregate amount of 25 cents per Accounting Period for each Active Subscriber.

(5) *Mixed Service Bundles.* In the case of a Mixed Service Bundle, the royalty floor for use in step 3 in paragraph (b)(3) of this section is the aggregate amount

of 25 cents per Accounting Period for each Active Subscriber.

(6) *Other Offerings.* A Standalone Limited Offering, a Paid Locker Service, a Purchased Content Locker Service, and a free nonsubscription/ad-supported service free of any charge to the End User shall not be subject to a royalty floor in step 3 in paragraph (b)(3) of this section.

(e) *Computation of per-subscriber rates and royalty floors.* For purposes of this section, to determine the per-subscriber rates in step 1 in paragraph (b)(1) of this section and the royalty floors in step 3 in paragraph (b)(3) of this section, as applicable to any particular Offering, the total number of subscribers for the Accounting Period shall be calculated by taking all End Users who were subscribers for a complete Accounting Period, prorating in the case of End Users who were subscribers for only part of an Accounting Period (such proration may take into account the subscriber's billing period), and deducting on a prorated basis for End Users covered by an Offering subject to subpart D of this part, except in the case of a Bundled Subscription Offering, subscribers shall be determined with respect to Active Subscribers. The product of the total number of subscribers for the Accounting Period and the specified number of cents per subscriber (or Active Subscriber, as the case may be) shall be used as the subscriber-based components of the royalty calculation for the Accounting Period. A Family Plan subscription shall be treated as 1.75 subscribers per Accounting Period, prorated in the case of a Family Plan subscription in effect for only part of an Accounting Period. A Student Plan subscription shall be treated as 0.5 subscribers per Accounting Period, prorated in the case of a Student Plan subscription in effect for only part of an Accounting Period. A Bundled Subscription Offering containing a Family Plan with one or more Active Subscriber(s) shall be treated as having 1.75 Active Subscribers. A Bundled Subscription Offering containing a Student Plan with an Active Subscriber shall be treated as having 0.5 Active Subscribers. For the purposes of calculating per-subscriber rates and royalty floors under this section, Artificial Accounts shall not be counted as subscribers, Active Subscribers, or End Users.

■ 4. Revise subpart D, consisting of §§ 385.30 and 385.31, to read as follows:

Subpart D—Promotional Offerings, Free Trial Offerings, and Certain Purchased Content Locker Services

§ 385.30 Scope.

This subpart establishes rates and terms of royalty payments for Promotional Offerings, Free Trial Offerings, and certain Purchased Content Locker Services provided by subscription and nonsubscription digital music Service Providers in accordance with the provisions of 17 U.S.C. 115.

§ 385.31 Royalty rates.

(a) *Promotional Offerings.* For Promotional Offerings of audio-only Eligible Interactive Streams and Eligible Limited Downloads of sound recordings embodying musical works that the Sound Recording Company authorizes royalty-free to the Service Provider, the royalty rate is zero.

(b) *Free Trial Offerings.* For Free Trial Offerings, the royalty rate is zero.

(c) *Certain Purchased Content Locker Services.* For every Purchased Content Locker Service for which the Service Provider receives no monetary consideration, the royalty rate is zero.

David P. Shaw,

Chief Copyright Royalty Judge.

[FR Doc. 2022–24300 Filed 11–3–22; 4:15 pm]

BILLING CODE 1410–72–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2022–0612; FRL–10300–01–R8]

Approval and Promulgation of Implementation Plans; Colorado; Revisions to Colorado Code of Regulations; Regulation Number 3

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to Regulation Number 3 of the Colorado Code of Regulations (CCR) submitted to the EPA by the State of Colorado on March 22, 2021. These revisions reflect changes made by the State to update dates of incorporation by reference of sections of the Code of Federal Regulations (CFR) related to Global Warming Potentials (GWPs). The revisions also include updated references to other sections of the CCR that were previously moved to a new location as well as changes to Regulation 3 to reflect digitalization of public notice and comment procedures. The EPA is taking this action pursuant to the Clean Air Act (CAA).

DATES: Written comments must be received on or before December 7, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2022–0612, to the Federal Rulemaking Portal: *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *www.regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically in *www.regulations.gov.* To reduce the risk of COVID–19 transmission, for this action we do not plan to offer hard copy review of the docket. Please email or call the person listed in the **FOR FURTHER INFORMATION CONTACT** section if you need to make alternative arrangements for access to the docket.

FOR FURTHER INFORMATION CONTACT: Matthew Lang, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD–IO, 1595 Wynkoop Street, Denver, Colorado 80202–1129, telephone number: (303) 312–6709, email address: *lang.matthew@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

I. Background

On March 22, 2021, the State of Colorado submitted SIP revisions to EPA for approval which included Serious ozone nonattainment area required elements for the Denver Metro/North Front Range nonattainment area, conformity related revisions, and revisions to Regulation Number 3 and Regulation Number 7 of the CCR. In this action we are solely addressing the submitted revisions to Regulation 3. All other components of the March 22, 2021 submittal are not being addressed in this rulemaking. The revisions that are the subject of this proposed rule include revisions to Regulation 3, Parts A (Concerning General Provisions Applicable to Reporting and Permitting), Part B (Concerning Construction Permits) and Part D (Concerning Major Stationary Source New Source Review and Prevention of Significant Deterioration) and are described further in section II of this preamble. Revisions to Regulation 3, Part C that are included in the State's submittal are included for completeness and are not being proposed for approval into the Colorado SIP by the EPA since Regulation 3, Part C is not included in the SIP. Therefore, the revisions to Regulation 3, Part C that are included in the State's submittal are not being addressed in this action.

II. The EPA's Evaluation

On March 22, 2021, the State of Colorado submitted revisions titled ''Regulation Number 3, Regulation Number 7, Air Quality Standards, Designations and Emission Budgets, and Ozone State Implementation Plan Element.'' [1] Colorado met the reasonable notice and public hearing requirements of CAA section 110(l) for these revisions through reasonable notice published on September 26, 2020, in the Denver Post, and a public hearing held on December 16–18, 2020.[2]

A. Revisions to Regulation 3, Part A (General Provisions Applicable to Reporting and Permitting)

Sections 1.B.10 and 1.B.44.b(i)

In the submitted revisions, the date of incorporation by reference of Table A–1—Global Warming Potentials at 40 CFR part 98, subpart A was updated to reflect revisions made to Table A–1 by the EPA on December 11, 2014.[3] The previous date of incorporation by reference of November 29, 2013, is replaced with December 11, 2014, by the State's submitted revisions in both sections 1.B.10 and 1.B.44.b(i). No other revisions to Regulation 3, Part A were submitted.

B. Revisions to Regulation 3, Part B (Construction Permits)

Sections III.C.1.e, III.C.4, and III.D.1

The State's submitted revisions to Regulation 3, Part B include several grammatical revisions, an updated reference to Regulation 23 regarding sources submitting applications for a Best Available Retrofit Technology (BART) determination or BART alternative, and revisions to public comment procedures under Part B.[4] The updated reference reflects the move of regional haze provisions from Regulation 3, Part F to Regulation 23. The grammatical revisions and updated reference are clerical in nature and do not substantively change these sections of Regulation 3, Part B. In addition to these clerical revisions, the State's submittal also included revisions to the public comment procedures contained in sections III.C.4 and III.D.1 of Part B. The revisions to section III.C.4 clarify that the Colorado Air Pollution Control Division (APCD) may provide the county clerk of the county in which a source is, or will be located, with copies of construction permit applications, the preliminary analysis, and the draft permit or information on how to access digital versions of these documents. The revisions describe that such documents provided directly to the county clerk may be in digital or hard copy format. The revisions to section III.C.4 further clarify that when the APCD sends electronic notice to persons requesting notice of permit applications subject to public notice requirements that such electronic notice may include email notification to persons on an email list maintained by the APCD. The revision to section III.D.1, which outlines the timeframes that the APCD will grant permits, clarifies that sources subject to the provisions of Part D, section V and VI are those sources described in the section that may require a public comment hearing.

C. Revisions to Regulation 3, Part D (Concerning Major Stationary Source New Source Review and Prevention of Significant Deterioration)

Sections II.A.11.a(viii), IV.A, IV.A.1, and IV.A.7

The State's submitted revisions to Regulation 3, Part D include clarifying revisions to public notice and comment procedures for New Source Review (NSR) permit applications as well as revisions which update language to align with corresponding federal language.[5] In sections II.A.11.a.(viii), IV.A, IV.A.1, and IV.A.7 of Part D, language that requires filing of permit related materials with the county clerk is removed. This removed language relating to the availability of permit related materials is replaced with newly added language in section IV.A of Part D detailing how the APCD will make available in at least one location in each region in which a proposed source would be constructed, copies of all materials submitted by an applicant, a copy of the preliminary permit determination, and a copy or summary of other material, if any, that were considered in making the preliminary determination. Additionally, the revisions to section IV.A describe that this requirement may be met by making such materials available at a physical location or on a public website identified by the APCD. The language added to section IV.A aligns with the language found at 40 CFR 51.166(q)(2)(ii). The submitted revisions to section IV.A also clarify that the APCD will send written or electronic notice to persons requesting notice of permit applications and that this notice may include email notification to persons on an email list developed and maintained by the APCD. Following a final decision on a permit application subject to Part D, additional revisions to Part D, section IV.A.7 require that the APCD make available for public inspection the decision and all public comments in accordance with the defined notification procedure in section IV.A. Finally, the state submittal includes a clerical revision to the title of Regulation 3, Part D section IV to reflect that this section describes public hearing requirements in addition to public comment requirements.

III. Proposed Action

We are proposing to approve the revisions submitted by the State of Colorado on March 22, 2021, to Regulation 3, Parts A, B and D because

[1] Letter dated March 22, 2021, From Jill Hunsaker Ryan, Executive Director, CDPHE, to Deb Thomas, Acting Regional Administrator, EPA, Region 8 (''CO SIP Revision'').

[2] CO SIP Revision, Document Set 1, Attachments 2 and 5.

[3] CO SIP Revision, Document Set 4, Attachment 2, Pages 1–2.

[4] CO SIP Revision, Document Set 4, Attachment 2, Pages 3–5.

[5] CO SIP Revision, Document Set 4, Attachment 2, Pages 12–14.

the specific revisions that are the subject of this action do not interfere with attainment or maintenance of any of the NAAQS and would not interfere with any other applicable requirement of the CAA and are therefore approvable under CAA 110(l) and 40 CFR 51.160–166. Specifically, we are approving the previously described revisions to sections 1.B.10 and 1.B.44.b(i) of Part A, sections III.C.1.e, III.C.4, and III.D.1 of Part B, and sections II.A.11.a(viii), IV.A, IV.A.1, and IV.A.7 of Part D. The EPA is soliciting public comments on the revisions discussed in this document. The EPA will consider any comments before taking final action.

IV. Incorporation by Reference

In this document, the EPA is proposing to include regulatory text in an EPA final rule that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the revisions described in sections II.A, II.B and II.C of this preamble. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 8 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the CAA, 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 CAA. Accordingly, this action merely proposes to approve 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 CAA; and
- Does not provide 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 EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed 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).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Greenhouse gases, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: October 30, 2022.

KC Becker,

Regional Administrator, Region 8.

[FR Doc. 2022–24076 Filed 11–4–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2021–0060; FF09E21000 FXES1111090FEDR 234]

RIN 1018–BE49

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Southern Sierra Nevada Distinct Population Segment of Fisher

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; revisions and reopening of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce revisions to the critical habitat we proposed on October 19, 2021, for the federally endangered Southern Sierra Nevada distinct population segment (DPS) of fisher (*Pekania pennanti*) under the Endangered Species Act of 1973, as amended (Act). As a result of the critical habitat revisions, we now propose to designate a total of approximately 595,495 acres (240,988 hectares) as critical habitat for the Southern Sierra Nevada DPS of fisher across six units (one unit of which is further subdivided into two subunits) in California. This amounts to an overall increase of 41,041 acres (16,609 hectares) in our proposed critical habitat designation for the DPS, which includes revisions to all six units. We invite interested parties to comment on the revisions described in this document. Comments previously submitted on the October 19, 2021, proposed rule need not be resubmitted, as they will be fully considered in preparation of the final rule.

DATES: The comment period is reopened for the proposed rule published on October 19, 2021, at 86 FR 57773. So that we can fully consider your comments on the revisions described in this document in our final determination, submit your comments on or before December 22, 2022. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date.

ADDRESSES:

Document availability: You may obtain copies of the October 19, 2021, proposed rule and associated documents on the internet at *https://www.regulations.gov* under Docket No. FWS–R8–ES–2021–0060.

Written comments: You may submit written comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter FWS–R8–ES–2021–0060, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment.''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R8–ES–2021–0060, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *https://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Public Comments, below, for more information).

FOR FURTHER INFORMATION CONTACT: Michael Fris, Field Supervisor, U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office, 2800 Cottage Way, Rm. W–2605, Sacramento, CA 95825; telephone 916–414–6600. 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.

SUPPLEMENTARY INFORMATION:

Public Comments

We will accept written comments and information during this reopened comment period on our October 19, 2021, proposed rule to designate critical habitat for the Southern Sierra Nevada DPS of fisher (86 FR 57773), the revisions to the proposed critical habitat designation that are described in this document, and our revised draft economic assessment (DEA) of the proposed critical habitat designation. We will consider information and recommendations from all interested parties. We are particularly interested in comments concerning:

(1) Specific information on:

(a) The amount and distribution of habitat for the Southern Sierra Nevada DPS of fisher;

(b) What areas that were occupied at the time of listing (85 FR 29532, May 15, 2020) and that contain the physical or biological features essential to the conservation of the DPS should be included in the designation and why;

(c) Any additional areas occurring within the range of the DPS in Tulare, Kern, Fresno, Madera, Mariposa, and Tuolumne Counties in California that should be included in the designation (in particular, areas that occur outside of the new model described in this document) because they either were occupied at the time of listing and contain the physical or biological feature that is essential to the conservation of the species and that may require special management considerations, or were unoccupied at the time of listing and are essential for the conservation of the species;

(d) Special management considerations or protection that may be needed in critical habitat areas we are proposing, including managing for the potential effects of climate change; and

(2) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat.

(3) Information on the projected and reasonably likely impacts of climate change on the DPS's proposed critical habitat.

(4) Any probable economic, national security, or other relevant impacts of designating any area that may be included in the final designation, and the benefits of including or excluding specific areas.

(5) Information on the extent to which the description of probable economic impacts in the DEA is a reasonable estimate of the likely economic impacts.

(6) Whether any specific areas, in particular those covered by a conservation program or plan, that we are proposing for critical habitat designation should be considered for exclusion under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act, and why. These areas may include Federal, Tribal, State, county, local, or private lands with permitted conservation plans (such as habitat conservation plans, safe harbor agreements, or conservation easements) covering the species or non-permitted conservation agreements and partnerships that would be encouraged by designation of, or exclusion from, critical habitat. Detailed information regarding these plans, agreements, easements, and partnerships is also requested, including:

(a) The location and size of lands covered by the plan, agreement, easement, or partnership;

(b) The duration of the plan, agreement, easement, or partnership;

(c) Who holds or manages the land;

(d) What management activities are conducted;

(e) What land uses are allowable; and

(f) If management activities are beneficial to the Southern Sierra Nevada DPS of fisher and its habitat.

(7) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments.

If you submitted comments or information on the October 19, 2021, proposed rule or the associated DEA during the comment period that was open from October 19, 2021, to December 20, 2021, please do not resubmit them. Any such comments are already part of the public record of this rulemaking proceeding, and we will fully consider them in the preparation of our final determination. Our final determination will take into consideration all written comments and any additional information we receive during the initial comment period and this reopened comment period. The final decision may differ from this revised proposed rule, based on our review of all information we receive during this rulemaking proceeding.

You may submit your comments and materials by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit a comment via *https://www.regulations.gov,* your entire comment—including any personal identifying information—will be posted on the website. We will post all hardcopy comments on *https://www.regulations.gov* as well. If you submit a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we used in preparing the proposed rule and DEA, will be available for public inspection on *https://www.regulations.gov* at Docket No. FWS–R8–ES–2021–0060, or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION**

CONTACT). You may obtain copies of the proposed rule and the DEA on the internet at *https://www.regulations.gov* at Docket No. FWS–R8–ES–2021–0060, or by mail from the Sacramento Fish and Wildlife Office.

Background

It is our intent to discuss in this document only those topics directly relevant to the revisions of the proposed designation of critical habitat for the Southern Sierra Nevada (SSN) DPS of fisher. For more information on the species, its habitat, and previous Federal actions concerning the SSN DPS of fisher, refer to the proposed rule published in the **Federal Register** on October 19, 2021 (86 FR 57773). Our proposed critical habitat for the SSN DPS of fisher consists of the October 19, 2021, proposed rule as modified by the revisions described in this document.

On October 19, 2021, we published in the **Federal Register** (86 FR 57773) a proposed rule to designate critical habitat for the SSN DPS of fisher in six units (one unit of which was further divided into three subunits) encompassing approximately 554,454 acres (ac) (224,379 hectares (ha)) in California. In addition, we announced the availability of a DEA of the proposed critical habitat designation. We accepted comments on the proposed rule and DEA for 60 days, ending December 20, 2021. Based on information we received during the public comment period, we propose to revise the critical habitat designation and are, therefore, reopening the comment period to allow the public additional time to submit comments on the revisions outlined herein.

Although the critical habitat designation for the fisher was proposed when the regulatory definition of habitat (85 FR 81411, December 16, 2020) and the 4(b)(2) exclusion regulations (85 FR 82376, December 18, 2020) were in place and in effect, those two regulations have been rescinded (87 FR 37757, June 24, 2022, and 87 FR 43433, July 21, 2022) and no longer apply to any designations of critical habitat. Therefore, for the final rule designating critical habitat for the fisher, we will apply the regulations at 424.19 and the 2016 Joint Policy on 4(b)(2) exclusions (81 FR 7226, February 11, 2016).

New Information and Revisions to Proposed Critical Habitat

During the public comment period for the October 19, 2021, proposed rule, we received 63 comment letters on the proposed critical habitat designation. We received information regarding site-specific areas that two Federal landowners and a peer reviewer believe meet the definition of critical habitat but were not included in the October 19, 2021, proposed rule. We also received comments notifying us of a new Fisher Reproductive Habitat Suitability Model (2021 Reproductive Model). We also had conversations with species experts to identify additional areas that meet the definition of critical habitat (see *Habitat Analysis,* below, for more details). We subsequently determined that the 2021 Reproductive Model and comments received on site-specific habitat areas are now the best available information upon which to base critical habitat. Under our methodology, the use of this new information results in needed revisions to the critical habitat boundaries presented in our October 19, 2021, proposed rule; specifically, our new analysis of the best available information (*i.e.,* the 2021 Reproductive Model and other site-specific information) has resulted in changes to all six units described in the October 19, 2021, proposed critical habitat designation. The revised proposed units are in the same counties in California as those in the October 19, 2021, proposed critical habitat designation. The revised proposed units are described in this document.

We propose the following unit revisions, all of which are areas occupied by the SSN DPS of fisher at the time of listing. The revisions are summarized here, and the full descriptions and acreage changes follow in *Revised Proposed Critical Habitat Designation,* below:

(1) We are revising the six existing proposed units of critical habitat based on the 2021 Reproductive Model that prompted our reanalysis of the best available information and on the comments we received during the October 19, 2021, proposed rule's initial comment period. Proposed Unit 3 no longer includes subunits, and proposed Unit 4 now includes two subunits.

(2) We are adding some area to Units 1, 3, 4, and 5 based on comments we received from Federal partners and one peer reviewer during the October 19, 2021, proposed rule's initial comment period regarding the accuracy of existing versions of habitat models and follow-up conversations with species experts to evaluate the new modeled reproductive habitat information (Craig 2021, *in. litt.,* pp. 3–4, 13–14; Sweitzer 2021, *in litt.,* pp. 3–7; Muldoon 2021, *in litt.,* p. 1; Tucker 2022, pers. comm.). According to Thompson et al. (2021a, pp. 8, 10) and species expert opinion, the 2021 Reproductive Model's accuracy is decreased in certain areas due to a sampling bias in the data used to create the model (see *Habitat Analysis,* below, for more details). Therefore, this revised proposed rule includes areas that species experts suggest support the physical and biological feature despite being omitted by the 2021 Reproductive Model. The areas added include extending Unit 1 to the south to better reflect fisher habitat use on the Kern Plateau based on regional monitoring; extending Unit 3 towards the Hume Lake area where occupancy monitoring and recent detections of adult females indicate habitat quality was undervalued by the 2021 Reproductive Model; adding an area east of Mammoth Pool Reservoir in Unit 4 that supports successful reproduction in atypical, high-elevation habitat that was underrepresented by the 2021 Reproductive Model; extending Unit 5 around the Shuteye Pass area that supports multiple female home ranges and contains atypical, high-elevation habitat that was underrepresented by the 2021 Reproductive Model; and extending Unit 5 to include atypical, high-elevation habitat underrepresented by the 2021 Reproductive Model along Glacier Point Road in Yosemite National Park where fishers have been consistently detected.

(3) We are editing the physical and biological feature to ensure its clarity and to better reflect the inclusivity of reproductive habitat, which consists of denning, foraging, and dispersal areas. This is consistent with the approach taken by experts for the development of the 2021 Reproductive Model.

(4) We are revising the criteria used to identify critical habitat to use the best available science including the 2021 Reproductive Model, expert opinion on additional areas that contain the physical and biological feature that is essential to the conservation of the species, and research on fisher use of post-fire landscapes.

(5) We are continuing to consider the exclusion of Southern California Edison Company (SCE) lands and the Tule River Indian Reservation as described in our October 19, 2021, proposed rule. However, the acreages of revised proposed critical habitat on SCE and Tule River Indian Tribe lands, and thus the acreages considered for exclusion, have changed based on the revised criteria. As described in our October 19, 2021, proposed rule, the considered exclusion of the Tule River Indian Reservation is based on our partnership with the Tribe, the Tribe's long history of managing and protecting forest resources, and fisher-specific conservation measures the Tribe implements when conducting activities (Live Oak Associates, Inc. 2021, pp. 16–

27). The Tribal acreage within Unit 2 considered for exclusion has decreased from 16,246 ac (6,574 ha) to 14,622 ac (5,917 ha) due to a reduction in the amount of predicted suitable habitat on the Reservation according to the 2021 Reproductive Model. The SCE acreage within Unit 4 and considered for exclusion has decreased from 10,254 ac (4,150 ha) to 8,322 (3,368 ha) mainly due to our consideration of the effects of the Creek Fire on fisher habitat.

All of the lands in the above-described revised proposed units were occupied at the time of listing and are currently occupied, contain the physical or biological feature to support life-history functions essential to the conservation of the SSN DPS of fisher, and may require special management considerations or protection from threats as described in the October 19, 2021, proposed rule (86 FR 57773). Revised proposed unit descriptions follow for all six units, and short textual descriptions of each proposed unit are also updated in the regulatory text of the critical habitat designation.

The DEA for the proposed critical habitat designation (IEc 2021, entire) has been revised (IEc 2022, entire) and addresses additional information and considerations by the Service. Based on consultation history for the SSN DPS of fisher and with consideration of this revised proposed rule, the number of section 7 efforts is likely to be approximately 8 formal consultations, 52 informal consultations, and 4 technical assistance per year on average, with the highest costs anticipated in Units 2 and 5 (IEc 2022, pp. 2, 14–15). The additional administrative (incremental) cost of addressing adverse modification in these consultations is likely to be less than $180,100 (2022 dollars) per year (IEc 2022, pp. 2, 17, 19). This represents an $800 increase in the annual administrative cost relative to the July 1, 2021, version of the DEA.

Revised Physical or Biological Feature Essential to the Conservation of the Species

We derive the specific physical or biological feature essential for the SSN DPS of fisher from studies of the species' habitat, ecology, and life history, which are described more fully in the final listing rule (85 FR 29532, May 15, 2020) and the species report (Service 2016, entire) that was developed to supplement the proposed listing rule (79 FR 60419, October 7, 2014) and revised proposed listing rule (84 FR 60278, November 7, 2019).

We have determined that there is one feature, which is considered both physical and biological, that is essential to the conservation of the SSN DPS of fisher. Additional information can be found in the final listing rule (85 FR 29532, May 15, 2020) and the species report (Service 2016, entire) that was developed in conjunction with the proposed listing rule. These background documents are available on the internet at *https://www.regulations.gov* under Docket No. FWS–R8–ES–2021–0060.

After reviewing the 2021 Reproductive Model and comments we received on our October 19, 2021, proposed rule, we are revising the physical and biological feature to better align with the best available science. While the 2015 Pre-Drought Fisher Denning Habitat Suitability Model and the 2020 Post-Drought Fisher Denning Habitat Suitability Model we used as the basis of our October 19, 2021, proposed rule focused entirely on known dens, the 2021 Reproductive Model took a broader approach at identifying the habitats that fishers require to successfully reproduce. In addition to habitat required for denning, the 2021 Reproductive Model also took into consideration rearing habitat (Thompson et al. 2021a, p. 2). This includes foraging areas where females can capture prey to feed their young, and dispersal areas that mothers use to move their kits between dens and juveniles use to disperse from their natal home ranges to establish their own home ranges. Oftentimes, these denning and rearing habitats can overlap or even be the same (Thompson et al. 2021a, p. 2). Collectively, these habitats each play an important role in a female fisher successfully raising her kits. Therefore, we revise our physical and biological feature to better capture this more inclusive ''reproductive habitat'' that is essential to the conservation of the species. We also revise the physical and biological feature to include additional forest types that fishers use to support reproduction (Muldoon 2021, *in litt.,* p. 1; Thompson et al. 2020, p. 7).

We have determined that the following feature, which is considered both physical and biological in character, is essential to the conservation of the SSN DPS of fisher: Suitable reproductive habitat that includes intermixed denning, foraging, and dispersal areas. Such habitat provides structural features for parturition, raising kits, protection from adverse weather conditions, facilitation of safe movement, sites to rest and thermoregulate, foraging opportunities, and cover to reduce predation risk for adults and young. The characteristics of this physical and biological feature include:

(a) Forest types described as Douglas fir (*Pseudotsuga menziesii*), eastside pine, Jeffrey pine (*Pinus jeffreyi*), montane hardwood-conifer, montane hardwood, montane riparian, ponderosa pine (*Pinus ponderosa*), Sierran mixed conifer, white fir (*Abies concolor*), red fir (*Abies magnifica*), or lodgepole pine (*Pinus contorta*) of California Wildlife Habitat Relationships size and density classes 4M, 4D, 5M, 5D, or 6 (Mayer and Laudenslayer 1988, entire; Thompson et al. 2020, p. 7).

(b) Forest stands in or near drainages with clusters of large, mature trees and snags, high canopy cover (generally greater than or equal to 60 percent), complex horizontal and vertical forest structure (*e.g.,* multilayered canopy, moderate shrub cover, downed wood, vegetation of varying age classes), a moderate intermix of California black oak (*Quercus kelloggii*), and fairly steep slopes (greater than or equal to 17 percent) (Zhao et al. 2012, p. 117; Spencer et al. 2015, pp. 33–35; Green et al. 2019, entire).

(c) Multiple large diameter trees (live or dead), such as conifers greater than or equal to 35 inches (in) (89 centimeters (cm)) and hardwoods greater than or equal to 25 in (63 cm) in diameter (Spencer et al. 2015, p. 39), with cavities that provide secure natal and maternal den sites (Green et al. 2019, p. 136). Some of these large diameter trees or snags should also have branch platforms, broken top platforms, mistletoe (*Arceuthobium* spp.) infections, and other deformities or structures that provide resting sites (Green et al. 2019, p. 136).

(d) Shrub and tree clumps, large downed logs, and other structures that provide continuous dense cover or patches of dense cover that are close together to provide protection from predators (Spencer et al. 2015, p. 33; Green 2017, pp. 101–102).

(e) Intermixed foraging areas that typically include a diversity of vegetation types and seral stages to support a variety of prey species (such as western gray squirrels (*Sciurus griseus*), Douglas squirrels (*Tamiasciurus douglasii*), California ground squirrels (*Otospermophilus beecheyi*), dusky-footed woodrats (*Neotoma fuscipes*), and other small mammals) (Spencer et al. 2015, p. 30), and structures that provide fishers resting sites and protection from predators.

(f) Intermixed dispersal areas that provide connectivity between patches of denning habitat to allow for movement of individuals within subpopulations. Dispersal areas must contain structures and habitat characteristics that facilitate

resting and safe movement (Spencer et al. 2015, p. 52). These habitat characteristics and structures include some overhead cover from trees or shrubs (*i.e.,* greater than 30 percent for male dispersal and greater than 60 percent for female dispersal (Tucker et al. 2017, pp. 14–15; Spencer et al. 2016, p. 10)), snags, downed logs, or other components to protect fishers from predation and allow for sufficient resting opportunities.

Revised Criteria Used To Identify Critical Habitat

Based on the release of the 2021 Reproductive Model and after reviewing peer and public comments on our October 19, 2021, proposed rule, we revised the criteria used to identify critical habitat. This new information represents the best available science that forms the basis of our proposed designation. In summary, we made the following revisions to the criteria for identifying critical habitat:

(1) Replace the 2015 Pre-Drought Fisher Denning Habitat Suitability Model and the 2020 Post-Drought Fisher Denning Habitat Suitability Model with the 2021 Reproductive Model;

(2) Include additional areas that species experts suggest were underrepresented or undervalued by the 2021 Reproductive Model but support the physical and biological feature and are essential to the conservation of the species (see *Habitat Analysis,* below, for more details);

(3) Use wildfire burn severity data to identify areas that no longer support the physical and biological feature due to impacts of recent wildfires; and

(4) Exclude buildings and the defensible space around buildings solely via text instead of using Cal Fire's housing density data to spatially remove these areas on the associated critical habitat maps.

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b), we review available information pertaining to the habitat requirements of the species and identify specific areas within the geographical area occupied by the species at the time of listing and any specific areas outside the geographical area occupied by the species to be considered for designation as critical habitat. We are not currently proposing to designate any areas outside the geographical area occupied by the species because we have not identified any unoccupied areas that meet the definition of critical habitat. We determined that occupied areas are sufficient for contributing to the conservation of the SSN DPS of fisher, following our evaluation of all suitable habitat across the DPS's range that has documented use by fishers.

For areas within the geographic area occupied by the species at the time of listing, we employed the following basic steps to delineate critical habitat (which are described in detail in the text following this list):

(1) We compiled fisher detection data and determined the geographic area that was occupied by the species at the time of listing (see *Occupancy Analysis,* below).

(2) Using the best available science, including habitat models, expert opinion, and reasonable inferences regarding female home range size and the effect of high severity wildfire, we conducted a habitat analysis to identify the spatial extent of the physical and biological feature (see *Habitat Analysis,* below).

(3) Based on the results of these analyses, we delineated six discrete critical habitat units (including one unit—Unit 4—that is subdivided into two subunits) separated by evidence of genetic discontinuity and gaps in contiguous reproductive habitat typically associated with major river canyons (see *Mapping Critical Habitat Units,* below).

Data Sources

For our occupancy analysis, habitat analysis, and subsequent unit delineations, we used a variety of data sources that provide information regarding the occupied range of the fisher, the spatial extent of suitable fisher habitat, and habitat condition, including:

(1) Fisher observation data from the U.S. Forest Service (USFS) Natural Resource Information System, University of California (UC) Berkeley Sierra Nevada Adaptive Management Project, USFS Sierra Nevada Carnivore Monitoring Program, and National Park Service (NPS) databases;

(2) Models developed by the Conservation Biology Institute (CBI), including the 2021 Reproductive Model and the 2020 Post-Drought Fisher Landscape-Scale Habitat Suitability Model (2020 Landscape-Scale Model);

(3) Wildfire data from the joint U.S. Geological Survey (USGS)–USFS Monitoring Trends in Burn Severity (MTBS) project; and

(4) Lake, reservoir, and pond dataset from California Department of Fish and Wildlife.

Occupancy Analysis

We used recent fisher observation data to identify the geographic area occupied by the species at the time of listing. We reviewed USFS, NPS, and UC Berkeley fisher detection data including visual observations, remote camera detections, scat and hair samples, tracks, and radio telemetry locations from 1990–2020. This timeframe overlaps with the beginning of extensive surveying and monitoring efforts in the Sierra Nevada that continue today (Zielinski et al. 1995, entire) and recent northward population expansion of fishers that has occurred over the last few decades (Tucker et al. 2014, p. 131). Fisher occupancy has remained relatively stable throughout the southern Sierra Nevada from 2002 through 2015 (Zielinski et al. 2013, pp. 8–10; Tucker 2019, pers. comm.), indicating that, in general, sites that were previously occupied continued to be occupied into the mid-2010s. Analyses on occupancy during recent years (2016–2021) are ongoing (Craig 2021, *in litt.,* p. 3).

Based on these data, we determined that the northern extent of the geographic area occupied at the time of listing was the Tuolumne River in Yosemite National Park (Mariposa County) and the southern limit was the Greenhorn Mountains in Sequoia National Forest (Kern County). The eastern limit of the current species' range is the high-elevation, granite-dominated mountains and the western limit is the low-elevation extent of mixed-conifer forest.

Habitat Analysis

We used two habitat models developed by CBI to better understand the broad-scale spatial extent of reproductive habitat in the southern Sierra Nevada. Our analysis was largely focused on reproductive habitat because this habitat type is essential for successful denning, rearing of kits, and juvenile recruitment. Reproductive habitat also supports other life-history activities necessary for female and male survival, such as foraging, resting, and dispersal. Therefore, sustaining and enhancing the broad-scale spatial extent of reproductive habitat, composed of fine-scale denning, foraging, and dispersal areas, is vital to conservation and recovery of the species (Thompson et al. 2021a, p. 9).

We used the 2021 Reproductive Model (Thompson et al. 2021a, entire) to identify the broad-scale spatial extent of reproductive habitat. This 2021 Reproductive Model used a combination of fisher observations indicative of

habitat used by female fishers for raising their young, including known den locations, detections of family groups, and detections of adult females during the denning period (Thompson et al. 2021a, p. 3). The 2021 Reproductive Model also includes 12 biotic and abiotic predictors including climate, hydrology, and forest structure variables (Thompson et al. 2021a, pp. 4, 6). By using a combination of fisher observation data paired with a variety of environmental variables, the 2021 Reproductive Model's results are representative of habitat that is most likely to support fisher reproduction (*i.e.,* habitat that supports potential dens plus foraging areas that females use to capture prey and dispersal areas that connect multiple dens within a home range and allows juveniles to disperse from their natal ranges to establish their own home ranges). There are known instances where female fishers have denned and successfully reproduced outside of the modeled extent of predicted reproductive habitat (see more details regarding underrepresentation and undervaluation of habitat quality below). Model results are not intended to conclude complete absence of dens or fishers outside of the predicted areas. It is important to note that the 2021 Reproductive Model merely predicts the areas that are most likely to support fisher reproduction, rather than representing the absolute area where fishers will successfully reproduce (Thompson et al. 2021a, p. 9).

The 2021 Reproductive Model's output is presented as two classes: high-quality and moderate-quality reproductive habitat. However, the suitability thresholds are somewhat subjective, and the modelers cautioned that the boundaries between the two classes should not be treated as absolutes (Thompson et al. 2021a, p. 10). For the purposes of identifying the spatial extent of the physical and biological feature, we considered both high-quality and moderate-quality modeled reproductive habitat to represent suitable habitat most likely to support successful reproduction.

The Kern Plateau, where females have repeatedly been detected during regional monitoring surveys (Craig 2021, *in litt.,* p. 3), has unique environmental conditions due to differences in climate, geology, and vegetation compared to the west slope of the Sierra Nevada (Spencer et al. 2015, p. 44). These unique conditions result in true differences in habitat value on the Kern Plateau compared to the rest of the fisher's range (Spencer et al. 2015, p. 35). For this reason, the Kern Plateau is excluded from the 2021 Reproductive Model (Thompson et al. 2021a, p. 4). To ensure that essential areas of suitable habitat on the Kern Plateau are considered for inclusion in critical habitat, we used CBI's 2020 Landscape-Scale Model, which predicts the probability of fisher occurrence (also interpreted as a measure of habitat quality) (Spencer et al. 2015, pp. A–1–A–4). Areas that are strongly selected for by fishers have a predicted probability of fisher occupancy (*i.e.,* habitat suitability) of 0.41 and higher (Spencer et al. 2015, p. 42). For the purposes of our analysis, we consider habitat above this threshold to be ''high-quality habitat.'' Using the 2020 Landscape-Scale Model, we identified all high-quality habitat on the Kern Plateau. We compared this high-quality habitat with fisher detection data and determined that this output is an appropriate surrogate for reproductive habitat on the Kern Plateau.

To determine if a patch of reproductive habitat, or high-quality habitat in the case of the Kern Plateau, is essential to the conservation of the DPS, we considered the size of the patch in relation to fisher ecology. We compared patch size with female territory size to determine the minimum size patch necessary to aid in the conservation of the species. Based on an analysis of female home ranges, species experts identified an average female breeding territory size of 2,471 acres as the appropriate scale to assess fisher habitat (Spencer et al. 2016, p. 27). This average territory size takes into account overlap between neighboring female home ranges and variation in habitat quality. This territory size is also similar to the average size of a female fisher's core use area, which is the portion of the home range where an animal spends a majority of its time (Spencer et al. 2015, pp. 17–18). For the purposes of our analysis, we rounded this territory size up and consider a female home range size to be 2,500 acres. We determined patches of reproductive habitat that are of an appropriate size to support a subpopulation (*i.e.,* at least five female fishers based on analyses conducted by Spencer et al. (2015, pp. 41–42)) as essential to the conservation of the species. Therefore, patches of reproductive habitat 12,500 ac (5,059 ha) or larger are included in the revised proposed critical habitat designation. We also included one additional patch that plays an important role for the DPS despite being slightly smaller than our minimum size threshold. This patch is approximately 12,049 ac (4,876 ha) and is located within the average juvenile female dispersal distance (3.04 mi (4.9 km) (Spencer et al. 2015, p. 20)) of two subpopulations with high occupancy rates. In addition to providing a moderately large patch of reproductive habitat, this patch also provides important connectivity between the two robust subpopulations (Coleman 2022, pers. comm.). Further, this patch is of heightened importance to the DPS when considering the impacts that recent fires have had on surrounding habitats (Coleman 2022, pers. comm.).

The models used for our analysis resulted in outputs with several ''holes'' where modeled reproductive habitat quality dropped below a threshold set by the modelers based on their understanding of reproductive habitat selection by fishers. Based on our review of aerial imagery, canopy cover, and other data, the habitat within these holes is still expected to support fisher foraging or dispersal, especially for males. Due to their proximity to denning habitat and their utility to support other life-history needs of the fisher, we determined that the habitat within these holes can play an essential role in an established home range or for a dispersing female or male fisher. Therefore, we determined that these areas contain the physical and biological feature essential to the conservation of the SSN DPS of fisher and we include them in the proposed critical habitat designation.

The modelers note that sampling bias in the 2021 Reproductive Model's training data (*i.e.,* data used to build the model) may result in limited accuracy of the model's results in certain areas (Thompson et al. 2021a, pp. 8, 10). In some circumstances, this sampling bias resulted in the 2021 Reproductive Model predicting certain areas to be of low quality even though the area supports fisher and fisher habitat. This undervaluing of habitat quality is most likely to occur at higher elevations where training data were lacking or in areas with slightly different habitat composition than represented by the training data (Thompson et al. 2021a, pp. 8, 10). Thus, Thompson et al. (2021a, p. 10) recommends using the 2021 Reproductive Model in concert with additional information, such as species expert opinion on habitat quality and availability in local areas. To ensure our methodology does not inadvertently omit areas that support the physical and biological feature and are essential to the conservation of the species, we solicited expert opinion to identify areas where the 2021 Reproductive Model or the 2020 Landscape-Scale Model may have underrepresented habitat availability and quality. Using these identified areas

of additional habitat availability, we include the following areas that support the physical and biological feature and are essential to the conservation of the species despite being outside of the modeled area:

(1) We added unmodeled habitat to the southern extent of Unit 1 on the Kern Plateau. This model correction better reflects fisher habitat use based on regional monitoring (Craig 2021, *in litt.,* pp. 3, 13). This added area is also important considering the impacts of wildfires that have altered habitat in surrounding areas (Craig 2021, *in litt.,* p. 3).

(2) We added unmodeled habitat to the northern extent of Unit 3 in the Hume Lake area where consistent occupancy throughout the duration of USFS's monitoring program and recent detections of adult females confirm the use of habitat in this area and thus suggest the 2021 Reproductive Model undervalues habitat quality here (Tucker 2022, pers. comm.).

(3) We added a patch of unmodeled habitat east of Mammoth Pool Reservoir that contains the physical and biological feature, has been consistently occupied throughout the duration of USFS's monitoring program's history, and supports successful reproduction as indicated by detections of adult females and kits (Craig 2021, *in litt.,* pp. 4, 14; Tucker 2022, pers. comm.). In addition to supporting reproduction, this area also provides important connectivity between occupied areas to the south and west. This area contains atypical, high-elevation habitat that the 2021 Reproductive Model undervalued in quality (Tucker 2022, pers. comm.).

(4) We added unmodeled habitat to the southeastern extent of Unit 4 to include an area around Shuteye Peak, Little Shuteye Peak, and Shuteye Pass. This area, which consists of atypical habitat at higher elevations that the 2021 Reproductive Model undervalues in quality, supports several adult females' home ranges that were monitored for the Sierra Nevada Adaptive Management Project Fisher Study (Sweitzer 2021, *in litt.,* pp. 3–7; Sweitzer et al. 2015, entire). In addition to supporting known reproduction, this area was also identified as an important habitat corridor for fishers making both long- and short-distance dispersal movements (Sweitzer 2021, *in litt.,* pp. 4, 6–7; Sweitzer et al. 2015, p. D109).

(5) We added unmodeled habitat to the northeastern extent of Unit 5 to include occupied habitat along Glacier Point Road in Yosemite National Park based on consistent detections of males and females by the NPS (Muldoon 2021, *in litt.,* p. 1). This area consists of atypical habitat types at high elevations that were underrepresented in the 2021 Reproductive Model despite the importance for the persistence of the species.

Within the areas modeled as reproductive habitat and the additional essential areas that support reproduction according to species experts, we identified and removed certain areas that do not contain the physical and biological feature or are not essential to the conservation of the species. First, we removed all lakes, reservoirs, and ponds from the proposed designation because these features do not support the fisher's life-history activities.

Next, we considered the impact of recent wildfires on fisher habitat. The fisher's use of post-fire landscapes is not well understood because few studies on the topic exist, but high-severity fire is believed to have significant negative effects on the fisher and its habitat (Craig 2021, *in litt.,* p. 2). One recent study in the southern Sierra Nevada found that fishers avoid areas dominated by high- and moderate-severity fire and the fisher's use of post-fire habitat may center on larger, more contiguous patches of low-severity burns or unburned islands and on fine-scale topographic features associated with landscape concavity (*e.g.,* ravines) (Thompson et al. 2021b, p. 235). A study conducted on the Northern California-Southern Oregon DPS of fisher concluded that fisher abundance decreased significantly in areas of low-, moderate-, and high-severity wildfire (Green et al. 2022, p. 12). The fisher's use of a burned area appears to gradually increase as time since the fire passes. Both Thompson et al. (2021b, pp. 235–236) and Green et al. (2022, p. 14) found that fishers began to explore the burned landscape after 2 or more years post-fire as vegetative cover, such as shrubs, begin to recover. In a study on the Kern Plateau, fishers were detected deeper into burned patches when surveyed 10+ years post-fire, mirroring Thompson et al.'s (2021b, p. 236) conclusion that fishers' willingness to venture farther into burned habitat increases over time (Hanson 2013, pp. 26–27; Hanson 2015, pp. 499–500).

While high-severity fire may not completely remove all suitable fisher habitat, it likely precludes successful reproduction, at least until the habitat structure required for raising kits recovers. Hanson (2015, p. 500) concluded that the fisher's use of high-severity burn areas revolves around foraging, rather than denning. Green et al. (2022, p. 14) posited that the two fishers detected within the studied burned areas were likely dispersing individuals that were attempting to establish home ranges, although one of the individuals (a female) was not detected in follow-up surveys, indicating she did not successfully establish a home range in the area. Similarly, Thompson et al. (2021b, p. 238) concluded that dispersing fishers may be drawn to burned landscapes with increased prey availability and reduced conflict with territorial adults, but post-burn habitat is unlikely to support reproduction due to lack of resting and denning structures, at least in the short term.

Based on the best available science, we determined that the physical and biological feature does not occur in areas that recently burned in large, contiguous patches at high severity, especially along the periphery of modeled reproductive habitat patches. The 2021 Reproductive Model used vegetation data from 2016, and, therefore, does not account for impacts of recent wildfires. We used MTBS Differenced Normalized Burn Ratio data from all wildfires that overlapped modeled fisher habitat from 2016 through 2020 to identify vegetation burn severity classes of individual fires. Using these data, we excluded from the critical habitat designation the burned areas that no longer support the physical and biological feature. Although MTBS data for 2021 wildfires are not currently available for analysis in this revised proposed designation, we will consider the appropriateness of using 2021 data following our methodology described here if the data become available while we are preparing the final rule. Incorporating these data in our final rule could potentially reduce the area designated as critical habitat if burn severity data suggest the physical and biological feature was removed in certain areas due to the 2021 fires.

Finally, we considered areas with high human activity (*i.e.,* areas immediately surrounding houses and buildings) that, although they may support fishers and their habitat, are not essential to the conservation of the DPS. Fishers are less likely to den in areas with high levels of human activity, such as immediately adjacent to human structures (Spencer et al. 2017, p. 4). Further, areas surrounding homes and buildings generally have been and will be treated heavily to reduce the risk of fire to human life and property. These intense fuels treatments (such as removing all ground vegetation within the defensible space surrounding a building) typically result in reduced habitat quality for fishers. We did not

geospatially remove houses and buildings and the defensible space around them from the maps under Proposed Regulation Promulgation, below, because accurate geospatial data were not available to us. However, buildings and the 100 feet (30.5 meters) of defensible space around buildings have been excluded by text in the proposed rule and are not proposed for designation as critical habitat because they do not contain the physical and biological feature. Therefore, if the critical habitat is finalized as proposed, a Federal action involving these textually excluded lands, even if within the boundaries of critical habitat as shown by the maps of the rule, would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical and biological feature in the adjacent critical habitat.

Mapping Critical Habitat Units

Consistent with previous analyses conducted for the Southern Sierra Nevada Fisher Conservation Assessment (Spencer et al. 2015, pp. 41–52, A–4–A–5), six discrete units (including one unit—Unit 4—that is subdivided into two subunits) were delineated based on evidence of genetic discontinuity and gaps between patches of modeled habitat, typically associated with major river canyons. Unit 1 (Kern Plateau) and Unit 2 (South Sequoia) were separated based on a break in modeled habitat continuity along the Kern River Canyon. Unit 2 abuts Unit 3 (North Sequoia), but the units were delineated based on evidence of genetic discontinuity (Tucker et al. 2014, pp. 129–132; Spencer et al. 2015, pp. 10, 46). Consistent with Spencer et al. (2015, pp. 41, 46), we used Bear Creek in Mountain Home Demonstration State Forest to separate Units 2 and 3. Unit 3 and Unit 4 (South Sierra; Subunit 4A—Blue Canyon) are separated by a gap in suitable habitat and evidence of genetic subdivision associated with the Kings River Canyon (Tucker et al. 2014, pp. 129–132). A break in modeled reproductive habitat separates Subunit 4A from Subunit 4B (Mammoth Pool East). Unit 4 (Subunit 4B) and Unit 5 (North Sierra) are separated by the San Joaquin River and the associated discontinuity of suitable fisher habitat. Tucker et al. (2014, pp. 131–132) found slight genetic separation between the areas mapped as Unit 4 and Unit 5. Finally, Unit 5 and Unit 6 (Stanislaus) are separated by the break in modeled habitat in the vicinity of the Merced River.

Under this revised proposal, six units (including one unit—Unit 4—that is subdivided into two subunits) are proposed for designation based on the physical and biological feature being present to support the fisher's life-history processes. All of the units contain the identified physical and biological feature (and all characteristics of the physical and biological feature) and support multiple life-history processes.

The revised proposed critical habitat designation is defined by the maps, as modified by any accompanying regulatory text, presented at the end of this document under Proposed Regulation Promulgation. We include more detailed information on the boundaries of the critical habitat designation in the preamble of this document. We will make the coordinates or plot points or both on which each map is based available to the public on *https://www.regulations.gov* at Docket No. FWS–R8–ES–2021–0060.

Revised Proposed Critical Habitat Designation

In total, we now propose to designate approximately 595,495 ac (240,988 ha) in six units (one unit of which is subdivided into two subunits). The six areas we propose as critical habitat (from south to north) are: (1) Kern Plateau; (2) South Sequoia; (3) North Sequoia; (4) South Sierra, including two subunits; (5) North Sierra; and (6) Stanislaus. The revised proposed critical habitat areas described below constitute our best assessment, at this time, of areas that meet the definition of critical habitat, and all units were occupied at the time of listing and are considered currently occupied by the species. The table below shows the proposed unit names, land ownership, and approximate acreage.

This document also presents brief descriptions of the revised units, including the reasons why they meet the definition of critical habitat for the SSN DPS of fisher. All units contain the physical and biological feature essential to the conservation of the species and that may require special management considerations or protection. This revised proposed critical habitat designation includes overlap of two units with portions of designated critical habitat for the federally threatened Yosemite toad (*Anaxyrus canorus*) (see 50 CFR 17.95(d) and 81 FR 59046, August 26, 2016). This revised proposed rule also includes overlap of one unit each with portions of designated critical habitat for the federally threatened Little Kern golden trout (*Oncorhynchus aguabonita whitei*) (see 50 CFR 17.95(e) and 43 FR 15427, April 13, 1978) and the federally endangered California condor (*Gymnogyps californianus*) (see 50 CFR 17.95(b) and 41 FR 41914, September 24, 1976). Overlap of proposed critical habitat for the SSN DPS of fisher includes 6,568 ac (2,657 ha) of Yosemite toad designated critical habitat, 7,847 ac (3,176 ha) of Little Kern golden trout designated critical habitat, and 118 ac (48 ha) of California condor designated critical habitat. Acreages of overlap are noted in the applicable unit descriptions, below.

TABLE OF REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE SSN DPS OF FISHER

Critical habitat unit	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes in acres (hectares)	Previous unit numbering
Unit 1—Kern Plateau	Federal	77,397	31,322	+13,266 (5,369)	No Change.
	State	0	0	0 (0).	
	Tribal	0	0	0 (0).	
	Unclassified/Private	781	316	+127 (51).	
	Unit Total	78,178	31,637	+13,393 (5,419).	
Unit 2—South Sequoia	Federal	125,568	50,815	+32,462 (13,136)	No Change.
	State	3,461	1,401	+1,314 (532).	
	Tribal [1]	14,622	5,917	−1,624 (657).	
	Unclassified/Private	6,310	2,554	+2,172 (880).	

TABLE OF REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE SSN DPS OF FISHER—Continued

Critical habitat unit	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes in acres (hectares)	Previous unit numbering
	Unit Total	149,962	60,687	+34,325 (13,890).	
Unit 3—North Sequoia [2]	Federal	108,015	43,712	+177 (72)	Formerly Subunits 3A, 3B, and 3C.
	State	1,889	765	+188 (77)	
	Tribal	0	0	0 (0).	
	Unclassified/Private	5,048	2,043	+1,911 (774).	
	Unit Total	114,952	46,519	+2,276 (922).	
Unit 4—South Sierra [3]	Federal	60,462	24,467	+14,339 (5,802)	Unit subdivided into two subunits (below).
	State	0	0	0 (0)	
	Tribal	0	0	0 (0).	
	Unclassified/Private	15,638	6,328	+738 (298).	
	Unit Total	76,100	30,796	+15,077 (6,101).	
Subunit 4A: Blue Canyon	Federal	46,499	18,817	No subunit in previous proposed rule [4].	New Subunit.
	State	0	0		
	Tribal	0	0		
	Unclassified/Private	15,638	6,328		
	Subunit Total	62,137	25,146		
Subunit 4B: Mammoth Pool East.	Federal	13,963	5,650	No subunit in previous proposed rule [4].	New Subunit.
	State	0	0		
	Tribal	0	0		
	Unclassified/Private	0	0		
	Subunit Total	13,963	5,650		
Unit 5—North Sierra	Federal	135,918	55,004	−1,512 (612)	No Change.
	State	0	0	0 (0).	
	Tribal	0	0	0 (0).	
	Unclassified/Private	9,865	3,992	+65 (26).	
	Unit Total	145,783	58,996	−1,447 (586).	
Unit 6—Stanislaus	Federal	29,920	12,108	−22,384 (9,059)	No Change.
	State	0	0	0 (0).	
	Tribal	0	0	0 (0).	
	Unclassified/Private	601	243	−197 (80).	
	Unit Total	30,521	12,352	−22,581 (9,138).	
Total	Federal	537,279	217,429	+36,346 (14,708).	
	State	5,350	2,165	+1,502 (608).	
	Tribal	14,622	5,917	−1,624 (657).	
	Unclassified/Private	38,243	15,476	+4,817 (1,949).	
	Total	595,495	240,988	+41,041 (16,609).	

Note: Area sizes may not sum due to rounding.

[1] These lands are held in Federal trust status by the United States for the Tule River Indian Tribe of the Tule River Reservation, California.

[2] In the October 19, 2021, proposed rule (86 FR 57773), Unit 3 consisted of three subunits. Under this revised proposed rule, we determined that subdividing this unit into subunits was not appropriate because there is no genetic differentiation or significant breaks of contiguous habitat within the unit.

[3] In this revised proposed rule, we propose that Unit 4 consists of two subunits, whereas there were no subunits within Unit 4 in the October 19, 2021, proposed rule (86 FR 57773). For this revised proposed rule, a significant break in contiguous habitat within Unit 4 indicates that the unit should be managed as two subunits.

[4] Previous proposed rule refers to the October 19, 2021, proposed rule published at 86 FR 57773.

The revised proposed critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document under Proposed Regulation Promulgation. The rule portion of this document depicts all the proposed critical habitat units as revised by this proposal. We include more detailed information on the boundaries of the revised proposed critical habitat designation in the discussion of revised proposed individual units, below.

Unit 1: Kern Plateau

Unit 1 consists of 78,178 ac (31,637 ha) of lands in the Sierra Nevada mountains in Tulare County, California. Unit 1 is situated on the Kern Plateau, east of the Kern River, west of South Fork Kern River, north of Cannell Peak, and south of Templeton Mountain. Lands within this unit include approximately 77,397 ac (31,322 ha; 99 percent) in Federal ownership (Inyo National Forest and Sequoia National Forest, USFS) and 781 ac (316 ha; 1

percent) in private ownership. General land use within this unit includes forest management (*e.g.,* timber harvest, fuels reduction, hazard tree management, forest restoration, prescribed fire), grazing, and recreation.

Unit 1 is occupied by the fisher and contains the physical and biological feature essential to the conservation of the species. This unit is the only unit not on the west slope of the Sierra Nevada; is located on the Kern Plateau, which supports unique environmental conditions compared to the rest of the fisher's range due to differences in climate, geology, and vegetation; and has a complex mosaic of mixed-age forest stands intermixed with open areas and shrublands (Spencer et al. 2015, p. 44). Additionally, fishers in this unit occupy higher elevations than in other units, likely due to the lesser accumulation of snow on the Kern Plateau (Spencer et al. 2015, p. 44). The unique environmental conditions of this unit provide important redundancy and representation for the DPS.

Threats identified within this unit include wildfire and wildfire suppression; climate change; tree mortality from drought, disease, and insect infestation; vegetation management; and exposure to toxicants. Special management considerations or protection measures to reduce or alleviate the threats may include: (1) Implementing forest management practices, especially the use of prescribed fire, that reduce the risk of catastrophic wildfire and improve habitat resiliency in and adjacent to fisher habitat; (2) minimizing habitat disturbance, fragmentation, and destruction (at the stand scale, home-range scale, and landscape scale) from vegetation management activities through the use of conservation measures; and (3) preventing, locating, and remediating trespass marijuana grow sites and other sources of toxicants. Federal lands in this unit are managed under the Land Management Plan for the Inyo National Forest (USFS 2019, entire) and the Sierra Nevada Forest Plan Amendment (USFS 2004, entire).

Unit 2: South Sequoia

Unit 2 consists of 149,962 ac (60,687 ha) of lands in the Sierra Nevada mountains in Kern and Tulare Counties, California. This unit extends northward from approximately Woodward Peak in the Greenhorn Mountains until it abuts Unit 3 to the north, where there is evidence of genetic discontinuity between the two subpopulations in the area of Mountain Home Demonstration State Forest (Mountain Home) (Tucker et al. 2014, pp. 129–131). The northern boundary of Unit 2 roughly follows Bear Creek in the Tule River Watershed until its headwaters, then continues in a linear northeasterly path to the eastern edge of the unit. The unit lies west of Isabella Lake, the Kern River, and Sagebrush Gulch. Unit 2 is east of Springville and California Hot Springs. Lands within this unit include approximately 124,750 ac (50,484 ha; 83 percent) managed by USFS (Sequoia National Forest, Giant Sequoia National Monument) and 818 ac (331 ha; 1 percent) managed by the Bureau of Land Management (BLM). Also, there are 3,461 ac (1,401 ha; 2 percent) in State ownership (Cal Fire), 14,622 ac (5,917 ha; 10 percent) that are Tribal lands (*i.e.,* the Tule River Indian Tribe of the Tule River Reservation, California), and 6,310 ac (2,554 ha; 4 percent) in private ownership. We are considering excluding 14,622 ac (5,917 ha) of the Tule River Reservation based on the Tribe's long history of managing natural resources on the Reservation. General land use within this unit includes forest management (*e.g.,* timber harvest, fuels reduction, hazard tree management, forest restoration, prescribed fire), grazing, recreation, residential development, and management for protection of natural resources.

Unit 2 is occupied by the fisher and contains the physical and biological feature essential to the conservation of the species. This unit is important for the resiliency, redundancy, and representation of the DPS because it supports the highest recorded fisher occupancy rates (Tucker 2020, pers. comm.), the highest predicted average habitat quality (Spencer et al. 2015, p. 46), and the highest genetic diversity (Tucker et al. 2014, entire) in the DPS. This unit supports habitat features and conditions that are optimal for successful reproduction, such as scattered giant sequoia groves and relatively abundant old-growth mixed-conifer forest with large sugar pines, high basal areas, high diversity of tree diameter classes, and dense canopy cover (greater than 70 percent) (Spencer et al. 2015, p. 46). Approximately 7,847 ac (3,176 ha) of the unit overlap with designated critical habitat for the federally threatened Little Kern golden trout (see 50 CFR 17.95(e) and 43 FR 15427, April 13, 1978).

Threats identified within this unit include wildfire and wildfire suppression; climate change; tree mortality from drought, disease, and insect infestation; vegetation management; exposure to toxicants; and vehicle collisions. Special management considerations or protection measures to reduce or alleviate the threats may include: (1) Implementing forest management practices, especially the use of prescribed fire, that reduce the risk of catastrophic wildfire and improve habitat resiliency in and adjacent to fisher habitat; (2) minimizing habitat disturbance, fragmentation, and destruction (at the stand scale, home-range scale, and landscape scale) from vegetation management activities through the use of conservation measures; (3) preventing, locating, and remediating trespass marijuana grow sites and other sources of toxicants; and (4) improving the efficacy of existing road-crossing structures and installing new wildlife road crossings on major roadways. Federal lands in this unit are managed under the Sierra Nevada Forest Plan Amendment (USFS 2004, entire), the Giant Sequoia National Monument Management Plan (USFS 2012, entire), and the Approved Resource Management Plan for the Bakersfield Field Office (BLM 2014, entire).

Unit 3: North Sequoia

Unit 3 consists of 114,952 ac (46,519 ha) of lands in the Sierra Nevada mountains in Tulare and Fresno Counties, California. This unit runs mostly in a north-south linear pattern from the Kings River to the north until it abuts Unit 2 at Bear Creek to the south (see the boundary description for Unit 2, above). The unit is located west of the Great Western Divide and east of Blue Ridge and the communities of Miramonte and Three Rivers. Lands within this unit include approximately 31,313 ac (12,672 ha; 27 percent) managed by USFS (Sierra National Forest and Sequoia National Forest, including Giant Sequoia National Monument), 72,185 ac (29,212 ha; 63 percent) managed by NPS (Sequoia and Kings Canyon National Parks), and 4,517 ac (1,828 ha; 4 percent) managed by BLM. Also, there are 1,889 ac (765 ha; 2 percent) in State ownership (Cal Fire and State Lands Commission) and 5,048 ac (2,043 ha; 4 percent) in private ownership. General land use within this unit includes forest management (*e.g.,* timber harvest, fuels reduction, hazard tree management, forest restoration, prescribed fire), grazing, recreation, and management for protection of natural resources.

Unit 3 is occupied by the fisher and contains the physical and biological feature essential to the conservation of the species. This unit supports high fisher occupancy rates (Tucker 2020, pers. comm.), suggesting it supports relatively high population densities (Spencer et al. 2015, p. 46) compared to

other areas within its range, which provides resiliency for the DPS. This unit has high predicted habitat value due to mature forest conditions and numerous giant sequoia groves and other mixed-coniferous forests with high basal area, dense canopies, and abundant black oaks that support denning features (Spencer et al. 2015, p. 46). Approximately 118 ac (48 ha) of the unit overlap with designated critical habitat for the federally endangered California condor (see 50 CFR 17.95(b); 41 FR 41914, September 24, 1976; 42 FR 47840, September 22, 1977).

Threats identified within this unit include wildfire and wildfire suppression; climate change; tree mortality from drought, disease, and insect infestation; vegetation management; exposure to toxicants; and vehicle collisions. Special management considerations or protection measures to reduce or alleviate the threats may include: (1) Implementing forest management practices, especially the use of prescribed fire, that reduce the risk of catastrophic wildfire and improve habitat resiliency in and adjacent to fisher habitat; (2) minimizing habitat disturbance, fragmentation, and destruction (at the stand scale, home-range scale, and landscape scale) from vegetation management activities through the use of conservation measures; (3) preventing, locating, and remediating trespass marijuana grow sites and other sources of toxicants; and (4) improving the efficacy of existing road-crossing structures and installing new wildlife road crossings on major roadways. Federal lands in this unit are managed under the Sierra Nevada Forest Plan Amendment (USFS 2004, entire), the Giant Sequoia National Monument Management Plan (USFS 2012, entire), the Sequoia and Kings Canyon National Parks General Management Plan (NPS 2012, entire), and the Approved Resource Management Plan for the Bakersfield Field Office (BLM 2014, entire).

Unit 4: South Sierra

Unit 4 consists of 76,100 ac (30,796 ha) of lands in the Sierra Nevada mountains in Fresno County, California. Unit 4 is composed of two subunits.

Subunit 4A: Blue Canyon

Subunit 4A consists of 62,137 ac (25,146 ha) of lands in the Sierra Nevada mountains in Fresno County, California. Patterson Mountain marks the approximate southeastern tip of subunit 4A, which then continues to the northwest approximately to the communities of Shaver Lake and Pineridge. Subunit 4A is situated east of Cats Head Mountain and Burrough Mountain and west of Exchequer Meadow and Bald Mountain. Lands within this subunit include approximately 46,499 ac (18,817 ha; 75 percent) in Federal ownership (Sierra National Forest; USFS) and 15,638 ac (6,328 ha; 25 percent) in private ownership. Of the private lands within this subunit, we are considering excluding approximately 8,322 ac (3,368 ha) owned by Southern California Edison Company based on of their forest management practices that are compatible with fisher conservation by providing suitable habitat and reducing threats to the DPS. General land use within this subunit includes forest management (*e.g.,* timber harvest, fuels reduction, hazard tree management, forest restoration, prescribed fire), grazing, recreation, and residential development.

Subunit 4A is occupied by the fisher and contains the physical and biological feature essential to the conservation of the species. This subunit is located between areas with high occupancy rates to the south and the recently re-colonized areas to the north, indicating this subunit is essential for continued population and range expansion. Approximately 2,598 ac (1,051 ha) of the subunit overlap with designated critical habitat for the federally threatened Yosemite toad (see 50 CFR 17.95(d) and 81 FR 59046, August 26, 2016).

Threats identified within this subunit include wildfire and wildfire suppression; climate change; tree mortality from drought, disease, and insect infestation; vegetation management; exposure to toxicants; and vehicle collisions. Special management considerations or protection measures to reduce or alleviate the threats may include: (1) Implementing forest management practices, especially the use of prescribed fire, that reduce the risk of catastrophic wildfire and improve habitat resiliency in and adjacent to fisher habitat; (2) minimizing habitat disturbance, fragmentation, and destruction (at the stand scale, home-range scale, and landscape scale) from vegetation management activities through the use of conservation measures; (3) preventing, locating, and remediating trespass marijuana grow sites and other sources of toxicants; and (4) improving the efficacy of existing road-crossing structures and installing new wildlife road crossings on major roadways. Federal lands in this subunit are managed under the Sierra Nevada Forest Plan Amendment (USFS 2004, entire).

Subunit 4B: Mammoth Pool East

Subunit 4B consists of 13,963 ac (5,650 ha) of lands in the Sierra Nevada mountains in Fresno County, California. This subunit is located east of Mammoth Pool Reservoir and the San Joaquin River, north of Kaiser Wilderness, south of the South Fork San Joaquin River, and west of Tule and Sample Meadows. The entirety of lands within this subunit are in Federal ownership (Sierra National Forest; USFS). General land use within this subunit includes forest management (*e.g.,* timber harvest, fuels reduction, hazard tree management, forest restoration, prescribed fire), grazing, and recreation.

Subunit 4B is occupied by the fisher and contains the physical and biological feature essential to the conservation of the species. This subunit supports unique habitat and is at higher elevations than many other areas within the occupied range of the DPS. In addition to supporting successful reproduction, this subunit is also important in providing connectivity for fisher dispersing to and from Unit 5.

Threats identified within this subunit include wildfire and wildfire suppression; climate change; tree mortality from drought, disease, and insect infestation; vegetation management; exposure to toxicants; and vehicle collisions. Special management considerations or protection measures to reduce or alleviate the threats may include: (1) Implementing forest management practices, especially the use of prescribed fire, that reduce the risk of catastrophic wildfire and improve habitat resiliency in and adjacent to fisher habitat; (2) minimizing habitat disturbance, fragmentation, and destruction (at the stand scale, home-range scale, and landscape scale) from vegetation management activities through the use of conservation measures; (3) preventing, locating, and remediating trespass marijuana grow sites and other sources of toxicants; and (4) improving the efficacy of existing road-crossing structures and installing new wildlife road crossings on major roadways. Federal lands in this subunit are managed under the Sierra Nevada Forest Plan Amendment (USFS 2004, entire).

Unit 5: North Sierra

Unit 5 consists of 145,783 ac (58,996 ha) of lands in the Sierra Nevada mountains in Madera and Mariposa Counties, California. Unit 5 lies north and west of the San Joaquin River, east of Bass Lake, California State Route 49, and the community of El Portal, and

south of the Big Oak Flat Road. Lands within this unit include approximately 95,378 ac (38,598 ha; 65 percent) managed by USFS (Sierra National Forest and Stanislaus National Forest), 40,296 ac (16,307 ha; 28 percent) managed by NPS (Yosemite National Park), 51 ac (21 ha; less than 1 percent) managed by the Bureau of Indian Affairs (a public domain allotment held in trust status; not affiliated with a recognized Tribe), and 193 ac (78 ha; less than 1 percent) managed by BLM. Also, there are 9,865 ac (3,992 ha; 7 percent) in private ownership. General land use within this unit includes forest management (*e.g.,* timber harvest, fuels reduction, hazard tree management, forest restoration, prescribed fire), grazing, recreation, and residential development.

Unit 5 is occupied by the fisher and contains the physical and biological feature essential to the conservation of the species. This unit supports relatively high predicted habitat quality with a high proportion of shade-tolerant incense cedar and white fir that fishers use for denning and resting (Spencer et al. 2015, p. 49). This unit was recently re-colonized in the 1990s (Tucker et al. 2014, p. 131), and its habitat is essential to support the species' continued northern expansion. Approximately 3,970 ac (1,606 ha) of the unit overlap with designated critical habitat for the federally threatened Yosemite toad (see 50 CFR 17.95(d) and 81 FR 59046, August 26, 2016).

Threats identified within this unit include wildfire and wildfire suppression; climate change; tree mortality from drought, disease, and insect infestation; vegetation management; exposure to toxicants; and vehicle collisions. Special management considerations or protection measures to reduce or alleviate the threats may include: (1) Implementing forest management practices, especially the use of prescribed fire, that reduce the risk of catastrophic wildfire and improve habitat resiliency in and adjacent to fisher habitat; (2) minimizing habitat disturbance, fragmentation, and destruction (at the stand scale, home-range scale, and landscape scale) from vegetation management activities through the use of conservation measures; (3) preventing, locating, and remediating trespass marijuana grow sites and other sources of toxicants; and (4) improving the efficacy of existing road-crossing structures and installing new wildlife road crossings on major roadways. Federal lands in this unit are managed under the Sierra Nevada Forest Plan Amendment (USFS 2004, entire), Yosemite National Park General Management Plan (NPS 1980, entire), and Approved Resource Management Plan for the Bakersfield Field Office (BLM 2014, entire).

Unit 6: Stanislaus

Unit 6 consists of 30,521 ac (12,352 ha) of lands in the Sierra Nevada mountains in Mariposa and Tuolumne Counties, California. Unit 6 is situated north of the Merced River and the community of El Portal, south of Sawmill Mountain, east of Scott Ridge, west of Tamarack Flat, and southwest of Ackerson Meadow. The unit forms a ''U'' to the east, north, and west around Anderson Flat. Lands within this unit include approximately 22,078 ac (8,935 ha; 72 percent) managed by USFS (Stanislaus National Forest) and 7,842 ac (3,174 ha; 26 percent) managed by NPS (Yosemite National Park). Also, there are 601 ac (243 ha; 2 percent) in private ownership. General land use within this unit includes forest management (*e.g.,* timber harvest, fuels reduction, hazard tree management, forest restoration, prescribed fire), grazing, recreation, and residential development.

Unit 6 is occupied by the fisher and contains the physical and biological feature essential to the conservation of the species. This unit represents the northernmost extent of the species' current range and was recently re-colonized over the previous decade, with possible evidence of reproduction documented for the first time in 2020 (Stock 2021, pers. comm.). This northward expansion and establishment of a subpopulation north of the Merced River improves the redundancy of the DPS.

Threats identified within this unit include wildfire and wildfire suppression; climate change; tree mortality from drought, disease, and insect infestation; vegetation management; exposure to toxicants; and vehicle collisions. Special management considerations or protection measures to reduce or alleviate the threats may include: (1) Implementing forest management practices, especially the use of prescribed fire, that reduce the risk of catastrophic wildfire and improve habitat resiliency in and adjacent to fisher habitat; (2) minimizing habitat disturbance, fragmentation, and destruction (at the stand scale, home-range scale, and landscape scale) from vegetation management activities through the use of conservation measures; (3) preventing, locating, and remediating trespass marijuana grow sites and other sources of toxicants; and (4) improving the efficacy of existing road-crossing structures and installing new wildlife road crossings on major roadways. Federal lands in this unit are managed under the Sierra Nevada Forest Plan Amendment (USFS 2004, entire) and the Yosemite National Park General Management Plan (NPS 1980, entire).

References Cited

A complete list of references cited in this document is available on the internet at *https://www.regulations.gov* and upon request from the Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this document are the staff members of the U.S. Fish and Wildlife Service Species Assessment Team and Sacramento Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as proposed to be amended at 86 FR 57773 (October 19, 2021) as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Further amend § 17.95(a), as proposed to be amended at 86 FR 57773, in the entry for ''Fisher (*Pekania pennanti*), Southern Sierra Nevada Distinct Population Segment (DPS)'', by revising paragraphs (2) through (11) to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

(a) *Mammals.*

* * * * *

Fisher (*Pekania pennanti*), Southern Sierra Nevada Distinct Population Segment (DPS)

* * * * *

(2) Within these areas, the physical and biological feature essential to the conservation of the Southern Sierra Nevada DPS of fisher is suitable reproductive habitat that includes intermixed denning, foraging, and dispersal areas. Such habitat provides structural features for parturition,

raising kits, protection from adverse weather conditions, facilitation of safe movement, sites to rest and thermoregulate, foraging opportunities, and cover to reduce predation risk for adults and young. The characteristics of this physical and biological feature include:

(i) Forest types described as Douglas fir (*Pseudotsuga menziesii*), eastside pine, Jeffrey pine (*Pinus jeffreyi*), montane hardwood-conifer, montane hardwood, montane riparian, ponderosa pine (*Pinus ponderosa*), Sierran mixed conifer, white fir (*Abies concolor*), red fir (*Abies magnifica*), or lodgepole pine (*Pinus contorta*) of California Wildlife Habitat Relationships size and density classes 4M, 4D, 5M, 5D, or 6.

(ii) Forest stands in or near drainages with clusters of large, mature trees and snags, high canopy cover (generally greater than or equal to 60 percent), complex horizontal and vertical forest structure (*e.g.,* multilayered canopy, moderate shrub cover, downed wood, vegetation of varying age classes), a moderate intermix of California black oak (*Quercus kelloggii*), and fairly steep slopes (greater than or equal to 17 percent).

(iii) Multiple large diameter trees (live or dead), such as conifers greater than or equal to 35 inches (in) (89 centimeters (cm)) and hardwoods greater than or equal to 25 in (63 cm) in diameter, with cavities that provide secure natal and maternal den sites. Some of these large diameter trees or snags should also have branch platforms, broken top platforms, mistletoe (*Arceuthobium* spp.) infections, and other deformities or structures that provide resting sites.

(iv) Shrub and tree clumps, large downed logs, and other structures that provide continuous dense cover or patches of dense cover that are close together to provide protection from predators.

(v) Intermixed foraging areas that typically include a diversity of vegetation types and seral stages to support a variety of prey species (such as western gray squirrels (*Sciurus griseus*), Douglas squirrels (*Tamiasciurus douglasii*), California ground squirrels (*Otospermophilus beecheyi*), dusky-footed woodrats (*Neotoma fuscipes*), and other small mammals), and structures that provide fishers resting sites and protection from predators.

(vi) Intermixed dispersal areas that provide connectivity between patches of denning habitat to allow for movement of individuals within subpopulations. Dispersal areas must contain structures and habitat characteristics that facilitate resting and safe movement. These habitat characteristics and structures include some overhead cover from trees or shrubs (*i.e.,* greater than 30 percent for male dispersal and greater than 60 percent for female dispersal), snags, downed logs, or other components to protect fishers from predation and allow for sufficient resting opportunities.

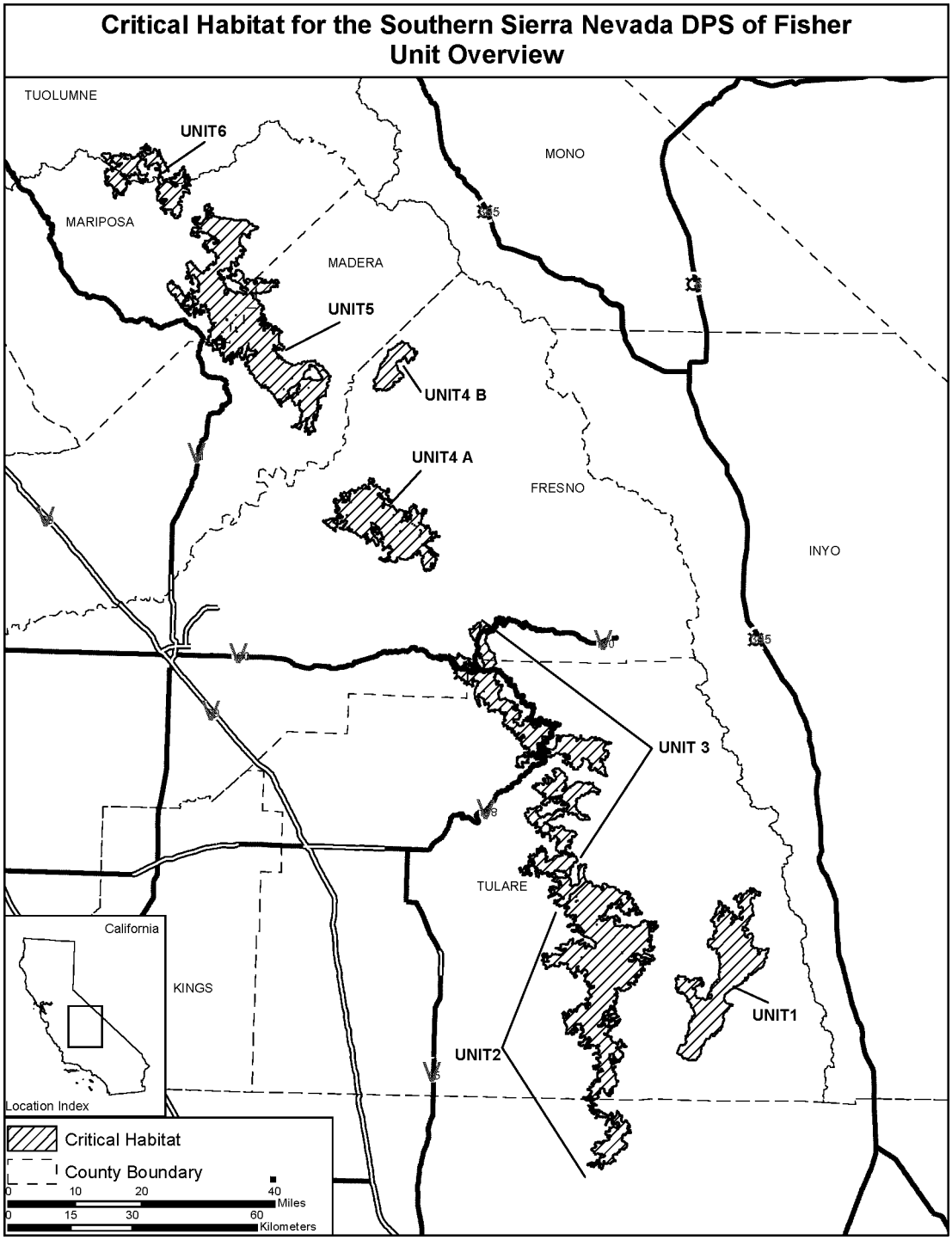
(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas), the defensible space around buildings (defined as the area of land surrounding a building that is 100 feet (30.5 meters) or less from the building's walls), and the land on which they are located existing within the legal boundaries on the effective date of the rule.

(4) Data layers defining map units were created using fisher habitat suitability models developed by the Conservation Biology Institute, wildfire burn severity data from the U.S. Geological Survey and U.S. Forest Service, and species expert opinion. Critical habitat units were then mapped using Universal Transverse Mercator Zone 11N coordinates. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at *https://www.regulations.gov* at Docket No. FWS–R8–ES–2021–0060 and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) Index map follows:

BILLING CODE 4333–15–P

Figure 1 to Fisher (*Pekania pennanti*), Southern Sierra Nevada DPS paragraph (5)

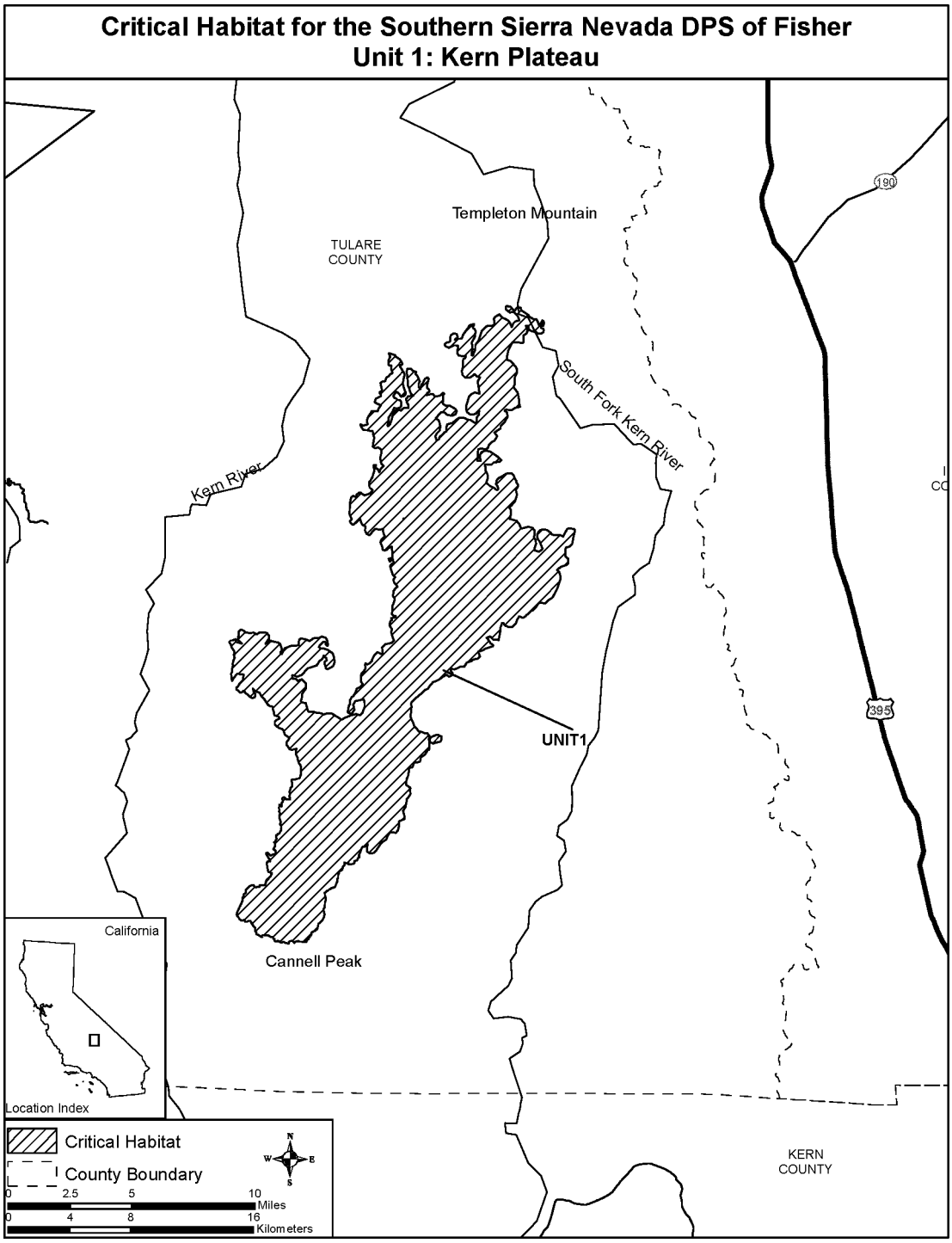


(6) Unit 1: Kern Plateau, Tulare County, California.

(i) Unit 1 consists of 78,178 acres (ac) (31,637 hectares (ha)) of occupied habitat on the Kern Plateau, east of the Kern River, west of South Fork Kern River and Kennedy Meadows, north of Cannell Peak, and south of Templeton Mountain. Lands within this unit include 77,397 ac (31,322) ac in Federal ownership (Inyo National Forest and Sequoia National Forest) and approximately 781 ac (316 ha) in private ownership.

(ii) Map of Unit 1 follows:

Figure 2 to Fisher (*Pekania pennanti*), Southern Sierra Nevada DPS paragraph (6)(ii)

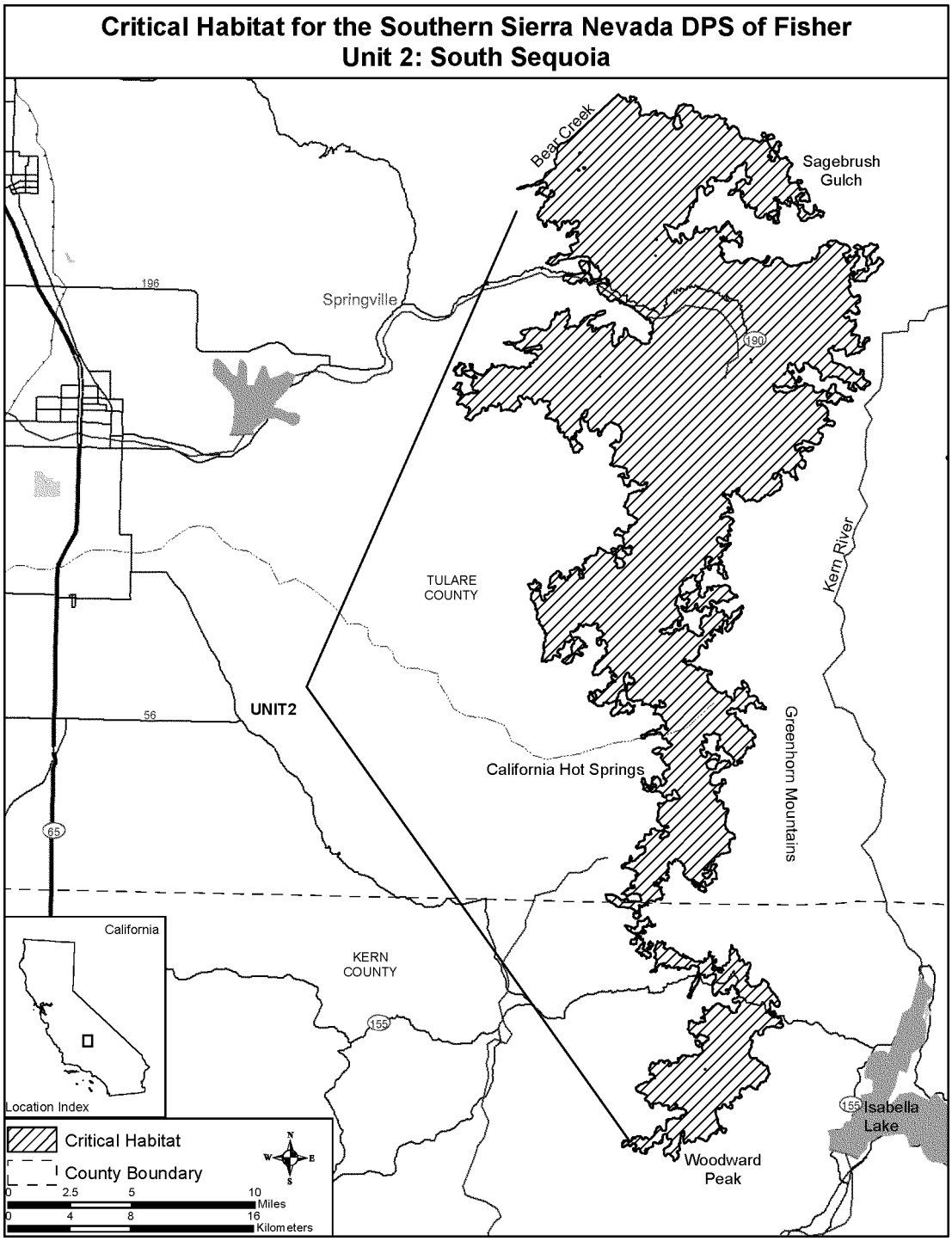


(7) Unit 2: South Sequoia, Kern and Tulare Counties, California.

(i) Unit 2 consists of approximately 149,962 ac (60,687 ha) of occupied habitat in the Sierra Nevada mountains, extending northward from approximately Woodward Peak in the Greenhorn Mountains until it abuts Unit 3 to the north. The northern boundary of Unit 2 roughly follows Bear Creek in the Tule River Watershed until its headwaters, then continues in a linear path to the eastern edge of the unit. The unit lies west of the Kern River from Isabella Lake to its confluence with the Little Kern River and west of the Little Kern River until the vicinity between Moses Mountain and Maggie Mountain. Unit 2 is east of Springville and California Hot Springs. Lands within this unit include 125,568 ac (50,815 ha) in Federal ownership (Sequoia National Forest, Giant Sequoia National Monument, and Bureau of Land Management), 3,461 ac (1,401 ha) in State ownership (California Department of Forestry and Fire Protection (Cal Fire) and State Lands Commission), 14,622 ac (5,917 ha) of lands that are held in trust by the United States through the Bureau of Indian Affairs for the Tule River Indian Tribe of the Tule River Reservation, and 6,310 ac (2,554 ha) in private ownership.

(ii) Map of Unit 2 follows:

Figure 3 to Fisher (*Pekania pennanti*), Southern Sierra Nevada DPS paragraph (7)(ii)

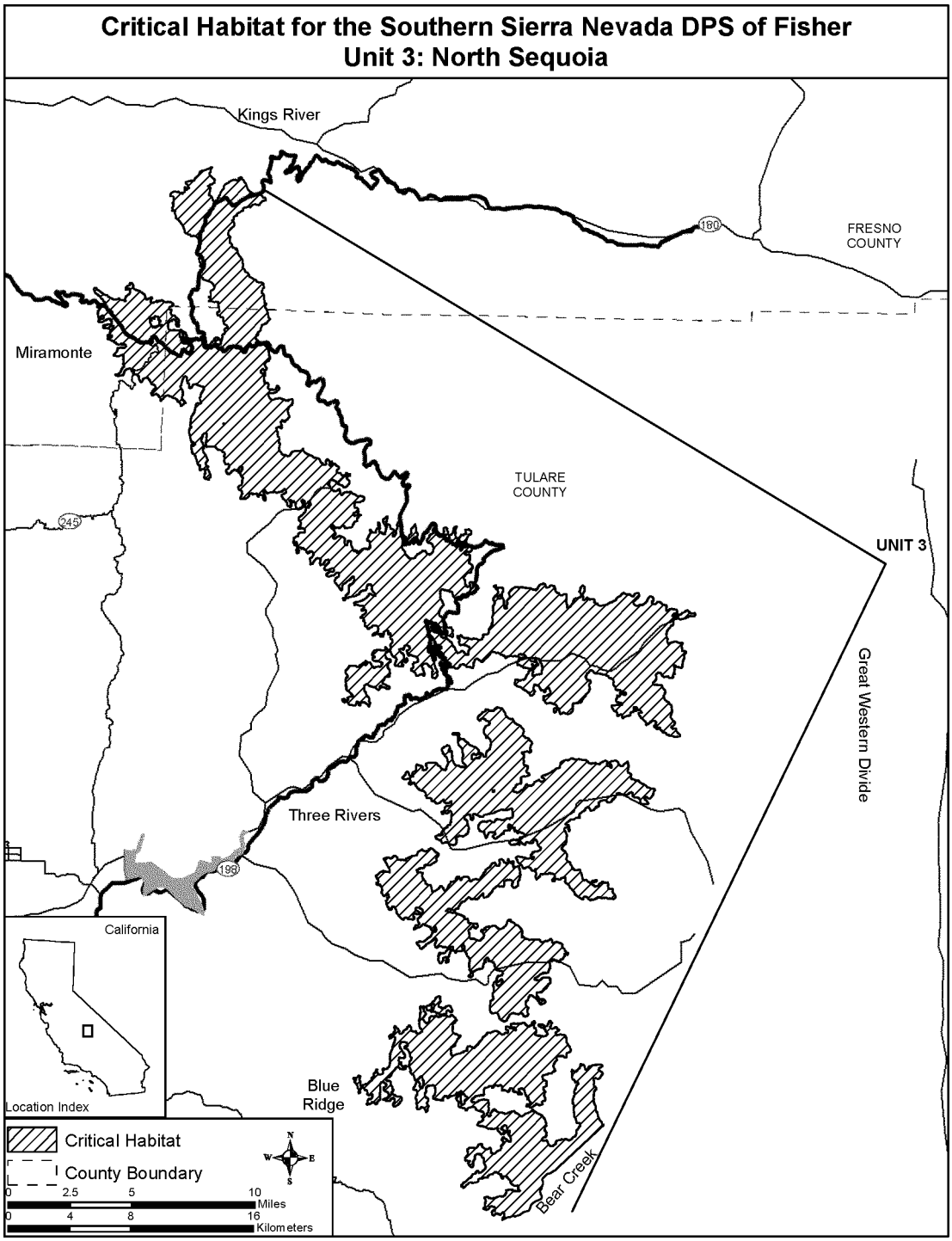


(8) Unit 3: North Sequoia, Tulare and Fresno Counties, California.

(i) Unit 3 consists of 114,952 ac (46,519 ha) of occupied habitat in the Sierra Nevada mountains. This unit runs mostly in a north-south liner pattern from the Kings River to the north until it abuts Unit 2 to the south. The unit is located west of the Great Western Divide and east of Blue Ridge and the communities of Miramonte and Three Rivers. Lands within this unit include approximately 108,015 ac (43,712 ha) in Federal ownership (Sierra National Forest, Sequoia National Forest, Giant Sequoia National Monument, Sequoia and Kings Canyon National Parks, and Bureau of Land Management), 1,889 ac (765 ha) in State ownership (Cal Fire and State Lands Commission) and 5,048 ac (2,043 ha) in private ownership.

(ii) Map of Unit 3 follows:

Figure 4 to Fisher (*Pekania pennanti*), Southern Sierra Nevada DPS paragraph (8)(ii)



(9) Unit 4: South Sierra, Fresno County, California.

(i) Unit 4 consists of two subunits comprising 76,100 ac (30,796 ha) of occupied habitat in the Sierra Nevada mountains.

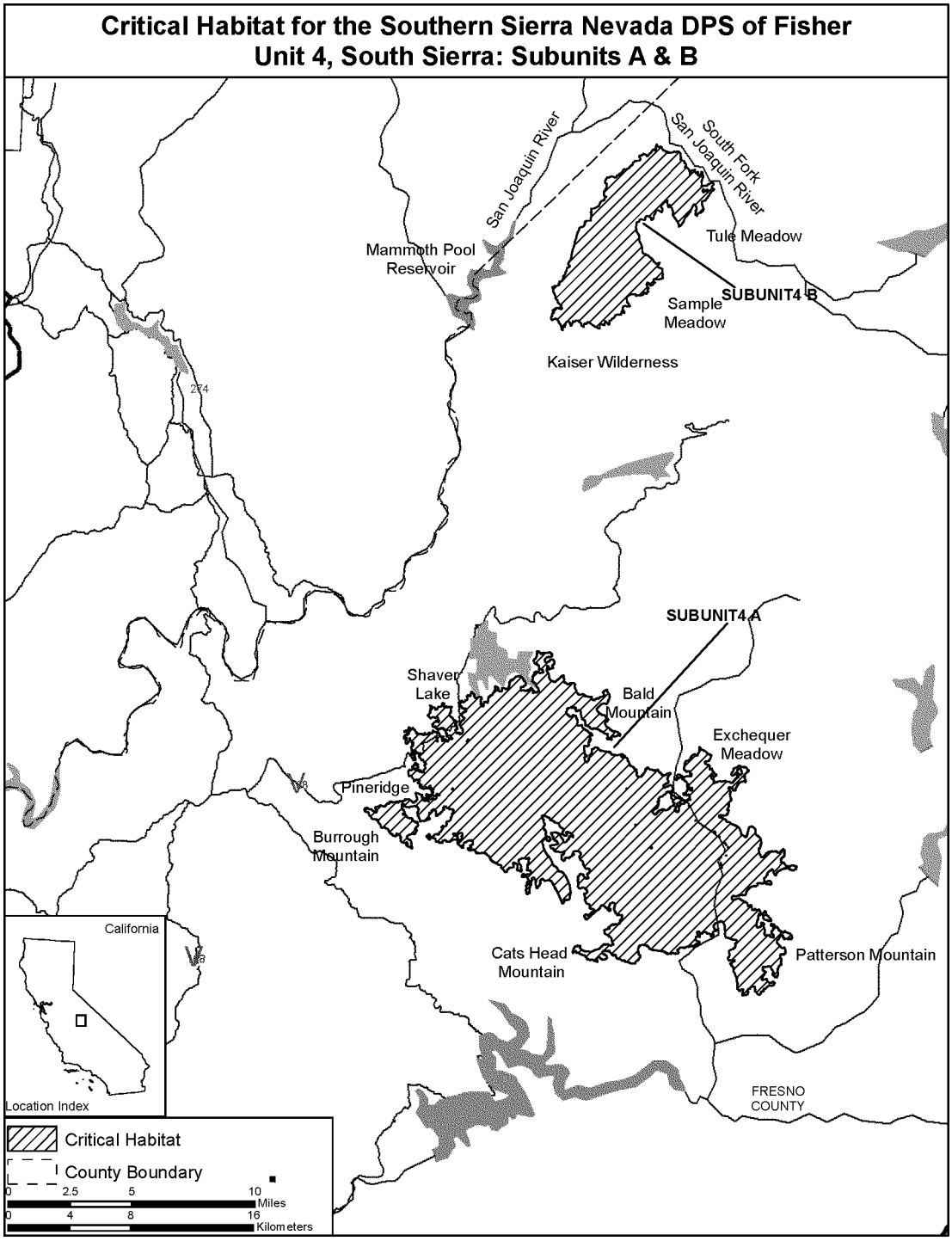
(A) Subunit 4A (Blue Canyon) consists of 62,137 ac (25,146 ha) of lands in the Sierra Nevada mountains. Patterson Mountain marks the approximate southeastern tip of Subunit 4A, which then continues to the northwest approximately to the communities of Shaver Lake and Pineridge. Lands within this subunit include approximately 46,499 ac (18,817 ha) in Federal ownership (Sierra National Forest) and 15,638 ac (6,328 ha) in private ownership.

(B) Subunit 4B (Mammoth Pool East) consists of 13,963 ac (5,650 ha) of lands in the Sierra Nevada mountains. This subunit is located west of Mammoth

Pool Reservoir and the San Joaquin River, north of Kaiser Wilderness, south of Ansel Adams Wilderness, and east of Tule, Half Corral, and Sample Meadows. The entirety of lands within subunit are in Federal ownership (Sierra National Forest).

(ii) Map of Unit 4 follows:

Figure 5 to Fisher (*Pekania pennanti*), Southern Sierra Nevada DPS paragraph (9)(ii)

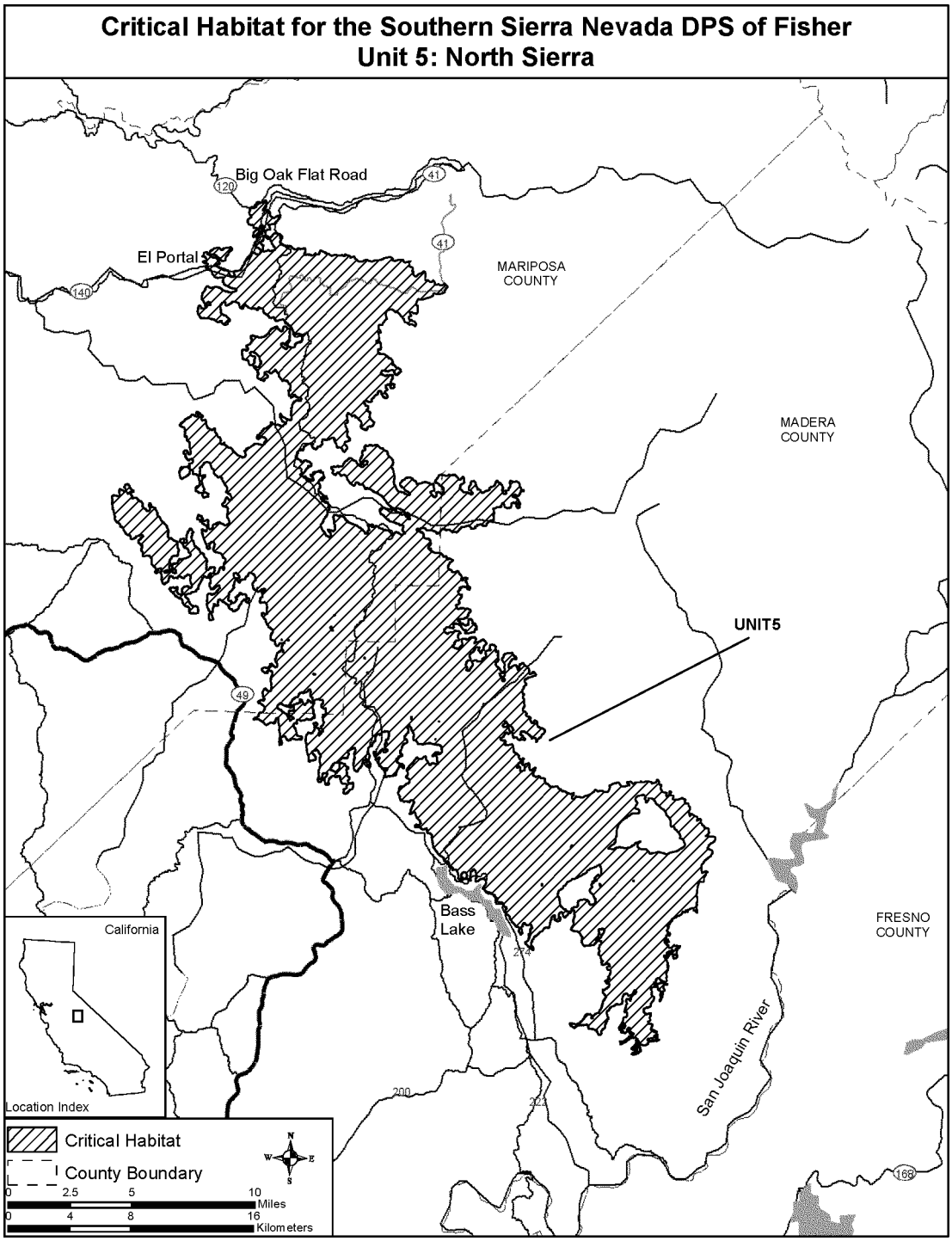


(10) Unit 5: North Sierra, Madera and Mariposa Counties, California.

(i) Unit 5 consists of 145,783 ac (58,996 ha) of occupied habitat in the Sierra Nevada mountains north and west of the San Joaquin River; east of Bass Lake, California State Route 49, and the unincorporated community of El Portal; and south of Big Oak Flat Road. Lands within this unit include 135,918 ac (55,004 ha) in Federal ownership (Sierra National Forest, Stanislaus National Forest, Yosemite National Park, Bureau of Indian Affairs, and Bureau of Land Management) and 9,865 ac (3,992 ha) in private ownership.

(ii) Map of Unit 5 follows:

Figure 6 to Fisher (*Pekania pennanti*), Southern Sierra Nevada DPS paragraph (10)(ii)

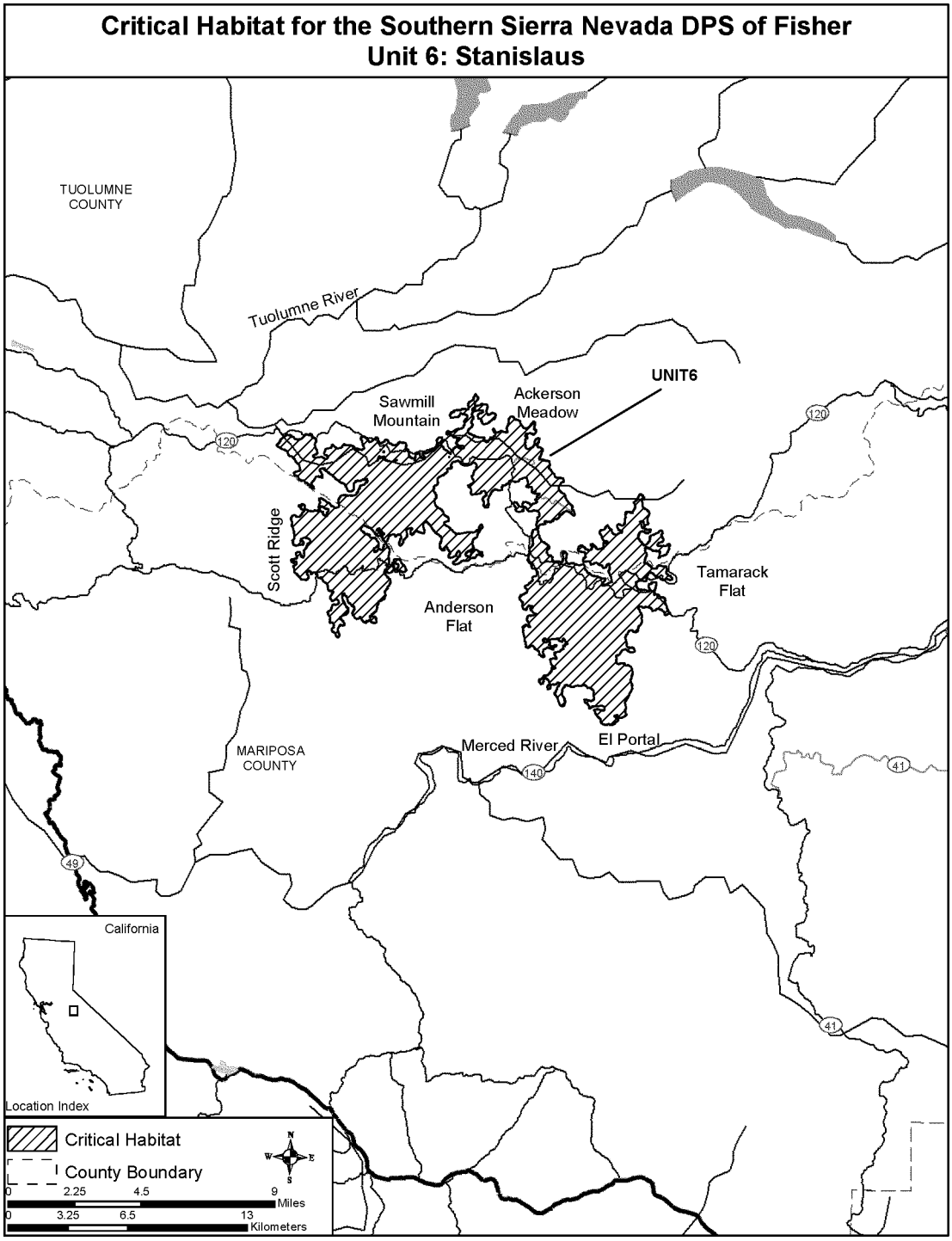


(11) Unit 6: Stanislaus, Mariposa and Tuolumne Counties, California.

(i) Unit 6 consists of 30,521 ac (12,352 ha) of occupied habitat situated north of the Merced River and the community of El Portal and southwest of Ackerson Meadow. The unit forms a ''U'' to the east, north, and west around Anderson Flat and Grizzly Flat. Lands within this unit include 29,920 ac (12,108 ha) in Federal ownership (Stanislaus National Forest and Yosemite National Park) and 601 ac (243 ha) in private ownership.

(ii) Map of Unit 6 follows:

Figure 7 to Fisher (*Pekania pennanti*), Southern Sierra Nevada DPS paragraph (11)(ii)



* * * * *

Martha Williams,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2022–23949 Filed 11–4–22; 8:45 am]

BILLING CODE 4333–15–C

Notices

Federal Register
Vol. 87, No. 214
Monday, November 7, 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

Animal and Plant Health Inspection Service

[Docket No. APHIS–2022–0062]

Notice of Request for Approval of an Information Collection; National Animal Health Monitoring System Backyard Animal Keeping 2023 Study

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: New information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request approval of a new information collection associated with the National Animal Health Monitoring System Backyard Animal Keeping 2023 Study.

DATES: We will consider all comments that we receive on or before January 6, 2023.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2022–0062 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2022–0062, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *regulations.gov* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the NAHMS Backyard Animal Keeping 2023 Study, contact Dr. Victoria Fields, Veterinary Medical Officer, Center for Epidemiology and Animal Health, VS, APHIS, 2150 Centre Avenue, Building B, Fort Collins, CO 80526; (970) 986–1514; email: *victoria.fields@usda.gov.* For more detailed information on the information collection process, contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator; (301) 851–2483; email: *joseph.moxey@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: National Animal Health Monitoring System Backyard Animal Keeping 2023 Study.

OMB Control Number: 0579–XXXX.

Type of Request: Approval of a new information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture is authorized to protect the health of livestock, poultry, and aquaculture populations in the United States by preventing the introduction and interstate spread of serious diseases and pests of livestock and for eradicating such diseases within the United States when feasible. This authority has been delegated to the Animal and Plant Health Inspection Service (APHIS).

In connection with this mission, APHIS operates the National Animal Health Monitoring System (NAHMS), which collects on a national basis statistically valid and scientifically sound data on the prevalence and economic importance of livestock, poultry, and aquaculture disease risk factors. NAHMS' studies have evolved into a collaborative government and industry initiative to help determine the most effective means of preventing and controlling diseases of livestock. APHIS is the only Federal agency responsible for collecting data on livestock and poultry health. Participation in any NAHMS study is voluntary and all data are confidential.

In 2010, NAHMS conducted the Poultry 2010 Study, which estimated prevalence of chicken ownership and attitudes toward urban chickens in four cities (Denver, Los Angeles, Miami, and New York). At that time, several cities throughout the United States were beginning to allow households to keep chickens, and the study evaluated this trend to gather data to be prepared in the event of a poultry disease outbreak. In 2021, the Centers for Disease Control and Prevention approached NAHMS with an interest in conducting a similar study given that there has been an apparent increase in backyard poultry ownership as well as an increase in *Salmonella* illnesses linked to contact with backyard poultry. In addition to updated information on percentage of households that own backyard chickens, since what was reported in the 2010 study, stakeholders have expressed interest in obtaining baseline information on the percentage of households that own any poultry, goats, pigs, and rabbits, and some basic information on how respondents provide care for these species since there is little information on this population of animals. Unless chickens are specifically referred to below, reference to poultry includes chickens, ducks, geese, turkeys, or gamebirds for the purposes of this study.

This study will consist of two components with five objectives as documented below. Objectives 1 through 3 will be answered by a survey (''national survey'') which will obtain national estimates of ownership of poultry, goats, pigs, and rabbits, and describe baseline information on ownership practices. For the fourth objective, a survey in two cities (''city survey'') will be performed to estimate the prevalence of chicken, goat, pig, and rabbit ownership in two of the four cities previously studied in the NAHMS Poultry 2010 study, as well as describe respondents' beliefs about chicken ownership. The fifth objective will be carried out in conjunction with Colorado State University to learn more about food security status and backyard animal keeping.

The collection will support the following objectives:

(1) Obtain national estimates of the percentage of households that own poultry, goats, pigs, and rabbits in urban and non-urban areas of the United States.

(2) For each species included in the study, describe animal management practices such as information sources owners use to learn about animal health, access to veterinary care, length of ownership, and biosecurity practices

including those relevant to antimicrobial stewardship.

(3) For households that both own and do not own poultry, goats, pigs, and rabbits, describe opinions of backyard and urban ownership of chickens and, for non-owners only, describe any contact with live poultry and intention to own any one of these species of interest in the future.

(4) Estimate the prevalence of chicken, goat, pig, and rabbit ownership in two of the cities surveyed on urban chicken ownership in 2012 (Denver and Miami), and describe respondents' beliefs about chicken ownership to determine changes in prevalence and beliefs between 2012 and 2023.

(5) Conduct a preliminary evaluation of the relationship between food security status and backyard animal keeping.

Respondent information will be protected by ensuring that no identifying information is linked to the data.

We are asking the Office of Management and Budget (OMB) to approve our use of this information collection activity for 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate 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;

(2) Evaluate the accuracy of our estimate of the burden of the 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, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 0.21 hours per response.

Respondents: Private individuals.

Estimated annual number of respondents: 112,745.

Estimated annual number of responses per respondent: 0.17.

Estimated annual number of responses: 18,770.

Estimated total annual burden on respondents: 4,074 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

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.

Done in Washington, DC, this 2nd day of November 2022.

Anthony Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2022–24206 Filed 11–4–22; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Supplemental Nutrition Assistance Program: State Agency Options for Standard Utility Allowances and Self-Employment Income

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This is a revision of a currently approved collection. This information collection addresses the State agency reporting and recordkeeping burden associated with the following State agency options under the Supplemental Nutrition Assistance Program (SNAP): establishing and reviewing standard utility allowances (SUAs) and establishing methodology for offsetting cost of producing self-employment income.

DATES: Written comments must be received on or before January 6, 2023.

ADDRESSES: The Food and Nutrition Service, USDA, invites interested persons to submit written comment.

- *Preferred Method:* Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.
- *Mail:* Send comments to Certification Policy Branch, Program Development Division, Food and Nutrition Service, 1320 Braddock Place, 5th Floor, Alexandria, Virginia 22314.

All responses to this notice will be summarized and included in the request for Office of Management and Budget (OMB) approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Muhammad Kara by telephone at 703–305–2022, by mail to the Certification Policy Branch, Program Development Division, Food and Nutrition Service, 1320 Braddock Place, 5th Floor, Alexandria, Virginia, 22314 or via email to *SNAPCPBRules@usda.gov.*

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed 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 proposed collection of information, including the validity of the methodology and assumptions that were 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 are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Supplemental Nutrition Assistance Program: State Agency Options for Standard Utility Allowances and Self-Employment Income.

Form Number: None.

OMB Number: 0584–0496.

Expiration Date: July 31, 2023.

Type of Request: Revision of a currently approved collection.

Abstract: The information collection addresses the mandatory State agency information and burden estimates associated with the following State agency options under SNAP: establishing and reviewing SUAs and establishing methodology for offsetting cost of producing self-employment income.

SNAP regulations at 7 CFR 273.9(d)(6)(iii) allow State agencies to establish SUAs in place of the actual utility costs incurred by a household. State agencies must review and adjust SUAs annually to reflect changes in the costs of utilities. As part of this annual update, State agencies may develop a new methodology and submit any updates to FNS via email for approval.

SNAP regulations at 7 CFR 273.11(b) allow State agencies to calculate a household's self-employment income by reducing the cost of producing such income. The regulations allow the State agencies, with approval from FNS, to establish the methodology for offsetting the costs of producing self-employment income, as long as the procedure does not increase program costs. Once

approved by FNS via email, States can use these methodologies to determine net self-employment income for SNAP eligibility purposes.

Using FNS–388 and 388A (both approved under OMB Control Number 0584–0594; expiration date: 07/31/2023). States send aggregate level data on participation, benefits issued, and other basic program information to FNS using the Food Programs Reporting System (FPRS) at *https://fprs.fns.usda.gov.* This collection uses information submitted in these FNS approved forms as supplemental data. However, this collection is not seeking approval for burden hours associated with the use of these forms because the burden is already accounted for under OMB Control Number 0584–0594.

Reporting Estimate

In the process of renewing this collection, FNS increased the estimated number of responses States submit as part of their SUA submission review. FNS estimates that 53 State agencies will submit two responses each, which includes States' review of their preliminary SUA amounts and their final SUA amounts. In prior renewals, FNS did not delineate between these two submissions, but considered them part of one process. In this renewal, FNS chose to more clearly reflect the two responses States submit and adjust its estimate accordingly.

FNS asks States to submit preliminary SUA amounts voluntarily as part of their annual SUA update process. By collecting preliminary SUA estimates ahead of final annual updates, FNS can plan for any significant changes in SUA amounts which may considerably impact SNAP benefit amounts.

In FY 2022, FNS received final SUA amounts from all 53 State agencies. FNS did not collect preliminary SUA amounts in FY 2021 or FY 2020. However, in the past three years that FNS collected preliminary numbers, most States submitted these amounts, and 52 out of 53 State agencies submitted preliminary SUA amounts in FY 2022. For the purpose of this renewal, FNS estimates that all 53 State agencies will submit preliminary amounts in addition to their final SUA amounts, increasing the total annual responses to 106 (53 State agencies × 2 responses each).

While FNS is adding a response to this burden item, this update will only result in an increase of total annual responses, not total annual burden hours. FNS estimates that even with the newly delineated response, the total amount of time for States to review their SUA estimates (both preliminary and final) remains the same as the previously approved burden estimate of 1,325 hours. To reflect this change, FNS is modifying each response to an estimated 12.5 hours. Therefore, FNS projects a total annual burden of 1,325 hours and 106 responses for the review of SUA preliminary and final submissions.

Based on information provided in the Fourteenth Edition of the SNAP State Options Report,[1] 23 out of 53 State agencies have already incorporated a methodology for determining the cost of doing business in self-employment cases, which was the basis of the previous burden estimate. Over the next three years this collection covers, FNS estimates that five (5) State agencies will establish a new methodology for offsetting the cost of producing self-employment income, either for the first time or as an update to their current methodology. This estimate is based on consultations with three (3) FNS regional offices. FNS estimates that each of these five (5) responses will have a response time of 10 hours, for a total annual burden of 50 hours.

Recordkeeping Estimate

All 53 State agencies are required to keep and maintain one record of the information gathered and submitted to FNS for the SUA and self-employment options. FNS estimates a response time of 0.25 hours for this recordkeeping burdens.

Total Burden Estimate

For both reporting and recordkeeping, FNS projects a total annual burden of 1,388.25 hours and 164 responses for this collection. This revision results in a decrease in burden hours due to updated assumptions based on consultations with three (3) FNS regional offices.

Reporting Burden

Affected Public: State, Local, or Tribal Governments.

Estimated Number of Respondents: 53.

Estimated Number of Responses per Respondent: 2.09433962 hours.

Estimated Total Annual Responses: 111.

Estimated Time per Response: 12.39 hours.

Estimated Total Annual Burden on Respondents: 1,375 hours.

Recordkeeping Burden

Affected Public: State, Local, or Tribal Governments.

Estimated Number of Respondents: 53.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Responses: 53.

Estimated Time per Response: 0.25 hours.

Estimated Total Annual Burden on Respondents: 13.25 hours.

See table below for estimated total annual burden for State agencies:

CFR citation	Respondent	Estimated number respondent	Responses annually per respondent	Total annual responses	Estimated average number of hours per response	Estimated total hours
Reporting Burden						
7 CFR 273.9(d)(6)(iii)	State Agency—Review of SUA Preliminary and Final Submissions.	53	2	106	12.50	1,325.00
7 CFR 273.11(b)	State Agency—Review of Self-Employment Methodology.	23	1	5	10.00	50.00
	Total Reporting Burden	53	2.09433962	111	12.3873874	1,375.00

[1] The 14th Edition of the SNAP State Options Report summarizes information related to State policy and administrative options. The 14th edition reflects the most current information available and was published May 31, 2018. For more information, please visit *https://www.fns.usda.gov/snap/waivers/state-options-report.*

CFR citation	Respondent	Estimated number respondent	Responses annually per respondent	Total annual responses	Estimated average number of hours per response	Estimated total hours
Recordkeeping Burden						
7 CFR 273.9(d)(6)(iii) and 7 CFR 273.11(b).	Recordkeeping Requirements for SUA and Self-Employment Methodologies.	53	1	53	0.25	13.25
	Total Recordkeeping Burden	53	1	53	0.25	13.25
Total of Reporting and Recordkeeping Burden						
	Total	53	3.09433962	164	8.46493902	1,388.25

Tameka Owens,

Assistant Administrator, Food and Nutrition Service.

[FR Doc. 2022–24151 Filed 11–4–22; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Rural Housing Service

Rural Utilities Service

[Docket No. RBS–22–BUSINESS–0022]

Notice of Solicitation of Applications for the Strategic Economic and Community Development Program for FY 2023

AGENCY: Rural Business-Cooperative Service, Rural Housing Service, and Rural Utilities Service, USDA.

ACTION: Notice of solicitation of applications.

SUMMARY: The Under Secretary for Rural Development (RD) is seeking applications for the Strategic Economic and Community Development (SECD) priority, as reauthorized by Section 6401 of the Agriculture Improvement Act of 2018 (2018 Farm Bill) for projects that support multi-jurisdictional and multi-sectoral strategic community investment plans. In Fiscal Year (FY) 2023, the Agency will implement SECD by reserving loan and/or grant funds from the appropriations of the programs covered by this funding priority. This notice describes the requirements by which the Agency will consider projects eligible for the covered programs' reserved appropriated funds and the information needed to submit an application. This NOSA is being issued prior to passage of a final appropriations act for FY 2023 to allow potential applicants time to submit applications for financial assistance under the covered programs and to give the Agency time to process applications. Once the FY 2023 funding amounts are determined, the Agency will publish them on its website at *https://www.rd.usda.gov/newsroom/notices-solicitation-applications-nosas.*

DATES: Each of the participating covered programs has a different established deadline for receipt of applications. Please refer to the Agency website or the appropriate covered program's **Federal Register** notice for application deadline information. All applicants are responsible for any expenses incurred in preparing and submitting applications. To apply for SECD funding in FY 2023, applicants must follow the instructions as published in this notice:

- All applicants must submit the Form RD 1980–88, ''Strategic Economic and Community Development (Section 6401),'' with their program application to the appropriate covered program.
- SECD applications, except for Community Connect Grant Program SECD applications, must be submitted electronically to the USDA Rural Development Office servicing the area where the project is located. A list of the USDA Rural Development State Offices can be found at: *https://www.rd.usda.gov/about-rd/state-offices.*
- Community Connect applicants must submit SECD applications electronically at: *https://www.rd.usda.gov/community-connect.*
- For lenders assigned a OneRD Loan Guarantee Initiative Customer Relationship Manager (CRM), SECD applications must be submitted to their assigned CRM.

ADDRESSES: SECD applications, except for Community Connect Grant Program SECD applications, must be submitted electronically to the USDA Rural Development Office servicing the area where the project is located. Community Connect applicants must submit SECD applications electronically at: *https://www.rd.usda.gov/community-connect.* For lenders assigned a CRM, SECD applications must be submitted to their assigned CRM.

FOR FURTHER INFORMATION CONTACT: For more information, please contact your respective Rural Development State Office listed here: *https://www.rd.usda.gov/about-rd/state-offices.*

For all other inquiries, you may contact Greg Batson, Rural Development Innovation Center, U.S. Department of Agriculture, Stop 0793, 1400 Independence Avenue SW, Washington, DC 20250–0783, Telephone: (573) 239–2945, Email: *gregory.batson@usda.gov.*

A checklist of all required application information for regional planning priority can be found at: *https://www.rd.usda.gov/programs-services/strategic-economic-and-community-development.*

SUPPLEMENTARY INFORMATION:

Overview

Federal Awarding Agency Name: Rural Business-Cooperative Service, Rural Housing Service, Rural Utilities Service.

Funding Opportunity Title: Strategic Economic and Community Development.

Announcement Type: Notice of Solicitation of Applications.

Dates: See information provided in the **DATES** section of this notice.

Rural Development Key Priorities: The Agency encourages applicants to consider projects that will advance the following key priorities of Rural Development:

- Assisting rural communities recover economically through more and better market opportunities and through improved infrastructure;
- Ensuring all rural residents have equitable access to USDA—Rural Development programs and benefits from Rural Development funded projects; and
- Reducing climate pollution and increasing resilience to the impacts of climate change through economic support to rural communities.

For further information, visit Rural Development: Key Priorities | Rural Development (usda.gov), *https://www.rd.usda.gov/priority-points.*

A. Program Description

1. Purpose of the Program

SECD supports projects that promote and partially or completely implement strategic community investment plans. These plans use the unique strengths of rural communities to advance prosperity. USDA Rural Development helps finance and/or fund these projects to build community prosperity by using community assets, identifying resources, convening partners and leveraging Federal, state, local or private funding.

In FY 2023, the Agency plans to implement SECD through reserving funds from the covered programs' appropriations as provided in 7 CFR part 1980, subpart K. This notice provides requirements to applicants submitting applications for the covered programs' reserved funds and establishes the above-mentioned priority effective upon the publication of this notice.

2. Statutory Authority

These funds are made available under the Authority of Section 6401 of the Agriculture Improvement Act of 2018 (Pub. L. 115–334); Consolidated Farm and Rural Development Act (7 U.S.C. 2008v).

3. The Covered Programs

Section 6401 of the 2018 Farm Bill (7 U.S.C. 2008v), authorizes any program under the Consolidated Farm and Rural Development Act (Pub. L. 87–128), as determined by the Secretary, to give priority to applications that support the implementation of multi-jurisdictional and multi-sectoral strategic community investment plans.

Accordingly, the Agency is giving priority to projects implementing strategic community investment plans in FY 23 through the following Rural Development programs:

- Community Facility Loans; see 7 CFR part 1942, subpart A.
- Community Facilities Grants; see 7 CFR part 3570, subpart B.
- Community Facilities Guaranteed Loans; see 7 CFR part 5001.
- Water and Waste Disposal Programs Guaranteed Loans; see 7 CFR part 5001.
- Water and Waste Loans and Grants; see 7 CFR part 1780.
- Rural Business Development Grants; see 7 CFR part 4280, subpart E.
- Community Connect Grants; see 7 CFR part 1739.

4. Application of Awards

The Agency will review, evaluate, and score each application based on the criteria specified in 7 CFR 1980.1020, to award points for each program's competition for the SECD reserved funds.

B. Federal Award Information

Type of Awards: Guaranteed loans, direct loans and grants.

Fiscal Year Funds: FY 2023 appropriated funds.

Available Funds: The amount of reserved funds available for SECD projects is dependent on the amount of available appropriated funding provided to each of the covered programs during the fiscal year. The NOSA is being issued prior to passage of a final appropriations act for FY 2023. Once the FY 2023 funding amount is determined, the Agency will publish it on its website at *https://www.rd.usda.gov/newsroom/notices-solicitation-applications-nosas.*

For FY 2023 applications, the following table specifies the percentage of funds being reserved:

Program	Percentage of funds reserved for SECD
Community Facility Loans	10
Community Facilities Grant Program	5
Community Facilities Guaranteed Loans	5
Water and Waste Disposal Programs Guaranteed Loans	10
Water and Waste Loans	5
Water and Waste Grants	3
Rural Business Development Grants	5
Community Connect Grant Program	10

Award Amounts: Guaranteed loans, direct loans and grants will be awarded in amounts consistent with each applicable covered program.

Anticipated Award Dates: Awards for SECD applications submitted to the covered programs in FY 23 will be obligated on or before June 30, 2023, except Community Connect. Community Connect SECD awards will be obligated upon completion of all required programmatic reviews. The Agency will return any reserved funds that are not obligated by the obligation deadline to each covered program's regular funding account for obligation of eligible projects in that program.

Performance Period: Performance period will vary by covered program.

Renewal or Supplemental Awards: N/A.

Type of Assistance Instrument: Grants, loans and loan guarantees.

C. Eligibility Information

1. Eligible Applicants

To be considered for SECD reserved funds, both the applicant and project must meet the eligibility requirements of the covered program. These requirements vary among the covered programs and applicants should refer to the regulations for those programs, which are referenced in A.2. of this notice.

The agency supports community and regional planning through the SECD regulation without making any changes to the applicant eligibility requirements of the covered programs. The SECD regulation includes three criteria that a project must meet in order to be considered for the SECD reserve funding (see 7 CFR 1980.1010):

The first criterion, as noted above, is that the project meets the applicable eligibility requirements of the covered program for which the applicant is applying.

The second criterion is that the project is ''carried out in a rural area'' as defined in 7 CFR 1980.1005. As defined, this means either the entire project is physically located in a rural area, or all the beneficiaries of the service(s) provided through the project must either reside in or be located in a rural area. Note that the definition of ''rural'' varies among the covered programs and the Section 6401 regulation does not change those definitions. Therefore, the applicable program regulations as outlined in A.2. should be reviewed as necessary.

The third criterion is that the project supports partial or complete implementation of a strategic community investment plan on a multi-jurisdictional and multi-sectoral basis as defined in 7 CFR 1980.1005.

In order to be considered for the reserved funds from covered programs in FY 2023, applicants must (1) meet all requirements of the covered program; (2) meet all requirements in accordance with 7 CFR part 1980, subpart K (see 7 CFR 1980.1010); and (3) submit Form RD 1980–88 and the supporting documentation required in 7 CFR 1080.1015 with their program application which includes:

- Sufficient information to show that the project will be carried out in a rural area, as defined by the appropriate covered program; and
- Identification of any current or previous applications the applicant has submitted for funds from the covered programs.

2. Cost Sharing or Matching

All cost sharing, matching, and cost participation requirements of the applicable covered program apply to projects seeking SECD reserved funds.

3. Other

All other eligibility requirements (beyond those identified in C.1 of this notice) found in the covered programs' regulations applying to applicants, their projects, and the beneficiaries of those projects are unchanged by either this notice or the regulations for the SECD program (7 CFR part 1980 subpart K).

D. Application and Submission Information

1. Address To Request Application Package

Information on how to submit applications is provided in the **ADDRESSES** section of this notice.

2. Content and Form of Application Submission

Applicants must submit the Form RD 1980–88, ''Strategic Economic and Community Development (Section 6401),'' with their program application to the appropriate covered program.

3. System for Award Management (SAM) and Unique Entity Identifier (UEI)

(a) At the time of application, each applicant must have an active registration in the System for Award Management (SAM) before submitting its application in accordance with 2 CFR part 25 (*https://www.ecfr.gov/current/title-2/subtitle-A/chapter-I/part-25*). To register in SAM, entities will be required to create Unique Entity Identifier (UEI). Instructions for obtaining the UEI are available at *https://sam.gov/content/entity-registration.*

(b) Applicant must maintain an active SAM registration, with current, accurate and complete information, at all times during which it has an active Federal award or an application under consideration by a Federal awarding agency.

(c) Applicant must ensure they complete the Financial Assistance General Certifications and Representations in SAM.

(d) Applicant must provide a valid UEI in its application, unless determined exempt under 2 CFR 25.110 (*https://www.ecfr.gov/current/title-2/subtitle-A/chapter-I/part-25/subpart-A/section-25.110*).

(e) The Agency will not make an award until the applicant has complied with all SAM requirements including providing the UEI. If an applicant has not fully complied with the requirements by the time the Agency is ready to make an award, the Agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

4. Application Submission Deadlines

Each of the participating covered programs has different established deadlines for receipt of applications. Please refer to the agency website or the appropriate covered program's **Federal Register** notice for application deadline information.

5. Intergovernmental Review

This notice is not subject to Executive Order 12372, ''Intergovernmental Review of Federal Programs.''

6. Funding Restrictions

All applicants are responsible for any expenses incurred in preparing and submitting applications.

7. Other Submission Requirements

(a) SECD applications, except for Community Connect Grant Program SECD applications, must be submitted electronically to the USDA Rural Development Office servicing the area where the project is located. Rural Development State Offices can be found here: *https://www.rd.usda.gov/about-rd/state-offices.*

(b) Community Connect applicants must submit SECD applications electronically to: *https://www.rd.usda.gov/community-connect.*

(c) For lenders assigned an OneRD Loan Guarantee Initiative Customer Relationship Manager (CRM), SECD applications must be submitted to their assigned CRM.

E. Application Review Information

1. Criteria

All FY 2023 applications for covered programs will be reviewed, evaluated, and scored based on the covered program's scoring criteria. This notice does not affect that process. This notice only affects the scoring of SECD applications competing for a covered program's SECD reserve funds.

For applicants wishing to be considered for reserved SECD funds in FY 23, the Agency will review, evaluate, and score each application based on the criteria specified in 7 CFR 1980.1020, to award points for each covered program's SECD reserved funds.

2. Review and Selection Process

The Agency will prioritize applications competing for a covered program's reserved funds based on the covered program's awarded points plus the SECD earned points to determine which projects receive reserved funds. SECD points awarded are added to the covered program's application score to elevate and prioritize projects for accessing reserved funds.

F. Federal Award Administration Information

1. Federal Award Notices

The Agency will notify SECD applicants who receive funding in a manner consistent with award notifications for the covered program.

2. Administrative and National Policy Requirements

Any and all additional requirements of the applicable covered programs apply to projects receiving funding in response to this notice. Please see the regulations for the applicable covered program.

3. Reporting Requirements

Any and all post-award covered program reporting requirements apply to all projects receiving reserved funds in response to this notice.

G. Federal Awarding Agency Contact(s)

For general questions about this notice, please contact your respective Rural Development State Office listed at: *https://www.rd.usda.gov/about-rd/state-offices* and other points of contact provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

H. Buy America

Awards under this announcement for Infrastructure projects to Non-Federal entities, defined pursuant to 2 CFR 200.1 as any State, local government, Indian tribe, Institution of Higher Education, or nonprofit organization, shall be governed by the requirements of Section 70914 of the Build America, Buy America Act (BABA) within the Infrastructure Investment and Jobs Act (IIJA), and its implementing regulations. The Act requires the following Buy America preference:

(1) All iron and steel used in the project are produced in the United States. This means all manufacturing processes, from the initial melting stage through the application of coatings, occurred in the United States.

(2) All manufactured products used in the project are produced in the United States. This means the manufactured

product was manufactured in the United States, and the cost of the components of the manufactured product that are mined, produced, or manufactured in the United States is greater than 55 percent of the total cost of all components of the manufactured product, unless another standard for determining the minimum amount of domestic content of the manufactured product has been established under applicable law or regulation.

(3) All construction materials are manufactured in the United States. This means that all manufacturing processes for the construction material occurred in the United States.

The Buy America preference only applies to articles, materials, and supplies that are consumed in, incorporated into, or affixed to an infrastructure project. As such, it does not apply to tools, equipment, and supplies, such as temporary scaffolding, brought to the construction site and removed at or before the completion of the infrastructure project. Nor does a Buy America preference apply to equipment and furnishings, such as movable chairs, desks, and portable computer equipment, that are used at or within the finished infrastructure project but are not an integral part of the structure or permanently affixed to the infrastructure project.

I. Other Information

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the information collection requirements contained in 7 CFR part 1980, subpart K, have been approved by Office of Management and Budget (OMB) under OMB Control Number 0570–0068.

Federal Funding Accountability and Transparency Act

All applicants, in accordance with 2 CFR part 25, must have an UEI number and must be registered in the System for Award Management (SAM) prior to submitting an application. Applicants may register for the SAM and locate or register for a UEI number at *https://www.sam.gov/SAM.* All recipients of Federal financial grant assistance are required to report information about first-tier sub-awards and executive total compensation in accordance with 2 CFR part 170. Applicants must ensure they complete the Financial Assistance General Certifications and Representations in SAM.

Civil Rights

Programs referenced in this Notice are subject to applicable Civil Rights Laws. These laws include the Equal Credit Opportunity Act, Title VI of the Civil Rights Act of 1964, Title VIII of the Civil Rights Act of 1968, and Section 504 of the Rehabilitation Act of 1973.

Nondiscrimination Statement

In accordance with Federal civil rights laws and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Mission Areas, agencies, staff offices, employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (*e.g.,* Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720–2600 (voice and TTY); or the Federal Relay Service at (800) 877–8339.

To file a program discrimination complaint, a complainant should complete a Form AD–3027, *USDA Program Discrimination Complaint Form,* which can be obtained online at *https://www.ocio.usda.gov/document/ad-3027,* from any USDA office, by calling (866) 632–9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights (ASCR) about the nature and date of an alleged civil rights violation. The completed AD–3027 form or letter must be submitted to USDA by:

(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; or

(2) *Fax:* (833) 256–1665 or (202) 690–7442; or

(3) *Email: program.intake@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

Xochitl Torres Small,

Under Secretary, Rural Development.

[FR Doc. 2022–24133 Filed 11–4–22; 8:45 am]

BILLING CODE 3410–XY–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Missouri 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 Missouri Advisory Committee (Committee) will hold a meeting on Thursday, November 10, 2022 at 11:30 a.m.–1 p.m. central time. The Committee will continue orientation and begin identifying potential civil rights topics for their first study of the 2022–2026 term.

DATES: The meeting will take place on Thursday, November 10, 2022 at 11:30 a.m. central time.

ADDRESSES:

Public Call Information: Dial: (833) 568–8864, Confirmation Code: 161 249 8007.

Zoom Link: https://www.zoomgov.com/j/1612498007.

- To join by phone only dial (833) 568–8864; Access Code: 161 249 8007.

FOR FURTHER INFORMATION CONTACT: David Barreras, DFO, at *dbarreras@usccr.gov* or (312) 353–8311.

SUPPLEMENTARY INFORMATION: Members of the public may listen to this discussion through the above call in number. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. 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 hear 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 confirmation code.

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 mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 230 S Dearborn, Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353–8324, or emailed to Corrine Sanders at *csanders@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

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, Mississippi 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 and roll call
II. Introductions
III. Discuss Civil Rights Topics
IV. Public comment
V. Next steps
VI. 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 pending committee invitations to speakers to present material to the committee.

Dated: November 2, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–24198 Filed 11–4–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–565–801]

Stainless Steel Butt-Weld Pipe Fittings From the Philippines: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that there were no shipments of merchandise subject to the antidumping duty (AD) order on stainless steel butt-weld pipe fittings (SSBWF) from the Philippines during the period of review (POR) February 1, 2021, through January 31, 2022, from any of the companies under review. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 7, 2022.

FOR FURTHER INFORMATION CONTACT: Mark Flessner, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6312.

SUPPLEMENTARY INFORMATION:

Background

On February 23, 2001, Commerce published the AD order on SSBWF from the Philippines in the **Federal Register**.[1] On February 8, 2022, we published a notice of opportunity to request an administrative review of the *Order* for the POR February 1, 2021, through January 31, 2022.[2] On February 28, 2022, Core Pipe Products, Inc. and Taylor Forge Stainless Inc. (collectively, the petitioners) timely requested an administrative review of the *Order* with respect to: E N Corporation (E N Corp.); Enlin Steel Corporation (Enlin); and Vinox Corporation (a/k/a Vinoc Corporation) (collectively, Vinox).[3] On April 12, 2022, Commerce initiated an administrative review of these companies consistent with section 751(a)(1) of the Tariff Act of 1930, as amended (the Act).[4]

Commerce queried U.S. Customs and Border Protection (CBP) data to identify suspended entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the POR from the companies under review. On April 18, 2022, Commerce placed the results of its CBP data query on the record.[5] The CBP data show no suspended entries of subject merchandise during the POR associated with the companies under review.

Commerce requested comments from interested parties on the CBP data.[6] On April 25, 2022, the petitioners commented on the CBP data, alleging that entries during the POR could have been misreported; the petitioners provided information which, they contend, supports their allegation.[7] Consequently, the petitioners requested that Commerce address evidence of evasion of the *Order*.[8]

Scope of the Order

For purposes of this *Order,* the product covered is certain stainless steel butt-weld pipe fittings (butt-weld fittings). Butt-weld pipe fittings are under 14 inches in outside diameter (based on nominal pipe size), whether finished or unfinished. The product encompasses all grades of stainless steel and ''commodity'' and ''specialty'' fittings. Specifically excluded from the definition are threaded, grooved, and bolted fittings, and fittings made from any material other than stainless steel. The butt-weld fittings subject to this order are generally designated under specification ASTM A403/A403M, the standard specification for Wrought Austenitic Stainless Steel Piping Fittings, or its foreign equivalents (*e.g.,* DIN or JIS specifications). This specification covers two general classes of fittings, WP and CR, of wrought austenitic stainless steel fittings of seamless and welded construction covered by the latest revision of ANSI B16.9, ANSI B16.11, and ANSI B16.28. Butt-weld fittings manufactured to specification ASTM A774, or its foreign equivalents, are also covered by this *Order*.

This *Order* does not apply to cast fittings. Cast austenitic stainless steel pipe fittings are covered by specifications A351/A351M, A743/743M, and A744/A744M.

The butt-weld fittings subject to this *Order* are currently classifiable under subheadings 7307.23.00.30 and 7307.23.00.90 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this *Order* is dispositive.

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[1] *See Antidumping Duty Orders: Stainless Steel Butt-Weld Pipe Fittings from Italy, Malaysia, and the Philippines,* 66 FR 11257 (February 23, 2001) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review and Join Annual Inquiry Service List,* 87 FR 7112 (February 8, 2022).

[3] *See* Petitioners' Letter, ''Stainless Steel Butt-Weld Pipe Fittings from the Philippines—Petitioners' Request for 2021/2022 Administrative Review,'' dated February 28, 2022.

[4] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 87 FR 21619 (April 12, 2022).

[5] *See* Memorandum, ''Stainless Steel Butt-Weld Pipe Fittings from the Philippines; 2021–2022: Placement on the Record of Results of Inquiry to U.S. Customs and Border Protection,'' dated April 18, 2022.

[6] *Id.*

[7] *See* Petitioners' Letter, ''Stainless Steel Butt-Weld Pipe Fittings from the Philippines; 2021–2022—Petitioners' Comments on CBP Data,'' dated April 25, 2022, at 1–2 and Attachment.

[8] *Id.* at 2–3.

Methodology

As noted above, CBP data show that there were no suspended entries of subject merchandise during the POR associated with the three companies under review. Section 751(a)(2) of the Act instructs Commerce that, when conducting an administrative review, it is to determine the dumping margin for entries during the relevant period and establish a revised cash deposit rate for estimated ADs for future entries of subject merchandise. Given that the record evidence shows that there are no suspended entries of subject merchandise during the POR from the three companies under review, we have not calculated or otherwise determined a weighted-average dumping margin or revised the cash deposit rate for these three companies for which this administrative review was initiated.

Allegation of Misreported Entries

Commerce is committed to preventing the evasion of ADs and takes allegations, such as the one made by the petitioners, seriously. The issue raised by the petitioners falls within the jurisdiction of CBP and is best addressed by CBP.[9] Consequently, Commerce referred this allegation of potential misclassification and/or fraud, and the evidence that the petitioners provided in support of their claim, by sending an Evasion Allegation Letter to CBP for investigation.[10]

Preliminary Determination of No Shipments

Based on the foregoing, Commerce preliminarily determines that the following companies did not have any reviewable entries during the POR: E N Corp.; Enlin; and Vinox. Consistent with Commerce's practice, we are not rescinding the review with respect to E N Corp., Enlin, and Vinox, but, rather, will complete the review with respect to E N Corp., Enlin, and Vinox, and issue appropriate instructions to CBP based on the final results of this review.

Preliminary Results of Review

Commerce has not calculated weighted-average dumping margins for E N Corp., Enlin, and Vinox because there are no suspended entries of subject merchandise during the POR for these three companies on which to perform such a calculation.

Disclosure and Public Comment

Because Commerce has not calculated weighted-average dumping margins for these preliminary results, there are no calculations to disclose to interested parties.

Interested parties are invited to comment on these preliminary results of the review. Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs no later than 30 days after the date of publication of this notice in the **Federal Register**. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the deadline for filing case briefs.[11] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each brief: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[12] Executive summaries should be limited to five pages total, including footnotes.[13] Case and rebuttal briefs should be filed using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS).[14] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[15]

Pursuant to 19 CFR 351.310(c), any interested party may request a hearing within 30 days of the date of publication of this notice in the **Federal Register**. Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS, by the deadline noted above. If a hearing is requested, Commerce will notify interested parties of the hearing date and time. Requests for a hearing should contain: (1) the requesting party's name, address, and telephone number; (2) the number of individuals from the requesting party's firm that will attend the hearing; and (3) a list of issues the party intends to discuss at the hearing. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs.

Unless we extend the deadline for the final results of this review, we intend to issue the final results of this administrative review, including the results of our analysis of issues raised by the parties in their briefs, within 120 days of the date of publication of this notice in the **Federal Register**.[16]

Assessment

Upon issuance of the final results, Commerce will determine, and CBP shall assess, ADs on all appropriate entries in accordance with 19 CFR 351.212(b)(1). For any entries found to be associated with the three companies under review, we will instruct CBP to liquidate such entries at the all-others rate if there is no rate for the intermediate company (or companies) involved in the transaction, consistent with Commerce's reseller policy.[17]

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 statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all entries of SSBWF from the Philippines entered, or withdrawn from warehouse, for consumption on or after the date of publication of the notice of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the three companies under review will continue to be equal to the company-specific weighted-average dumping margin established for each company in the most recently completed segment of this proceeding (except, if the rate is *de minimis, i.e.,* less than 0.5 percent, then the cash deposit will be zero percent) or, if a company-specific weighted-average dumping margin has not been established for the company, the cash deposit rate will continue to be equal to the all-others rate; (2) for merchandise exported by a company not covered in this review but covered in a prior completed segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for that company in the most recently completed segment of this proceeding in which the company was included; (3) if

[9] *See Globe Metallurgical Inc.,* v. *United States,* 722 F. Supp. 2d 1372, 1381 (CIT 2010); *see also Light-Walled Rectangular Pipe and Tube from Turkey: Preliminary Results of Antidumping Duty Administrative Review; 2019–2020,* 86 FR 18035, 18036 (April 7, 2021), unchanged in *Light-Walled Rectangular Pipe and Tube from Turkey: Final Results of Antidumping Duty Administrative Review; 2019–2020,* 86 FR 41440 (August 2, 2021).

[10] *See* Commerce's Letter, ''Stainless Steel Butt-Weld Pipe Fittings from the Philippines, 2021–2022 Administrative Review,'' dated September 2, 2022 (Evasion Allegation Letter).

[11] *See* 19 CFR 351.309(d).

[12] *See* 19 CFR 351.309(c)(2) and (d)(2).

[13] *Id.*

[14] *See* 19 CFR 351.303.

[15] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[16] *See* section 751(a)(3)(A) of the Act; and 19 CFR 351.213(h)(1).

[17] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

the exporter of the subject merchandise does not have its own rate but the producer has its own rate, the cash deposit rate will be the rate established in the most recently completed segment of the proceeding for the producer of the subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 33.81 percent, the all-others rate established in the less-than-fair-value investigation.[18]

These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

Commerce is issuing and publishing these results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.213(h)(1).

Dated: October 31, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–24167 Filed 11–4–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–105]

Carbon and Alloy Steel Threaded Rod From the People's Republic of China: Final Results of Countervailing Duty Administrative Review; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being provided to the producers and exporters subject to the administrative review of carbon and alloy steel threaded rod (threaded rod) from the People's Republic of China (China) during the period of review (POR) July 29, 2019, through December 31, 2020.

DATES: Applicable November 7, 2022.

FOR FURTHER INFORMATION CONTACT: Thomas Schauer or Allison Hollander, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0410 or (202) 482–2805, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 6, 2022, Commerce published the preliminary results of the 2019–2020 administrative review of the countervailing duty order on threaded rod from China.[1] This review covers two mandatory respondents, Zhejiang Junyue Standard Part Co., Ltd. (Junyue) and Ningbo Zhongjiang High Strength Bolts Co., Ltd. (Zhongjiang Bolts), and three non-examined producers or exporters of subject merchandise. We invited interested parties to comment on the *Preliminary Results.*[2] On June 6, 2022, we received timely case briefs from Vulcan Threaded Products Inc. (the petitioner), Junyue, and Zhongjiang Bolts. On June 13, 2022, we received timely rebuttal briefs from the petitioner, Junyue, and Zhongjiang Bolts. For a complete description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[3]

Scope of the Order [4]

The product covered by the *Order* is threaded rod from China. A full description of the scope of the *Order* is contained in the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised by interested parties in briefs are addressed in the Issues and Decision Memorandum accompanying this notice. A list of the issues addressed in the Issues and Decision Memorandum is provided in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on comments in case and rebuttal briefs and record evidence, Commerce made certain changes from the *Preliminary Results* regarding the calculation of wire rod and steel bar benchmarks and we have corrected several ministerial errors. As a result of these changes, the final rates for Junyue and Zhongjiang Bolts have changed and the rate for non-selected respondents also changed. These changes are explained in the Issues and Decision Memorandum.

Methodology

Commerce conducted this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each subsidy program found to be countervailable, Commerce finds that there is a subsidy, *i.e.,* a financial contribution from a government or public entity that gives rise to a benefit to the recipient, and that the subsidy is specific.[5] For a full description of the methodology underlying all of Commerce's conclusions, including any determination that relied upon the use of adverse facts available pursuant to section 776(a) and (b) of the Act, *see* the Issues and Decision Memorandum.

Companies Not Selected for Individual Review

The statute and Commerce's regulations do not address the establishment of a rate to be applied to companies not selected for examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 705(c)(5) of the Act, which provides instructions for determining the all-others rate in an investigation, for guidance when calculating the rate for companies

[18] *See Notice of Final Determination of Sales at Less Than Fair Value: Stainless Steel Butt-Weld Pipe Fittings from the Philippines,* 65 FR 81823 (December 27, 2000).

[1] *See Carbon and Alloy Steel Threaded Rod From the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review and Rescission of Administrative Review in Part; 2019–2020,* 87 FR 27104 (May 6, 2022) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See Preliminary Results,* 87 FR at 27106.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Countervailing Duty Administrative Review of Carbon and Alloy Steel Threaded Rod from the People's Republic of China; 2019–2020,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See Carbon and Alloy Steel Threaded Rod from India and the People's Republic of China: Countervailing Duty Orders,* 85 FR 19927 (April 9, 2020) (*Order*).

[5] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

which were not selected for individual examination in an administrative review. Under section 705(c)(5)(A) of the Act, the all-others rate is normally an amount equal to the weighted average of the countervailable subsidy rates established for exporters and producers individually investigated, excluding any zero or *de minimis* countervailable subsidy rates, and any rates determined entirely on the basis of facts available.

There are three companies for which a review was requested and not rescinded, and which were not selected as mandatory respondents or found to be cross owned with a mandatory respondent: (1) Ningbo Dingtuo Imp. & Exp. Co., Ltd.; (2) Ningbo Dongxin High-Strength Nut Co., Ltd.; and (3) Ningbo Jinding Fastening Piece Co., Ltd. For these non-selected companies, because the rates calculated for the mandatory respondents, Junyue and Zhongjiang Bolts, were above *de minimis* and not based entirely on facts available, we are applying the weighted average of the net countervailable subsidy rates calculated for the mandatory respondents, which we calculated using the publicly-ranged sales data submitted by Junyue and Zhongjiang Bolts.[6] This methodology to establish the non-selected subsidy rate is consistent with our practice with regard to the all-others rate, pursuant to section 705(c)(5)(A)(i) of the Act.

Final Results of Administrative Review

In accordance with 19 CFR 351.221(b)(5), Commerce calculated the following net countervailable subsidy rates for the period July 29, 2019, through December 31, 2020:

Company	Subsidy rate—2019 (percent *ad valorem*)	Subsidy rate—2020 (percent *ad valorem*)
Ningbo Zhongjiang High Strength Bolts Co., Ltd[1]	6.42	5.64
Zhejiang Junyue Standard Part Co., Ltd[2]	5.09	5.79
Review-Specific Average Rate Applicable to the Following Companies:		
Ningbo Dingtuo Imp. & Exp. Co., Ltd	5.94	5.69
Ningbo Dongxin High-Strength Nut Co., Ltd	5.94	5.69
Ningbo Jinding Fastening Piece Co., Ltd	5.94	5.69

[1] In the original investigation, Commerce found Ningbo Zhongmin Metal Product Co., Ltd., to be cross-owned with Ningbo Zhongjiang High Strength Bolts Co., Ltd. *See Carbon and Alloy Steel Threaded Rod from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Duty Determination,* 84 FR 36578 (July 29, 2019), and accompanying PDM, at 28, unchanged in *Carbon and Alloy Steel Threaded Rod from the People's Republic of China: Final Affirmative Countervailing Duty Determination,* 85 FR 8833 (February 18, 2020). As the facts have not changed in this review, we continue to find Ningbo Zhongmin Metal Product Co., Ltd., to be cross-owned with Ningbo Zhongjiang High Strength Bolts Co., Ltd. *See also Preliminary Results* PDM.

[2] As discussed in the *Preliminary Results* PDM, Commerce finds the following companies to be cross-owned with Zhejiang Junyue Standard Part Co., Ltd.: Jiaxing Chengyue Trading Co., Ltd.; and Haiyan County Brothers Paper Industry Co., Ltd.

Disclosure

We intend to disclose the calculations performed in connection with the final results of review to parties in this proceeding within five days after public announcement of the final results or, if there is no public announcement, within five days of the date of publication of the notice of final results in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(2), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries of subject merchandise covered by this review. We intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these final results of review. 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 statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Instructions

In accordance with section 751(a)(1) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the respective companies listed above on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review. For all non-reviewed firms subject to the *Order,* we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, effective upon publication of the final results of review, shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

Commerce is issuing and publishing the final results of review in accordance

[6] With two respondents under examination, Commerce normally calculates (A) a weighted-average of the estimated subsidy rates calculated for the examined respondents; (B) a simple average of the estimated subsidy rates calculated for the examined respondents; and (C) a weighted-average of the estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010); *see also* Memorandum, ''Administrative Review of the Countervailing Duty Order on Carbon and Alloy Steel Threaded Rod from the People's Republic of China: Calculation of Rate for Respondents Not Selected for Individual Examination,'' dated concurrently with this notice.

with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5).

Dated: November 1, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2022–24213 Filed 11–4–22; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Green Sturgeon ESA 4(d) Rule Take Exceptions and Exemptions

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on July 19, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Marine Fisheries Service (NMFS), Commerce.

Title: Green Sturgeon ESA 4(d) Rule Take Exceptions and Exemptions.

OMB Control Number: 0648–0613.

Form Number(s): None.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 45.

Average Hours Per Response: Written notification describing research, monitoring, habitat restoration, or emergency fish rescue and salvage activities, 40 hours; research applications, 40 hours; development of state 4(d) research programs, 40 hours; development of a tribal fishery management or fishery management and evaluation plan, 160 hours; FMEP report, 20 hours; reports, 5 hours.

Total Annual Burden Hours: 1,510.

Needs and Uses: The Southern Distinct Population Segment of North American green sturgeon (Acipenser medirostris; hereafter, ''Southern DPS'') was listed as a threatened species in April 2006. Protective regulations under section 4(d) of the ESA were promulgated for the species on June 2, 2010 (75 FR 30714) (the final ESA 4(d) Rule) and codified at 50 CFR 223.210. To comply with the ESA and the protective regulations, entities must obtain take authorization prior to engaging in activities involving take of Southern DPS fish unless the activity is covered by an exception or exemption. ''Take'' is defined as to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture or collect, or to attempt to engage in any such conduct. Certain activities described in the ''exceptions'' provision of 50 CFR 223.210(b) are not subject to the take prohibitions if they adhere to specific criteria and reporting requirements. Under the ''exemption'' provision of 50 CFR 223.210(c), the take prohibitions do not apply to scientific research, scientific monitoring, and fisheries activities conducted under an approved 4(d) program or plan; similarly, take prohibitions do not apply to tribal resource management activities conducted under a Tribal Plan for which the requisite determinations described in 50 CFR 223.210(c)(3) have been made.

To ensure that activities qualify under exceptions to or exemptions from the take prohibitions, local, state, and federal agencies, non-governmental organizations, academic researchers, and private organizations are asked to voluntarily submit detailed information regarding their activity on a schedule to be determined by National Marine Fisheries Service (NMFS) staff. This information is used by NMFS to (1) track the number of Southern DPS fish taken as a result of each action; (2) understand and evaluate the cumulative effects of each action on the Southern DPS; and (3) determine whether additional protections are needed for the species, or whether additional exceptions may be warranted. NMFS designed the criteria to ensure that plans meeting the criteria would adequately limit effects on threatened Southern DPS fish, such that additional protections in the form of a federal take prohibition would not be necessary and advisable.

Affected Public: Not-for-profit institutions; State, local, or Tribal government; Federal government; business or other for-profit organizations.

Frequency: Written notification describing research, monitoring, habitat restoration, or emergency fish rescue and salvage activities, on occasion; development of fisheries management and evaluation plans, state 4(d) research programs, or tribal fishery management plans, on occasion; fisheries management and evaluation plan reports, biannually; all other reports, annually.

Respondent's Obligation: Required to Obtain or Retain Benefits.

Legal Authority: Endangered Species Act.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

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 and

entering either the title of the collection or the OMB Control Number 0648–0613.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–24211 Filed 11–4–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Designation of Fishery Management Council Members and Application for Reinstatement of State Authority

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 6, 2023.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *NOAA.PRA@noaa.gov.* Please reference OMB Control Number 0648–0314 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Morgan Corey, Fishery Management Specialist, Office of Sustainable Fisheries, 1315 East-West Highway, Silver Spring, MD 20910, (301) 427–8535, and *morgan.corey@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved information collection. The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) authorizes the establishment of eight Regional Fishery Management Councils to manage fisheries within regional jurisdictions. This collection pertains to several sections of the Magnuson-Stevens Act related to the Councils. Section 302(b) provides for appointment of Council members nominated by State Governors, Territorial Governors, or Tribal Governments and for designation of a principal state fishery official for the purposes of the Magnuson-Stevens Act. Section 306(b)(2) provides for a request by a state for reinstatement of state authority over a managed fishery. Nominees for Council membership must provide their State Governor, Territorial Governor, or Tribal Government leadership with background documentation, which is then submitted to NOAA, on behalf of the Secretary of Commerce to review qualifications for Council membership. The information collected with these actions is used to ensure that the requirements of the Magnuson-Stevens Act are being met in regards to Council membership and state authority.

II. Method of Collection

State Governors, Territorial Governors, and Tribal Governments submit written nominations to the Secretary of Commerce, together with recommendations and statements of candidates' qualifications. Designations of state officials and requests for reinstatement of state authority are also made in writing in response to regulations. NMFS provides guidance on what information to include in order to comply with current regulations. *See 50 CFR 600.215.* No forms are used.

III. Data

OMB Control Number: 0648–0314.

Form Number(s): None.

Type of Review: Regular submission (extension of a currently approved collection).

Affected Public: State, local, or Tribal government.

Estimated Number of Respondents: 275.

Estimated Time per Response: 80 hours for a nomination for Council appointment; 16 hours for background documentation for nominees; 1 hour to designate a principal state fishery official(s) or for a request to reinstate authority.

Estimated Total Annual Burden Hours: 4,607.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. 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 may 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.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–24210 Filed 11–4–22; 8:45 am]

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2022–0037]

Joint USPTO–FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments

AGENCY: United States Patent and Trademark Office, U.S. Department of Commerce.

ACTION: Notice of public listening session; request for comments.

SUMMARY: The United States Patent and Trademark Office (USPTO), Department of Commerce, in collaboration with the United States Food and Drug Administration (FDA), Department of Health and Human Services, is announcing a public listening session

on January 19, 2023, titled ''Listening Session on Joint USPTO–FDA Collaboration Initiatives.'' The purpose of the listening session is to seek public comments on proposed initiatives for collaboration between the agencies to advance President Biden's Executive Order on ''Promoting Competition in the American Economy'' and to promote greater access to medicines for American families. To assist in gathering public input, the USPTO and the FDA are announcing the establishment of a docket to track feedback received through this notice and a request for comments on these collaborative efforts.

DATES: The public listening session will be held on Thursday, January 19, 2023, from 10 a.m. to 5 p.m. ET. Persons seeking to speak at the listening session must register by 5 p.m. on January 5, 2023. Persons seeking to attend, either in person or virtually, but not speak at the event must register by January 17, 2023. Seating is limited for in-person attendance. Written comments will be accepted until February 6, 2023.

ADDRESSES:

Public Listening Session

The public listening session will take place in person in the Clara Barton Auditorium at the USPTO, 600 Dulany Street, Alexandria, VA 22313. The session will also be available via live feed for those wishing to attend remotely. Registration is required for both in-person and virtual attendance. Information on registration is available at www.uspto.gov/initiatives/uspto-fda-collaboration/engagements. Registrants must indicate whether they are registering as a listen-only attendee or as a speaker participant.

Requests to participate as a speaker must include:

1. The name of the person desiring to participate;
2. The organization(s) that person represents, if any;
3. Contact information (address, telephone number, and email); and
4. Information on the specific topic(s) of interest to the speaker (or their organization) and identification of the primary topic of interest.

Speaking slots are limited; preference will be given to speakers wishing to address one of the questions raised in this request for comments. We will attempt to group speakers by topic. Topics and speakers will be announced a few days prior to the public listening session. Speakers must attend in person and are required to submit their remarks for the listening session in advance through the Federal eRulemaking Portal at *www.regulations.gov*. We will inform each speaker in advance of their assigned time slot. If we receive more requests to speak than time allows and are unable to assign a time slot as requested, we will invite the requestor to submit written comments. Time slots will be at least three minutes but may be longer, depending on the number of speakers registered. A panel of USPTO and FDA personnel may reserve time to ask questions of particular speakers after the delivery of a speaker's remarks.

Request for Comments

You may submit written comments as follows. For reasons of Government efficiency, comments must be submitted through the Federal eRulemaking Portal at *www.regulations.gov*. To submit comments via the portal, enter docket number PTO–P–2022–0037 on the homepage and click ''search.'' The site will provide a search results page listing all documents associated with this docket. Find a reference to this request for comments and click on the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in ADOBE® portable document format (PDF) or MICROSOFT WORD® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic submission of comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions regarding how to submit comments by mail or by hand delivery.

FOR FURTHER INFORMATION CONTACT: Linda Horner, Administrative Patent Judge, USPTO, at 571–272–9797 or *USPTO-FDAcollaboration@uspto.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2021, President Biden issued an Executive Order on ''Promoting Competition in the American Economy,'' 86 FR 36987 (July 14, 2021) (Competition E.O.). To advance the Biden Administration's goals of promoting greater access to medicines for American families and increasing competition in the marketplace, section 5(p)(vi) of the Competition E.O. directs the Secretary of Health and Human Services, ''through the Commissioner of Food and Drugs'' and ''not later than 45 days after the date of this order,'' to ''write a letter to the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office enumerating and describing any relevant concerns of the FDA,'' in order ''to help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law.''

In response to the Competition E.O., on September 10, 2021, the FDA sent a letter to the USPTO outlining ideas for further engagement with the USPTO (FDA Letter). On July 6, 2022, the USPTO sent a responsive letter (USPTO Letter) discussing specific initiatives the USPTO was exploring to collaborate with the FDA to ensure that our patent system properly and adequately protects innovation while not unnecessarily delaying getting generic, biosimilar, and more affordable versions of pharmaceuticals into the hands of Americans who need them. The letters are available at www.uspto.gov/initiatives/fda-collaboration.

The FDA–USPTO exchange of letters recognizes that, while the two agencies have different missions and authorities, we share a commitment to ensuring our innovation system strikes the appropriate balance—encouraging meaningful innovation in drug development while supporting a competitive marketplace that can promote greater access to medicines for American families.

The United States is a global leader in the development of drugs and biologics due to its strong patent system, and the USPTO Letter describes ongoing efforts to further promote robust and reliable patent rights across all technologies. Robust and reliable patents are needed to incentivize and protect the immense research and development investment that is essential to bringing life-saving and life-altering products to market. Patent rights can spur the collaboration necessary for quick and speedy drug and biological product development. Congress also enacted laws to establish approval pathways for generic and biosimilar medicines, and these laws set forth patent dispute resolution mechanisms in the drug and biologic innovation space to encourage generic and biosimilar manufacturers to timely resolve patent issues in order to enter the market to increase competition.

The FDA Letter highlights the FDA's commitment to facilitating increased drug competition through its abbreviated pathways for the approval

of generic drugs and biosimilars, which play a foundational role in ensuring access to high-quality, safe, effective, and affordable medicines for American patients. The FDA has a ministerial role with regard to the patent listing provisions of the Federal Food, Drug, and Cosmetic Act. New drug application sponsors are statutorily required to submit certain patent information for listing, and the FDA is statutorily required to publish that information, which it does in Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book). Orange Book-listed patents may impact the timing of generic approval. In addition, under section 351(l) of the Public Health Service Act, if a reference product sponsor (*i.e.,* biologics license application holder) provides a list of patents to a biosimilar applicant within the context of patent litigation, then the FDA is statutorily required to publish that patent list. The FDA publishes such lists in the Purple Book Database of Licensed Biological Products (the Purple Book).

To further the objectives of the Competition E.O., the letters the FDA and the USPTO exchanged outline a number of initiatives to execute the President's agenda, with a focus on areas in which the agencies' functions overlap. The initiatives for collaboration with the FDA, as discussed in paragraph 1 of the USPTO Letter, are reproduced below.

1. Enhance collaboration with other agencies on key technology areas, including pharmaceuticals and biologics. The USPTO will seek to create formal mechanisms to collaborate with other agencies such as the Food and Drug Administration (FDA).[1] Specifically, the USPTO will:

a. Continue discussions with the FDA on this topic and the initiatives outlined here and work collaboratively on these and other initiatives.

b. Explore joint USPTO–FDA public engagement through listening sessions, dissemination of a Request for Comments and other procedures for collecting broader stakeholder input.

c. Provide examiners with training, in collaboration with the FDA, on publicly available FDA resources that can be utilized in prior art searches and on the state of the art in the pharmaceutical and biopharma areas and provide resources to the FDA to support its work on matters influenced by patent law and policy.

d. Explore consistency in representations made to the USPTO and the FDA. The USPTO will work with the FDA to evaluate consistency in representations to the USPTO (made both during prosecution of patent applications and in America Invents Act (AIA) and other post-issuance proceedings) and the FDA. The USPTO is also exploring initiatives to require patent applicants to provide relevant information to the USPTO that has been submitted to other agencies and to remind patent applicants of their disclosure obligations and the ramifications of failing to disclose required information at the USPTO.[2] The USPTO will explore with the FDA whether other avenues exist to determine whether patent applicants have submitted inconsistent statements between the agencies.

e. Engage in greater FDA collaboration in AIA proceedings. In addition to improving the robustness and reliability of patents that are granted in the first place, the USPTO will work with the FDA on processes and procedures for (1) notifying the FDA of AIA proceeding filings on any Orange Book-listed patents and/or Purple Book-listed patents, and (2) potentially sharing more information between the agencies. The USPTO will also work with the FDA to assess why there have been so few filings of AIA proceedings on Orange Book-listed patents and biologic patents and why the number of AIA filings for pharmaceutical patents has generally declined.[3]

f. Revisit patent term extension practice, required under 35 U.S.C. 156 due to the product being subject to an FDA regulatory review period. Though a recent report found that the USPTO accurately and fairly grants patent term extensions based on FDA regulatory review periods, the USPTO will collaborate with the FDA to determine if there are any areas for improvement through information sharing or otherwise. The USPTO also is exploring ways to facilitate public access to information on patent term extension applications and grants.

g. Work with the FDA to understand how else the agencies' authorities and responsibilities overlap, such as exploring the policies surrounding the use of ''skinny labels,'' the connection between method of use patents and associated use codes, and the patenting of risk evaluation and mitigation strategies that the FDA requires for certain medications with serious safety concerns. Where the agencies' functions overlap, the USPTO will work with FDA to optimize information sharing and policy within our respective frameworks and legal restrictions.

h. Remain open to discussing with the FDA, other agencies, the Administration, and stakeholders the FDA's concerns over practices referred to as ''patent thickets,'' ''evergreening,'' and ''product hopping.''

In this notice of public listening session and request for comments, the USPTO and the FDA seek public comments on the proposed initiatives outlined in the USPTO Letter (1(a)–1(h)) reproduced above.[4]

II. Purpose and Scope of the Listening Session and Request for Comments

The purpose of this listening session and request for comments is to obtain public input on areas for USPTO–FDA collaboration and engagement. We are seeking feedback from a broad group of stakeholders, including, but not limited to, patients and their caregivers, patient advocates, representatives from regulated industry, including companies that sell branded medicines, generics drugs and biosimilars, healthcare organizations, payors and insurers, academic institutions, public interest groups, and the general public.

To facilitate stakeholder feedback on the initiatives listed above, we provide the questions below. These questions are not meant to be exhaustive. We encourage interested stakeholders to address these and/or other related issues and to submit research and data that inform their comments on these topics. Commenters are welcome to respond to any or all of the questions and are encouraged to indicate which questions their comments address.

1. What publicly available FDA resources should be included when training USPTO patent examiners on tools they can use to assess the patentability of claimed inventions?

2. What mechanisms could assist patent examiners in determining

[1] Although these initiatives focus mostly on collaboration with the FDA, the USPTO is interested in exploring further interagency collaborations.

[2] On July 29, 2022, the USPTO published a **Federal Register** Notice clarifying the duty of disclosure and the duty of reasonable inquiry, including as to materials or statements material to patentability, or statements made to the USPTO that are inconsistent with statements submitted to the FDA and other Government agencies. *See* Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board, 87 FR 45764.

[3] Orange Book patent/biologic patent study update through June 2021, available at *www.uspto.gov/sites/default/files/documents/PTABOBbiologicpatentstudy8.10.2021draftupdatedthruJune2021.pdf.*

[4] The USPTO is also working in parallel on the other proposed initiatives described in the USPTO Letter that are not the focus of this listening session and request for comments. *See, e.g.,* Request for Comments on Initiatives Ensuring Robust and Reliable Patents, 87 FR 60130 (October 4, 2022).

whether patent applicants or patent owners have submitted inconsistent statements to the USPTO and the FDA? Please explain whether such mechanisms present confidentiality concerns and, if so, how those concerns could be addressed.

3. What are the opportunities and challenges related to the use of AIA proceedings to address the patentability of claims in pharmaceutical and biotechnological patents, including with respect to how such proceedings may intersect with Hatch-Waxman paragraph IV disputes and the Biologics Price Competition and Innovation Act ''patent dance'' framework that biosimilar applicants and reference product sponsors use to address any patent infringement concerns?

4. How can the USPTO and the FDA reinforce their collaboration and information exchange in relation to determining whether a patent qualifies for a patent term extension (PTE) and the length of any extension under 35 U.S.C. 156, as described in the Manual of Patent Examining Procedure § 2756? Identify any specific areas for improvement in the effectiveness of the current USPTO–FDA process for adjudicating applications for PTE and in the opportunity for public comment on such applications.

5. The FDA already publishes PTE applications on *www.regulations.gov*, and the USPTO publishes PTE applications on its Patent Center portal (*https://patentcenter.uspto.gov/*), which replaced the Public Patent Application Information Retrieval (PAIR) system. The USPTO also recently provided centralized access to a listing of PTE applications filed during the last five years at *www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156.* This list includes the patent application number, patent number, link to the electronic file wrapper in Patent Center, PTE application filing date, and trade name identified in the PTE application. The status of each PTE application, including disposition, may be determined by reviewing the electronic file wrapper in Patent Center. What additional information would be useful to include on this web page?

6. What policy considerations or concerns should the USPTO and the FDA explore as they relate to method of use patents and, as applicable, associated FDA use codes, including with respect to generic drug, 505(b)(2), and biosimilar applicants who do not seek approval for (*i.e.,* who seek to carve out from their labeling) information related to a patent-protected method of use (sometimes described as ''skinny labeling'')?

7. What policy considerations or concerns should the USPTO and the FDA explore in relation to the patenting of risk evaluation and mitigation strategies associated with certain FDA-approved products? What other types of patent claims associated with FDA-regulated products raise policy considerations or concerns for the USPTO and the FDA to evaluate?

8. Apart from, or in conjunction with, the initiatives set forth in the USPTO Letter, what other steps could the USPTO and the FDA take collaboratively to address concerns about the potential misuse of patents to improperly delay competition or to promote greater availability of generic versions of scarce drugs that are no longer covered by patents?

9. What additional input on any of the initiatives listed in the USPTO Letter (1(a)–1(h)), or any other related suggestions for USPTO–FDA collaboration, should the agencies consider?

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2022–24107 Filed 11–4–22; 8:45 am]

BILLING CODE 3510–16–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Notice of Intent To Extend Collection 3038–0025, Practice by Former Members and Employees of the Commission

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'' or ''Commission'') is announcing an opportunity for public comment on the proposed renewal of an information collection by the agency. Under the Paperwork Reduction Act (''PRA''), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including proposed extension of an existing collection of information, and to allow 60 days for public comment. This notice solicits comments regarding the reporting requirement imposed on former members and employees of the Commission who are employed or retained by third parties to appear before the Commission.

DATES: Comments must be submitted on or before January 6, 2023.

ADDRESSES: You may submit comments, identified by ''Practice by Former Members and Employees of the Commission, OMB Control No. 3038–0025,'' by any of the following methods:

- The Agency's website, at *https://comments.cftc.gov/.* Follow the instructions for submitting comments through the website.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.

Please submit your comments using only one method. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *https://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Frank Walsh, Alternate Designated Agency Ethics Official, Office of the General Counsel, Commodity Futures Trading Commission, (202) 418–6250; email: *fwalsh@cftc.gov,* and refer to OMB Control No. 3038–0025.

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501 *et seq.,* Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of a proposed extension of the currently approved information collection listed below. 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.[1]

Title: Practice by Former Members and Employees of the Commission (OMB Control No. 3038–0025). This is a request for an extension of a currently approved information collection.

[1] 44 U.S.C. 3512, 5 CFR 1320.5(b)(2)(i) and 1320.8 (b)(3)(vi).

Abstract: Commission Rule 140.735–6 governs the practice before the Commission of former members and employees of the Commission and is intended to ensure that the Commission is aware of any existing conflict of interest. The rule, at 17 CFR 140.735–6(e), requires former members and employees who are employed or retained to represent any person before the Commission within two years of their separation from the CFTC, to file a brief written statement with the Commission's Office of the General Counsel. The proposed rule was promulgated pursuant to the Commission's rulemaking authority contained in Section 8a(5) of the Commodity Exchange Act, 7 U.S.C. 12a(5) (1994), as amended.

With respect to the collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the CFTC, including whether the information will have a practical use;
- The accuracy of the CFTC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of 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 submission of responses.

You should submit only information that you wish to make available publicly. If you wish the CFTC to consider information that you believe is exempt from disclosure under the Freedom of Information Act (FOIA), then a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the CFTC's regulations.[2]

The CFTC reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *https://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the Information Correction Request will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under FOIA.

Burden statement: The respondent's burden for this collection is estimated to average 0.10 hours per response to file the brief written statement. This estimate includes the time needed to review instructions, utilize technology and systems for the purposes of collecting, validating, verifying, processing and disclosing information, and adjust/update existing methods to comply with any previously applicable instructions and requirements.

Respondents/Affected Entities: Former Commission members, employees, and their current employers.

Estimated number of respondents: 20.

Estimated annual burden hours per respondent: 0.10 hours (or 6 minutes).

Estimated total annual burden: 2 hours.

Frequency of collection: On occasion.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: November 2, 2022.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2022–24205 Filed 11–4–22; 8:45 am]

BILLING CODE 6351–01–P

[2] 17 CFR 145.9.

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2021–0017]

Notice and Request for Comment Regarding the CFPB's Inquiry Into Big Tech Payment Platforms

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice; request for comment.

SUMMARY: On October 21, 2021, the Consumer Financial Protection Bureau (Bureau or CFPB) ordered six large technology companies operating payments systems in the United States to provide information about certain of their business practices. Accompanying the orders, the Director of the Bureau issued a statement and invited interested parties to submit comments to inform the Bureau's inquiry. The statement and request for comment was published in the **Federal Register** on November 5, 2021, in a document titled, ''Notice and Request for Comment Regarding the CFPB's Inquiry into Big Tech Payment Platforms.'' The Bureau has determined that it is appropriate to re-open the docket for 30 days from **Federal Register** publication and add two questions.

DATES: Comments must be received on or before December 7, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CFPB–2021–0017, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: BigTechPaymentsInquiry@cfpb.gov.* Include Docket No. CFPB–2021–0017 in the subject line of the message.
- *Mail/Hand Delivery/Courier:* Comment Intake—Statement into Big Tech Payment Platforms, Consumer Financial Protection Bureau, c/o Legal Division Docket Manager, 1700 G Street NW, Washington, DC 20552. Because paper mail in the Washington, DC area and at the Bureau is subject to delay, commenters are encouraged to submit comments electronically.

Instructions: The Bureau encourages the early submission of comments. Please note the number of the topic on which you are commenting at the top of each response (you do not need to address all topics). All submissions should include document title and docket number. In general, all comments received will be posted without change to *https://www.regulations.gov.* All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Proprietary information or sensitive personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Comments will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Amy Zirkle, Program Manager for Payments & Deposits, (202) 435–7505. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION: On October 21, 2021, the CFPB ordered six large technology companies operating payments systems in the United States to provide information about certain of their business practices. Accompanying the orders, the Director of the Bureau issued a statement and invited interested parties to submit comments to inform the inquiry. The statement and request for comment were published in the **Federal Register** on November 5, 2021,[1] in a document titled ''Notice and Request for Comment

[1] 86 FR 61182 (Nov. 5, 2021).

Regarding the CFPB's Inquiry into Big Tech Payment Platforms.''

The CFPB has determined that it is appropriate to re-open the comment period to further inform the inquiry described by the Director in his October 21, 2021 Statement:

Faster, friction-less, and cheaper payment systems offer significant potential benefits to consumers, workers, their families, and small businesses in the United States. For example, families can send money to friends without delay, or to relatives overseas at lower costs. Fast payment systems can also help small businesses succeed with quicker transactions, lower cost, and more revenue conversion. And faster settlement can reduce the need for families and businesses to borrow.

But payments businesses are network businesses and can gain tremendous scale and market power, potentially posing new risks and undermining fair competition. Furthermore, knowing what we spend our money on is a valuable source of data on consumer behavior. This data can be monetized by companies that seek to profit from behavioral targeting, particularly around advertising and e-commerce. That many Big Tech companies aspire to grow in this space only heightens these concerns.

In China, we can already see the long-term implications of these forces. Alipay and WeChat Pay are deeply imbedded into the lives of the Chinese public, combining messaging, e-commerce and payment functionality into super-apps. In such a market, consumers have little choice but to use these apps and little market power to shape how their data is used.

Today the Consumer Financial Protection Bureau (CFPB) has ordered six technology platforms offering payment services to turn over information about their products, plans and practices when it comes to payments. The orders were issued to Google, Apple, Facebook, Amazon, Square, and PayPal. The CFPB will also study the practices of the Chinese tech giants that offer payments services, such as WeChat Pay and Alipay.

Congress has tasked the CFPB with ensuring that markets for consumer financial products and services are fair, transparent, and competitive. To that end, it has authorized the CFPB to require participants in the marketplace to provide information that help the Bureau monitor risks to consumers and to publish aggregated findings that are in the public interest.

Little is known publicly about how Big Tech companies will exploit their payments platforms. For example, will the operators engage in invasive financial surveillance and combine the data they collect on consumers with their geolocation and browsing data? [2] Will they in turn use this data to deepen behavioral advertising, engage in price discrimination, or sell to third parties?

Will these companies operate their payment platforms in a manner that interferes with fair, transparent, and competitive markets? Will the payment platforms be truly neutral, or will they use their scale to extract rents from market participants? Will small businesses feel coerced into participating in the payment platform out of fear of being suppressed or hidden in search or product listings? If these tech companies enter a market that competes with other providers on the platform, will these providers be removed or otherwise disadvantaged? What factors will these tech companies use when disqualifying or delisting an individual or business from participating on the platform?

Finally, how will these payment platforms ensure that key consumer protections are adhered to? How effectively do they manage complaints, disputes and errors? Are they sufficiently staffed to ensure adequate steps are taken to address consumer protection and provide responsive customer service when things go wrong? [3]

The CFPB's inquiry will help to inform regulators and policymakers about the future of our payments system. Importantly, it will also yield insights that may help the CFPB to implement other statutory responsibilities, including any potential rulemaking under Section 1033 of the Dodd-Frank Wall Street Reform and Consumer Protection Act. The CFPB's orders build on the efforts of the Federal Trade Commission's work to shed light on the business practices of the largest technology companies in the world.

The CFPB's inquiry is one of many efforts within the Federal Reserve System to plan for the future of real-time payments and to ensure a fair and competitive payments system in our country. The Bureau intends to open a Federal Register docket to invite public comment. I invite any interested parties to submit comments to inform the agency's inquiry.

In addition, the Bureau is inviting comment on the following questions related to the Bureau's inquiry:

1. What fees, fines, or other penalties do large technology companies assess on users of their payment platforms, including for:

a. Purported violations of the technology companies' acceptable use policies; or

b. Any other conduct?

2. Do the acceptable use policies for technology companies' payment platforms include provisions that can restrict access to their platforms? If so, under what circumstances can the technology companies restrict access to their platforms?

Re-opening the comment period will provide additional opportunity for the public to prepare comments related to this inquiry and to comment on the additional questions. Therefore, the CFPB is re-opening the comment period for an additional 30 days.

Rohit Chopra,

Director, Consumer Financial Protection Bureau.

[FR Doc. 2022–24214 Filed 11–4–22; 8:45 am]

BILLING CODE 4810–AM–P

[2] In 2019, I joined global privacy regulators to seek information about Facebook's Libra project. At the time, the company failed to substantively respond. *See https://www.priv.gc.ca/en/opc-news/speeches/2019/s-d_190805/.*

[3] The law currently provides for a number of safeguards in the payments sector, including but not limited to the Electronic Fund Transfer Act, the Gramm-Leach-Bliley Act, and the Consumer Financial Protection Act.

U.S. INTERNATIONAL DEVELOPMENT FINANCE CORPORATION

Notice of Public Hearing

AGENCY: U.S. International Development Finance Corporation.

ACTION: Announcement of public hearing.

SUMMARY: The Board of Directors of the U.S. International Development Finance Corporation (''DFC'') will hold a public hearing on December 7, 2022. This hearing will afford an opportunity for any person to present views in accordance the BUILD Act of 2018. Those wishing to present at the hearing must provide advance notice to the agency as detailed below.

DATES: Public hearing: 2 p.m., Wednesday, December 7, 2022.

Deadline for notifying agency of an intent to attend or present at the public hearing: 5 p.m., Tuesday, November 29, 2022.

Deadline for submitting a written statement: 5 p.m., Tuesday, November 29, 2022.

ADDRESSES: Public hearing: Virtual; access information provided at the time of attendance registration.

You may send notices of intent to attend, present, or submit a written

statement to Catherine F. I. Andrade, DFC Corporate Secretary, via email at *candrade@dfc.gov.*

Instructions: A notice of intent to attend the public hearing or to present at the public hearing must include the individual's name, title, organization, address, email, telephone number, and a concise summary of the subject matter to be presented. Oral presentations may not exceed five (5) minutes. The time for individual presentations may be reduced proportionately, if necessary, to afford all participants who have submitted a timely request an opportunity to be heard. Submission of written statements must include the individual's name, title, organization, address, email, and telephone number. The statement must be typewritten, double-spaced, and may not exceed ten (10) pages.

FOR FURTHER INFORMATION CONTACT: Catherine F. I. Andrade, DFC Corporate Secretary, (202) 336–8768, or *candrade@dfc.gov.*

SUPPLEMENTARY INFORMATION: The public hearing will take place via video- and teleconference. Upon registering, participants and observers will be provided instructions on accessing the hearing. DFC will prepare an agenda for the hearing identifying speakers, setting forth the subject on which each participant will speak, and the time allotted for each presentation. The agenda will be available at the time of the hearing.

Authority: 22 U.S.C. 9613(c).

Catherine F. I. Andrade,

DFC Corporate Secretary.

[FR Doc. 2022–24173 Filed 11–4–22; 8:45 am]

BILLING CODE 3210–02–P

DEPARTMENT OF THE DEFENSE

Department of the Army, Corps of Engineers

Notice of Intent To Prepare a Supplemental Environmental Impact Statement for the Mid-Chesapeake Bay Islands Ecosystem Restoration Project at James Island

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent.

SUMMARY: Pursuant to the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, the Baltimore District of the U.S. Army Corps of Engineers (USACE), in partnership with the Maryland Department of Transportation's Maryland Port Administration, the non-federal sponsor, plans to prepare a supplemental Environmental Impact Statement (sEIS) for the Mid-Chesapeake Bay Island Ecosystem Restoration Project at James Island (Mid-Bay Island Project). The Mid-Chesapeake Islands Restoration Project recommends remote island restoration at James Island and Barren Island, both on the Eastern Shore of Maryland and in Dorchester County, MD, through the beneficial use of dredged material. The project addresses two needs: (1) the restoration of remote island habitat to benefit wildlife including a diverse assemblage of birds, fish, herpetofauna, and invertebrates; and (2) the beneficial use of dredged material from the maintenance of the approach channels to Baltimore Harbor. Remote islands, a critical ecosystem component in the Chesapeake Bay, are offshore landforms that provide isolation, lack of human disturbance, and few predators. These conditions uniquely support isolated nesting and foraging habitat for a diverse assemblage of wildlife. Extensive island habitat loss has occurred within the Mid-Chesapeake Bay, and James Island has nearly vanished. Sea level rise and related erosion, as well as land subsidence and wave action are the primary drivers of island loss. The project provides an opportunity to utilize 30 to 70 million cubic yards of clean dredged material over a 20-year period to restore 2,072 acres of remote island habitat at James Island including uplands and wetlands. The project would convert over 2,000 acres of shallow water habitat in the waters surrounding James Island to external dikes and island habitat. There are expected to be long-term changes to the aesthetics of the project area as an effect of the restoration of James Island in the landscape. The sEIS will update documentation for NEPA focused on the James Island component of the project. USACE is requesting to be provided any supporting information, analyses, and alternative identification relevant to the action being evaluated by this sEIS.

DATES: Comments and suggestions must be submitted by December 7, 2022.

ADDRESSES: Send written comments and suggestions concerning the scope of issues to be evaluated within the sEIS to Angie Sowers, Integrated Water Resources Management Specialist, U.S. Army Corps of Engineers, Baltimore District, Planning Division—Civil Project Development Branch, (CENAP–PLP), 2 Hopkins Plaza, Baltimore, MD 21201, or via email to *angela.sowers@usace.army.mil.*

FOR FURTHER INFORMATION CONTACT: Questions about the overall Mid-Bay Island Project should be directed to Trevor Cyran, Project Manager at *trevor.p.cyran@usace.army.mil* or at (410) 962–4999. Additional information is available on the project's web page: *https://www.nab.usace.army.mil/Mid-Bay.*

SUPPLEMENTARY INFORMATION:

1. Background

USACE-Baltimore received the authority to conduct the Mid-Chesapeake Bay Island Ecosystem Restoration Feasibility Study under the resolution of the Senate Committee on Environment and Public Works on 5 June 1997. The feasibility study recommended remote island restoration at James Island and Barren Island, both on the Eastern Shore of Maryland and in Dorchester County, through the beneficial use of dredged material. The study built upon the Federal and State's Dredged Material Management Plan (DMMP) planning efforts to identify beneficial use sites to meet dredged material capacity needs and habitat restoration goals. The feasibility study determined the technical, economic, and environmental feasibility of protecting, restoring, and creating aquatic, intertidal wetland, and upland habitat for fish and wildlife within the Mid-Bay Island Project study area using clean dredged material from the Upper Chesapeake Bay Approach Channels.

Section 7002 of the Water Resources Reform and Development Act (WRDA) of 2014 authorized the Mid-Bay Island Project, as described in the Chief's Report, (*https://planning.erdc.dren.mil/toolbox/library/ChiefReports/mid_chesapeake.pdf*), dated August 2009, and the *Mid-Chesapeake Bay Island Ecosystem Restoration Integrated Feasibility Report and Environmental Impact Statement (IFR/EIS),* dated June 2009. The **Federal Register** notice (73 FR 56565, September 29, 2008) for the EIS being supplemented is available at *https://www.govinfo.gov/content/pkg/FR-2008-09-29/pdf/E8-22764.pdf.* The record of decision (ROD) was signed in July 2019 initiating the next phase of the study, Preconstruction Engineering and Design (PED). In March 2022, USACE published a supplemental Environmental Assessment (EA) with a signed finding of no significant impact (FONSI) to update NEPA compliance for the Barren Island component of the Mid-Bay Island Project. Acknowledging the scale of the James Island component of the project and the large-scale marine construction required to implement the project, a sEIS will be prepared.

The Mid-Bay Island Project recommended plan consists of restoring

2,072 acres of remote island habitat at James Island with a habitat proportion of 45% upland to 55% wetland, and an upland dike height of 20 ft MLLW.

The Mid-Bay Island Project provides for the restoration of remote island habitat to benefit wildlife including a diverse assemblage of birds, fish, herpetofauna, and invertebrates; and the beneficial use of dredged material. Remote islands, a critical ecosystem component in the Chesapeake Bay, are offshore landforms that provide isolation, lack of human disturbance, and few predators. These conditions uniquely support isolated nesting and foraging habitat for a diverse assemblage of wildlife. Extensive island habitat loss has occurred within the Mid-Chesapeake Bay. James Island, historically at least 1300 acres, has dwindled in the past 20 years from three remnants totaling less than 100 acres to multiple remnants summing to approximately 3 acres. Sea level rise and related erosion, as well as land subsidence and wave action are the primary drivers of island loss. Simultaneously, the project provides an opportunity for the beneficial use of dredged material. More than 130 miles of dredged shipping channels serve the Port of Baltimore, and channel maintenance and improvement projects require that approximately 4 to 5 million cubic yards of sediment be dredged from the Federal and State channels each year, 3.2 mcy of which comes from the upper Chesapeake Bay approach channels and the southern approach channels to the C&D Canal. The project will provide approximately 90 to 95 mcy, or approximately 28 to 30 years of dredged material placement capacity to meet the annual need for maintenance dredging activity.

The purpose of the current effort is to update NEPA documentation for the James Island component of the Mid-Bay Island Project during the project's design phase. The NEPA coordination/review schedule for the project will be coordinated with the appropriate Federal and state resource agencies

2. Study Area

The project is located in estuarine waters adjacent to James Island in Dorchester County, MD. James Island is situated along the eastern shore of the Chesapeake Bay, outside the mouth of the Little Choptank River, and slightly northeast of Taylors Island.

3. USACE Decision Making

As required by the Council on Environmental Quality's Principles, Requirements and Guidelines for Water and Land Related Resources Implementation Studies (2013), alternatives to the proposed Federal action that meet the purpose and need will be considered in the sEIS. These alternatives will include no action, the recommended plan as authorized by Section 7002 of WRDA 2014, and minor adjustments to account for changing conditions since the feasibility report was completed in 2009. The measures to be evaluated will consider applicable public stakeholder and agency input received since the beginning of PED and through future outreach efforts.

4. Scoping/Public Participation

Prior scoping meetings were held as part of the feasibility study. Public outreach events were held in May and June 2021. An additional community outreach session is planned for Saturday, November 19, 2022 from 10 a.m. to 12 p.m. at the Hoopers Island Fire Department [2756 Hoopers Island Road, Fishing Creek, MD 21634]. Any additional scoping input can be provided at that meeting or provided to the contacts identified here within, for 30 days following the meeting until December 19, 2022. Public meetings will be conducted during the public review period of the draft sEIS.

5. Lead and Cooperating Agencies

USACE is the lead federal agency and the Maryland Department of Transportation's Maryland Port Administration is the nonfederal sponsor for the project. The preparation of the sEIS meets the requirements of the NEPA and its Implementing Regulations of the President's Council on Environmental Quality (40 CFR 1500–1508). The U.S. Fish and Wildlife Service (FWS), the National Oceanic and Atmospheric Administration (NOAA), the U.S. Environmental Protection Agency (EPA), and the Maryland Department of Natural Resources (MDNR) have been invited to serve as cooperating agencies.

6. Alternatives To Be Considered

This sEIS evaluation will consider two alternatives: (1) No action, and (2) implementation of the feasibility study's recommended plan.

7. Study Schedule

The Draft sEIS is currently scheduled for distribution to the public in summer 2023, with a 45 day public review and comment period following release of the draft document.

8. Anticipated Impacts, Permits, and Authorization

The sEIS will analyze the full range of impacts, both beneficial and negative, of the alternatives. Potentially significant issues to be analyzed include impacts to waters of the United States, aquatic resources (including submerged aquatic vegetation), and endangered and threatened species and their habitats. Other impacts that will be analyzed include hydrology and water quality, air quality, navigation, cultural resources, aesthetics, environmental justice, and recreation. Anticipated permits and authorizations include water quality certification, Coastal Zone Consistency Determination, and a tidal wetlands license. In addition, many other federal, state, and local authorizations will be required for the Project. Applicable federal laws include the Endangered Species Act, Magnuson-Stevens Fishery Conservation and Management Act, Marine Mammals Protection Act, Rivers and Harbors Act, National Historic Preservation Act, Clean Water Act, and the Coastal Zone Management Act. USACE is also conducting government-to-government Tribal consultations.

Reinhard W. Koenig,

Programs Director, North Atlantic Division.

[FR Doc. 2022–24164 Filed 11–4–22; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2022–SCC–0106]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; National Student Loan Data System (NSLDS)

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before December 7, 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 (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms

and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, (202) 377–4018.

SUPPLEMENTARY INFORMATION: The Department, 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 ICR that is described below. The Department is especially interested in public comments 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 record.

Title of Collection: National Student Loan Data System (NSLDS).

OMB Control Number: 1845–0035.

Type of Review: Extension without change of a currently approved collection.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 16,212.

Total Estimated Number of Annual Burden Hours: 33,624.

Abstract: The United States Department of Education will collect data through the National Student Loan Data System (NSLDS) from Federal Perkins Loan holders (institutions or their servicers) and Guaranty Agencies (GA) about Federal Perkins, Federal Family Education, and William D. Ford Direct Student Loans to be used to manage the federal student loan programs, develop policy, and determine eligibility for programs under title IV of the Higher Education Act of 1965, as amended (HEA). NSLDS also holds data about Federal Grants, including Pell Grants, Academic Competitiveness Grants (ACG), National Science and Mathematics Access to Retain Talent (SMART) and Teacher Education Assistance for College and Higher Education (TEACH) Grants. NSLDS is used for research, policy analysis, monitoring student enrollment, calculating default rates, monitoring program participants and verifying student aid eligibility. This is a request for an extension to the current information collection 1845–0035 based on a decrease in the number of participants providing information to the system.

Dated: November 2, 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. 2022–24181 Filed 11–4–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Advisory Board

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open in-person/virtual hybrid meeting.

SUMMARY: This notice announces an in-person/virtual meeting of the Environmental Management Advisory Board (EMAB). The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, December 1, 2022, 1 p.m.–5 p.m. CST.

ADDRESSES: This hybrid meeting will be open to the public virtually (observation only). To attend, please contact Alyssa Petit by email, *Alyssa.Petit@em.doe.gov,* no later than 5:00 p.m. EDT on Friday, November 25, 2022.

For EMAB members, presenters, and staff, the meeting will be held, following COVID–19 precautionary measures, at: Sheraton New Orleans Hotel, Napoleon Room C–3, 500 Canal Street, New Orleans, Louisiana 70130.

Attendees should check the EMAB website listed below for any meeting format changes due to COVID–19 protocols.

FOR FURTHER INFORMATION CONTACT: Alyssa Petit, EMAB Federal Coordinator. U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585. Phone (202) 430–9624 or Email: *Alyssa.Petit@em.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of EMAB is to provide the Assistant Secretary for Environmental Management (EM) with independent advice and recommendations on corporate issues confronting the EM program. EMAB's membership reflects a diversity of views, demographics, expertise, and professional and academic experience. Individuals are appointed by the Secretary of Energy to serve as either special Government employees or representatives of specific interests and/or entities.

Tentative Agenda

- Remarks from EM leadership
- Recruitment and Retention Subcommittee Presentation
- Hybrid Work Subcommittee Presentation
- Reading of Public Comment
- EM Budget Update and Program Plan Presentation
- EM Regulatory and Policy Affairs Update
- Board Business

Public Participation: The online virtual meeting is open to the public. Public comments will be accepted via email prior to and after the meeting. Comments received no later than 5 p.m. EDT on Friday, November 25, 2022, will be read aloud during the virtual meeting. Comments will also be accepted after the meeting by no later than 5 p.m. EDT on Monday, December 5, 2022. Please send comments to Alyssa Petit at *Alyssa.Petit@em.doe.gov.* The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments should email them as directed above. If you require special accommodations due to a disability, please contact Alyssa Petit at least seven days in advance of the meeting at the email address listed above.

Minutes: Minutes will be available by writing or calling Alyssa Petit at the address or phone number listed above. Minutes will also be available at the following website: *https://www.energy.gov/em/listings/emab-meetings.*

Signing Authority

This document of the Department of Energy was signed on October 31, 2022,

by Shena Kennerly, Acting Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 2, 2022.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2022–24182 Filed 11–4–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15232–000]

Public Service Company of Colorado; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On August 23, 2021, Public Service Company of Colorado (PSCo), filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Unaweep Pumped Storage Hydropower Project (Unaweep Project or project), a closed-loop pumped storage project to be located in Mesa County, Colorado. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following new facilities: (1) a 96-foot-high concrete-faced rockfill dam with approximate crest elevation of 8,627 feet (NAVD88) creating a 5,912 acre-foot upper reservoir with a maximum surface elevation of 8,622 feet (NAVD88); (2) an approximately 4,900-foot-long, 22-foot-diameter concrete- and steel-lined underground conduit system to connect the upper and lower reservoirs to the powerhouse; (3) an underground powerhouse containing three fixed-speed pump-turbine units with a generation capacity of 267 megawatts each (total capacity of 800 megawatts) that would be directly coupled to motor-generators rated at approximately 281 megawatts each; (4) a 73-foot-high earthen fill dam with approximate crest elevation of 7,075 feet (NAVD88), creating a 5,912 acre-foot lower reservoir with a maximum surface elevation of 7,068 feet (NAVD88); (5) a new water supply wellfield located adjacent to the Gunnison River near Whitewater, Colorado and a water transmission system containing a pump station and an approximately 19-mile-long pipeline; (6) a 24-mile-long 345-kilovolt (kV) single, double-circuit transmission line interconnecting the project to the applicant's existing Grand Junction substation which serves an existing 345-kV transmission line; and (7) appurtenant facilities. The estimated average annual generation of the Unaweep Project would be 2,780 gigawatt-hours.

Applicant Contact: Terri Eaton, Public Service Company of Colorado, 1800 Larimer Street, Suite 1200, Denver, Colorado 80202; phone: (303) 571–7112; *terri.k.eaton@xcelenergy.com.*

FERC Contact: Khatoon Melick, (202) 502–8433, *khatoon.melick@ferc.gov.*

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. 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–15232–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's website at *https://www.ferc.gov/ferc-online/elibrary/overview.* Enter the docket number (P–15232) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: November 1, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–24236 Filed 11–4–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD21–15–000]

Joint Federal-State Task Force on Electric Transmission; Notice of Meeting and Agenda

As first announced in the Commission's September 8, 2022 Notice in the above-captioned docket,[1] the next public meeting of the Joint Federal-State Task Force on Electric Transmission (Task Force) will be held on November 15, 2022, at the New Orleans Marriott in New Orleans, LA, from approximately 8:00 a.m. to 10:30 a.m. Central time. Commissioners may attend and participate in this meeting. Attached to this Notice is an agenda for the meeting.

The meeting will be open to the public for listening and observing and on the record. There is no fee for attendance and registration is not required. The public may attend in person or via Webcast.[2] This conference will be transcribed. Transcripts will be available for a fee from Ace Reporting, 202–347–3700.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov* or call toll free 1–866–208–3372 (voice) or 202–208–8659 (TTY), or send a fax to 202–208–2106 with the required accommodations.

[1] *Joint Fed.-State Task Force on Elec. Transmission,* Notice, Docket No. AD21–15–000 (issued Sept. 8, 2022).

[2] A link to the Webcast will be available on the day of the event at *https://www.ferc.gov/TFSOET.*

More information about the Task Force, including frequently asked questions, is available here: *https://www.ferc.gov/TFSOET.* For more information about this meeting, please contact: Gretchen Kershaw, 202–502–8213, *gretchen.kershaw@ferc.gov;* or Jennifer Murphy, 202–898–1350, *jmurphy@naruc.org.* For information related to logistics, please contact Benjamin Williams, 202–502–8506, *benjamin.williams@ferc.gov;* or Rob Thormeyer, 202–502–8694, *robert.thormeyer@ferc.gov.*

For more information about this Notice, please contact: Gretchen Kershaw (Legal Information), Office of the General Counsel, (202) 502–8213, *Gretchen.Kershaw@ferc.gov*.

Dated: November 1, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–24241 Filed 11–4–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC23–18–000.

Applicants: Seneca Energy II, LLC, Innovative Energy Systems, LLC, PEI Power LLC, PEI Power II, LLC, INGENCO Wholesale Power L.L.C., Collegiate Clean Energy, LLC, Condor RTM Inc., Sunshine Gas Producers, LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Seneca Energy II, LLC, et al.

Filed Date: 10/31/22.

Accession Number: 20221031–5372.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: EC23–19–000.

Applicants: Northern Iowa Windpower LLC, Old Gold Energy Center, LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Northern Iowa Windpower LLC, et al.

Filed Date: 10/31/22.

Accession Number: 20221031–5380.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: EC23–20–000.

Applicants: Buena Vista Energy Center, LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act of Buena Vista Energy Center, LLC.

Filed Date: 11/1/22.

Accession Number: 20221101–5082.

Comment Date: 5 p.m. ET 11/22/22.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG23–19–000.

Applicants: Arroyo Solar LLC.

Description: Arroyo Solar LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 11/1/22.

Accession Number: 20221101–5170.

Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: EG23–20–000.

Applicants: Arroyo Energy Storage LLC.

Description: Arroyo Energy Storage LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 11/1/22.

Accession Number: 20221101–5172.

Comment Date: 5 p.m. ET 11/22/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1276–015; ER10–1287–014; ER10–1292–013; ER10–1303–013; ER10–1319–015; ER10–1353–015; ER18–1150–008; ER18–1183–006; ER18–1184–006; ER22–2187–001; ER22–2188–002.

Applicants: Northwest Ohio IA, LLC, Northwest Ohio Solar, LLC, Delta Solar Power II, LLC, Delta Solar Power I, LLC, Northwest Ohio Wind, LLC, Dearborn Industrial Generation, L.L.C., CMS Generation Michigan Power, LLC, Genesee Power Station Limited Partnership, CMS Energy Resource Management Company, Grayling Generation Station Limited Partnership, Consumers Energy Company.

Description: Notice of Change in Status of Consumers Energy Company, et al.

Filed Date: 10/31/22.

Accession Number: 20221031–5236.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: ER10–1355–012.

Applicants: Southern California Edison Company.

Description: Notice of Change in Status of Southern California Edison Company.

Filed Date: 10/31/22.

Accession Number: 20221031–5384.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: ER10–1616–017; ER10–2359–012; ER10–2756–011; ER10–2783–019; ER10–2798–018; ER10–2799–018; ER10–2878–019; ER10–2879–018; ER10–2960–015; ER10–2969–019; ER14–891–001; ER18–1821–009; ER18–2418–007; ER19–2231–006; ER19–2232–006; ER21–2423–006; ER21–2424–006; ER22–46–005; ER22–1402–002; ER22–1404–002; ER22–1449–002; ER22–1450–002; ER22–1662–002; ER22–2713–001.

Applicants: Walleye Power, LLC, Sunrise Power Company, LLC, Parkway Generation Sewaren Urban Renewal Entity LLC, Parkway Generation Operating LLC, Parkway Generation Keys Energy Center LLC, Parkway Generation Essex, LLC, Oswego Harbor Power LLC, New Covert Generating Company, LLC, Montville Power LLC, Middletown Power LLC, Long Beach Generation LLC, Griffith Energy LLC, Great River Hydro, LLC, Generation Bridge M&M Holdings, LLC, Generation Bridge Connecticut Holdings, LLC, GB II New York LLC, GB II New Haven LLC, GB II Connecticut LLC, Devon Power LLC, Connecticut Jet Power LLC, Chief Keystone Power II, LLC, Chief Conemaugh Power II, LLC, Astoria Generating Company, L.P., Arthur Kill Power LLC.

Description: Notice of Change in Status of New Covert Generating Company, LLC, et al.

Filed Date: 10/31/22.

Accession Number: 20221031–5394.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: ER10–1946–016; ER14–1468–013.

Applicants: KMC Thermo, LLC, Broad River Energy LLC.

Description: Notice of Non-Material Change in Status of Broad River Energy LLC, et al.

Filed Date: 10/31/22.

Accession Number: 20221031–5373.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: ER10–2124–024; ER10–2125–025; ER10–2127–023; ER10–2128–024; ER10–2132–024; ER10–2764–024; ER15–1873–016; ER18–471–010; ER18–1197–007; ER20–2444–004; ER20–2445–004; ER22–1999–001; ER22–2091–001.

Applicants: Calhoun Solar Energy LLC, Number Three Wind LLC, Prineville Solar Energy LLC, Millican Solar Energy LLC, Camilla Solar Energy LLC, States Edge Wind I LLC, Buckeye Wind Energy LLC, Vantage Wind Energy LLC, Willow Creek Energy LLC, Wolverine Creek Energy LLC, Invenergy TN LLC, Judith Gap Energy LLC, Spring Canyon Energy LLC.

Description: Notice of Change in Status of Spring Canyon Energy LLC, et al.

Filed Date: 10/28/22.

Accession Number: 20221028–5391.

Comment Date: 5 p.m. ET 11/18/22.

Docket Numbers: ER10–2374–017.

Applicants: Puget Sound Energy, Inc.

Description: Notice of Non-Material Change in Status of Puget Sound Energy, Inc.

Filed Date: 10/27/22.
Accession Number: 20221027–5188.
Comment Date: 5 p.m. ET 11/17/22.
Docket Numbers: ER10–2984–061.
Applicants: Merrill Lynch Commodities, Inc.
Description: Notice of Non-Material Change in Status of Merrill Lynch Commodities, Inc.
Filed Date: 10/31/22.
Accession Number: 20221031–5377.
Comment Date: 5 p.m. ET 11/21/22.
Docket Numbers: ER10–3050–010; ER10–3053–010.
Applicants: Whitewater Hill Wind Partners, LLC, Cabazon Wind Partners, LLC.
Description: Notice of Non-Material Change in Status of Cabazon Wind Partners, LLC, et al.
Filed Date: 10/31/22.
Accession Number: 20221031–5379.
Comment Date: 5 p.m. ET 11/21/22.
Docket Numbers: ER16–581–010; ER16–582–010; ER16–2271–009; ER17–1370–009; ER20–1385–003; ER20–1853–002; ER21–2204–003.
Applicants: ENGIE Power & Gas LLC, Whitehorn Solar LLC, Bluestone Farm Solar, LLC, ENGIE Energy Marketing NA, Inc., ENGIE Resources LLC, ENGIE Retail, LLC, ENGIE Portfolio Management, LLC.
Description: Notice of Change in Status of ENGIE Portfolio Management, LLC, et al.
Filed Date: 10/28/22.
Accession Number: 20221028–5392.
Comment Date: 5 p.m. ET 11/18/22.
Docket Numbers: ER18–730–002.
Applicants: Linden VFT, LLC.
Description: Linden VFT submits a Post-Open Solicitation Compliance Filing and request for Expedited Action and Confidential Treatment.
Filed Date: 10/14/22.
Accession Number: 20221014–5252.
Comment Date: 5 p.m. ET 11/4/22.
Docket Numbers: ER19–357–001; ER22–1095–001.
Applicants: KCE NY 6, LLC, KCE NY 1, LLC.
Description: Notice of Change in Status of KCE NY 1, LLC, et al.
Filed Date: 10/31/22.
Accession Number: 20221031–5378.
Comment Date: 5 p.m. ET 11/21/22.
Docket Numbers: ER20–956–005; ER18–784–006; ER23–300–001.
Applicants: Jayhawk Wind, LLC, Upstream Wind Energy LLC, Thunderhead Wind Energy LLC.
Description: Notice of Non-Material Change in Status of Thunderhead Wind Energy LLC, et al.
Filed Date: 10/31/22.
Accession Number: 20221031–5383.
Comment Date: 5 p.m. ET 11/21/22.
Docket Numbers: ER20–1863–007.
Applicants: Ingenco Wholesale Power, L.L.C.
Description: Compliance filing: Informational Filing on Reactive Tariff ER20–1863 and Request for Waiver to be effective N/A.
Filed Date: 10/31/22.
Accession Number: 20221031–5260.
Comment Date: 5 p.m. ET 11/21/22.
Docket Numbers: ER21–2674–004.
Applicants: Borderlands Wind, LLC.
Description: Notice of Change in Status of Borderlands Wind, LLC, et al.
Filed Date: 10/31/22.
Accession Number: 20221031–5375.
Comment Date: 5 p.m. ET 11/21/22.
Docket Numbers: ER22–80–003.
Applicants: Coyote Ridge Wind, LLC.
Description: Compliance filing: Settlement Compliance Filing to be effective 1/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5131.
Comment Date: 5 p.m. ET 11/22/22.
Docket Numbers: ER22–1085–001.
Applicants: Panorama Wind, LLC.
Description: Notice of Change in Status of Panorama Wind, LLC.
Filed Date: 10/31/22.
Accession Number: 20221031–5382.
Comment Date: 5 p.m. ET 11/21/22.
Docket Numbers: ER22–1370–003.
Applicants: Sunlight Storage, LLC.
Description: Notice of Change in Status of Sunlight Storage, LLC, et al.
Filed Date: 10/31/22.
Accession Number: 20221031–5374.
Comment Date: 5 p.m. ET 11/21/22.
Docket Numbers: ER22–2314–001.
Applicants: Langdon Renewables, LLC.
Description: Supplement to September 2, 2022 filing of Langdon Renewables, LLC.
Filed Date: 10/28/22.
Accession Number: 20221028–5315.
Comment Date: 5 p.m. ET 11/18/22.
Docket Numbers: ER22–2808–001.
Applicants: AEP Texas Inc.
Description: Tariff Amendment: AEPTX-Southwest Texas EC-Golden Spread EC 6th A&R IA—Amend Pending to be effective 8/16/2022.
Filed Date: 10/31/22.
Accession Number: 20221031–5215.
Comment Date: 5 p.m. ET 11/21/22.

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: November 1, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–24240 Filed 11–4–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER23–303–000]

Danske Commodities US LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Danske Commodities US LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 21, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the

eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

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://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 the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: November 1, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–24237 Filed 11–4–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: ER23–307–000.

Applicants: Black Hills Colorado Electric, LLC.

Description: § 205(d) Rate Filing: Filing of Second Amended and Restated 69kV Distribution Wheeling Agr and NOA to be effective 1/1/2023.

Filed Date: 10/31/22.

Accession Number: 20221031–5218.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: ER23–308–000.

Applicants: Black Hills Colorado Electric, LLC.

Description: § 205(d) Rate Filing: Filing of Second Amended and Restated 69kV Distribution Wheeling Agr and NOA to be effective 1/1/2023.

Filed Date: 10/31/22.

Accession Number: 20221031–5223.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: ER23–309–000.

Applicants: Tucson Electric Power Company.

Description: Compliance filing: Report Regarding Wholesale Sales in WECC to be effective 5/3/2022.

Filed Date: 10/31/22.

Accession Number: 20221031–5231.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: ER23–310–000.

Applicants: New England Power Pool Participants Committee.

Description: § 205(d) Rate Filing: Nov 2022 Membership Filing to be effective 10/1/2022.

Filed Date: 10/31/22.

Accession Number: 20221031–5233.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: ER23–311–000.

Applicants: Wisconsin Public Service Corporation.

Description: § 205(d) Rate Filing: Revisions to the AS Tariff for Suspension of Weston Unit 2 to be effective 1/1/2023.

Filed Date: 10/31/22.

Accession Number: 20221031–5237.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: ER23–312–000.

Applicants: Townsite Solar, LLC.

Description: Compliance filing: Townsite Solar Notice and Justification for Spot Sales Above WECC Soft Cap to be effective N/A.

Filed Date: 10/31/22.

Accession Number: 20221031–5245.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: ER23–313–000.

Applicants: Public Service Company of New Mexico.

Description: Compliance filing: WECC Price cap September 2022 to be effective 4/8/2022.

Filed Date: 10/31/22.

Accession Number: 20221031–5255.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: ER23–314–000.

Applicants: Evergy Kansas Central, Inc.

Description: § 205(d) Rate Filing: Revision, FreeState Full Requirements Electric Service Agreement to be effective 1/1/2023.

Filed Date: 10/31/22.

Accession Number: 20221031–5257.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: ER23–315–000.

Applicants: MidAmerican Central California Transco, LLC.

Description: § 205(d) Rate Filing: 2022 Annual TRBAA Update Filing to be effective 1/1/2023.

Filed Date: 10/31/22.

Accession Number: 20221031–5258.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: ER23–316–000.

Applicants: Calpine Energy Services, L.P.

Description: Compliance filing: Notice and Justification for Spot Sales above WECC Soft Cap to be effective N/A.

Filed Date: 10/31/22.

Accession Number: 20221031–5261.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: ER23–317–000.

Applicants: Riverstart Solar Park LLC.

Description: Baseline eTariff Filing: Reactive Power Compensation Baseline Filing to be effective 11/2/2022.

Filed Date: 11/1/22.

Accession Number: 20221101–5014.

Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: ER23–318–000.

Applicants: Midcontinent Independent System Operator, Inc., Ameren Services Company.

Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 2022–11–01_ Amendment to AMMO–ATXI-Wabash JPZ Agrmt RE MJMEUC to be effective 1/1/2023.

Filed Date: 11/1/22.

Accession Number: 20221101–5039.

Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: ER23–320–000.

Applicants: Flemington Solar, LLC, Frenchtown I Solar, LLC, Frenchtown II Solar, LLC, Frenchtown III Solar, LLC, Lakehurst Solar, L.L.C., PA Solar Park, LLC, PA Solar Park II, LLC, Pilesgrove Solar, LLC.

Description: Joint Request For Partial Waiver of the 90-day prior notice requirement set forth in Schedule 2 of the PJM Tariff and Request For Expedited Consideration.

Filed Date: 10/31/22.

Accession Number: 20221031–5393.

Comment Date: 5 p.m. ET 11/21/22.

Docket Numbers: ER23–321–000.

Applicants: Consolidated Edison Company of New York, Inc.

Description: § 205(d) Rate Filing: Energy Storage NYISO 11–1–2022 to be effective 11/1/2022.

Filed Date: 11/1/22.

Accession Number: 20221101–5077.

Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: ER23–322–000.

Applicants: Midcontinent Independent System Operator, Inc., ALLETE, Inc.

Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2022–11–01_ALLETE Depreciation Rates Filing to be effective 1/1/2022.

Filed Date: 11/1/22.

Accession Number: 20221101–5094.
Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: ER23–323–000.
Applicants: Tampa Electric Company.
Description: § 205(d) Rate Filing: Attachment N—Non Firm Energy Exchange Transmission Service to be effective 12/31/9998.
Filed Date: 11/1/22.
Accession Number: 20221101–5137.
Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: ER23–324–000.
Applicants: Tampa Electric Company.
Description: § 205(d) Rate Filing: Rate Schedule 105—SEEM Joinder Agreement to be effective 1/1/2023.
Filed Date: 11/1/22.
Accession Number: 20221101–5138.
Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: ER23–325–000.
Applicants: Duke Energy Florida, LLC.
Description: § 205(d) Rate Filing: DEF–RS No. 388–Joinder Agreement to Southeast Energy Exchange Market Agreement to be effective 1/1/2023.
Filed Date: 11/1/22.
Accession Number: 20221101–5139.
Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: ER23–326–000.
Applicants: Arroyo Solar LLC.
Description: Baseline eTariff Filing: Application for Market-Based Rate Authority to be effective 12/31/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5144.
Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: ER23–327–000.
Applicants: Arroyo Energy Storage LLC.
Description: Baseline eTariff Filing: Application for Market-Based Rate Authority to be effective 12/31/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5145.
Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: ER23–328–000.
Applicants: Arroyo Solar LLC.
Description: Initial rate filing: Filing of Shared Facilities Agreement and Request for Waivers to be effective 12/31/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5146.
Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: ER23–329–000.
Applicants: Tri-State Generation and Transmission Association, Inc.
Description: § 205(d) Rate Filing: Amendment to Rate Schedule FERC No. 12 to be effective 1/2/2023.
Filed Date: 11/1/22.
Accession Number: 20221101–5151.
Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: ER23–330–000.
Applicants: Puget Sound Energy, Inc.
Description: § 205(d) Rate Filing: Clearwater 1—Dynamic Transfer Operating Agreement to be effective 11/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5155.
Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: ER23–331–000.
Applicants: DATC Path 15, LLC.
Description: § 205(d) Rate Filing: Normal filing 2023 Appendix I to be effective 1/1/2023.
Filed Date: 11/1/22.
Accession Number: 20221101–5163.
Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: ER23–332–000.
Applicants: Transource Oklahoma, LLC, Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: Transource Oklahoma, LLC submits tariff filing per 35.13(a)(2)(iii: Transource Oklahoma, LLC Regulatory Asset Recovery Filing to be effective 1/1/2023.
Filed Date: 11/1/22.
Accession Number: 20221101–5166.
Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: ER23–333–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: Revisions to Remove Barriers to Requesting Surplus Interconnection Service to be effective 1/1/2023.
Filed Date: 11/1/22.
Accession Number: 20221101–5178.
Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: ER23–334–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 1875R5 Kansas Electric Power Cooperative, Inc. NITSA and NOA to be effective 1/1/2023.
Filed Date: 11/1/22.
Accession Number: 20221101–5184.
Comment Date: 5 p.m. ET 11/22/22.

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: November 1, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–24239 Filed 11–4–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15233–000]

Nature and People First Arizona PHS, LLS; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On October 5, 2021, Nature and People First Arizona PHS, LLC (NFPA) filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of Black Mesa Pumped Storage Project North to be located in Navajo County, Arizona. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) a new upper reservoir with a surface area of 3,300 acres and a total storage capacity of 100,000 acre-feet at a normal maximum operating elevation of 7,910 feet average mean sea level (msl); (2) a new lower reservoir west with a surface area of 1,200 acres and a total storage capacity of 39,000 acre-feet at a normal maximum operating elevation of 5,960 feet msl; (3) a new lower reservoir middle with a surface area of 420 acres and a total storage capacity of 15,000 acre-feet at a normal maximum operating elevation of 5,960 feet msl; (4) a new lower reservoir south with a surface area of 1,300 acres and a total storage capacity of 46,000 acre-feet at a normal maximum operating elevation of 5,960 feet msl; (5) a 6,800-foot-long, 23-foot-diameter concrete lined tunnel and 1,800-foot-long with three 18-foot-diameter concrete lined draft tube tunnel penstock connecting the upper and lower reservoir west to the powerhouse; (6) a 9,400-foot-long, 23-foot-diameter concrete lined tunnel and 2,100-foot-long with three 18-foot-diameter concrete lined draft tube tunnel penstock connecting the upper and lower reservoir middle to the powerhouse; (7) a 6,750-foot-long, 23-

foot-diameter concrete lined tunnel and 2,500-foot-long with three 18-foot-diameter concrete lined draft tube tunnel penstock connecting the upper and lower reservoir south to the powerhouse; (8) three 320-foot-long, 60-foot-wide and 100-foot-high new underground powerhouses containing three turbine-generator units each with a total rated capacity of 2,250 megawatts; (9) a new 80-mile-long, 230-kilovolt (kV) transmission line connecting the powerhouses to either Powell Glen Canyon's existing substation or the Navajo Generating Station's substation; and (10) appurtenant facilities. The estimated annual power generation at the Black Mesa Pumped Storage North would be 4,927.5 gigawatt-hours.

Applicant Contact: Mr. Denis Payre, President and CEO, Nature and People First Arizona PHS, LLC 405 Waltham St, Suite 145 Lexington, MA 02421, *Denis.Payre@natureandpeoplefirst.com.*

FERC Contact: Ousmane Sidibe; Phone: (202) 502–6245.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. 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–15233–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's website at *https://www.ferc.gov/ferc-online/elibrary/overview.* Enter the docket number (P–15233) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: November 1, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–24235 Filed 11–4–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP23–112–000.
Applicants: NEXUS Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—DTE Electric 860002 eff 11–1–22 to be effective 11/1/2022.
Filed Date: 10/31/22.
Accession Number: 20221031–5172.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–113–000.
Applicants: NEXUS Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Union Gas 860007 eff 11–1–22 to be effective 11/1/2022.
Filed Date: 10/31/22.
Accession Number: 20221031–5176.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–114–000.
Applicants: DBM Pipeline, LLC.
Description: § 4(d) Rate Filing: Revisions to Preliminary Statement and Contract Summaries to be effective 11/1/2022.
Filed Date: 10/31/22.
Accession Number: 20221031–5178.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–115–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—JP Morgan 911865 eff 11–1–22 to be effective 11/1/2022.
Filed Date: 10/31/22.
Accession Number: 20221031–5189.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–116–000.
Applicants: Destin Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: Destin Pipeline Negotiated Rate Agreement Filing to be effective 11/1/2022.
Filed Date: 10/31/22.
Accession Number: 20221031–5204.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–117–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: REX 2022–10–31 Negotiated Rate Agreements to be effective 11/1/2022.
Filed Date: 10/31/22.
Accession Number: 20221031–5209.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–118–000.
Applicants: Trailblazer Pipeline Company LLC.
Description: § 4(d) Rate Filing: TPC 2022–10–31 Negotiated Rate Agreement Amendment to be effective 11/1/2022.
Filed Date: 10/31/22.
Accession Number: 20221031–5211.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–119–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: TETLP ASA DEC 2022 Filing to be effective 12/1/2022.
Filed Date: 10/31/22.
Accession Number: 20221031–5221.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–120–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Cherokee AGL—Replacement Shippers—Nov 2022 to be effective 11/1/2022.
Filed Date: 10/31/22.
Accession Number: 20221031–5238.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–121–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Amended NJN K910185 eff 11–1–22 to be effective 11/1/2022.
Filed Date: 10/31/22.
Accession Number: 20221031–5253.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–122–000.
Applicants: Maritimes & Northeast Pipeline, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rates—Northern to Direct to be effective 11/1/2022.
Filed Date: 11/1/22
Accession Number: 20221101–5005.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–123–000.
Applicants: Carlsbad Gateway, LLC.
Description: Compliance filing: Carlsbad Gateways 2022 Penalty Revenue Crediting Report to be effective N/A.
Filed Date: 11/1/22.
Accession Number: 20221101–5024.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–124–000.
Applicants: Carlsbad Gateway, LLC.
Description: § 4(d) Rate Filing: Carlsbad Gateway Administration Updates to Tariff to be effective 12/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5025.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–125–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases to be effective 11/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5036.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–126–000.
Applicants: Columbia Gas Transmission, LLC.
Description: § 4(d) Rate Filing: OTRA Winter 2022 to be effective 12/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5068.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–127–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Amended Nextera K911729 eff 11–1–22 to be effective 11/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5069.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–128–000.
Applicants: Great Lakes Gas Transmission Limited Partnership.
Description: § 4(d) Rate Filing: TCPL—18966_7 Neg. Rate Amendment to be effective 11/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5070.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–129–000.
Applicants: Alliance Pipeline L.P.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Nov 1 2022 Contract Adjustments to be effective 11/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5073.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–130–000.
Applicants: Alliance Pipeline L.P.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Nov 1 2022 Releases to be effective 11/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5074.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–131–000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: § 4(d) Rate Filing: Filing to Remove Expired Agreements November 2022 to be effective 12/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5075.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–132–000.
Applicants: Enable Mississippi River Transmission, LLC.
Description: Compliance filing: 2022 Annual Report of Penalty Revenue Credits to be effective N/A.
Filed Date: 11/1/22.
Accession Number: 20221101–5079.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–133–000.
Applicants: Enable Gas Transmission, LLC.
Description: Compliance filing: 2022 Annual Report of Penalty Revenue Credits to be effective N/A.
Filed Date: 11/1/22.
Accession Number: 20221101–5081.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–134–000.
Applicants: Enable Gas Transmission, LLC.
Description: Compliance filing: 2022 Annual Report of Linked Firm Service Penalty Revenue Credits to be effective N/A.
Filed Date: 11/1/22.
Accession Number: 20221101–5084.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–135–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Bug Co Nat 911814 Releases 11–1–2022 to be effective 11/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5085.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–136–000.
Applicants: Rover Pipeline LLC.
Description: § 4(d) Rate Filing: Summary of Negotiated Rate Capacity Release Agreements on 11–1–22 to be effective 11/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5086.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–137–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Keyspan Gas 8978785 eff 11–1–2022 to be effective 11/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5087.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–138–000.
Applicants: NEXUS Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases eff 11–1–2022 to be effective 11/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5095.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–139–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Con Ed 911792 Releases 11–1–2022 to be effective 11/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5098.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–140–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Con Ed 910950 Releases 11–1–2022 to be effective 11/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5100.
Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: RP23–141–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Con Ed Releases 510371 11–1–2022 to be effective 11/1/2022.
Filed Date: 11/1/22.
Accession Number: 20221101–5104.
Comment Date: 5 p.m. ET 11/14/22.

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.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

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: November 1, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–24238 Filed 11–4–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15234–000]

Nature and People First Arizona PHS, LLS; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On October 5, 2021, Nature and People First Arizona PHS, LLC (NFPA) filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of Black Mesa Pumped Storage Project East to be located in Navajo County, Arizona. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) a new upper reservoir west with a surface area of 2,700 acres and a total storage capacity of 55,000 acre-feet at a normal maximum operating elevation of 7,510 feet average mean sea level (msl); (2) a new upper reservoir east with a surface area of 1,300 acres and a total storage capacity of 45,000 acre-feet at a normal maximum operating elevation of 7,510 feet msl; (3) a new lower reservoir with a surface area of 2,800 acres and a total storage capacity of 100,000 acre-feet at a normal maximum operating elevation of 5,810 feet msl; (4) a 15,500-foot-long, 23-foot-diameter concrete lined tunnel and 2,000-foot-long with three 18-foot-diameter concrete lined draft tube tunnel penstock connecting the upper and lower reservoir west to the powerhouse; (5) a 9,100-foot-long, 23-foot-diameter concrete lined tunnel and 2,400-foot-long with three 18-foot-diameter concrete lined draft tube tunnel penstock connecting the upper and lower reservoir east to the powerhouse; (6) two 320-foot-long, 60-foot-wide and 100-foot-high new underground powerhouses containing three turbine-generator units each with a total rated capacity of 1,500 megawatts; (7) a new 110-mile-long, 230-kilovolt (kV) transmission line connecting the powerhouses to Shiprock's existing substation; and (8) appurtenant facilities. The estimated annual power generation at the Black Mesa Pumped Storage East would be 3,285 gigawatt-hours.

Applicant Contact: Mr. Denis Payre, President and CEO, Nature and People First Arizona PHS, LLC 405 Waltham St., Suite 145, Lexington, MA 02421, *Denis.Payre@natureandpeoplefirst.com.*

FERC Contact: Ousmane Sidibe; Phone: (202) 502–6245.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. 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–15234–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's website at *https://www.ferc.gov/ferc-online/elibrary/overview.* Enter the docket number (P–15234) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: November 1, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–24234 Filed 11–4–22; 8:45 am]

BILLING CODE 6717–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–PBS–2022–06; Docket No. 2022–0002; Sequence No. 26]

Notice of Intent To Prepare an Environmental Impact Statement and Initiate Section 106 Consultation for Four Buildings at 202, 208–212, 214 and 220 South State Street, Chicago, Illinois, and Notice of Public Scoping Meetings and Comment Period; Correction

AGENCY: Public Buildings Service (PBS), General Services Administration (GSA).

ACTION: Notice; correction.

SUMMARY: This document corrects a billing code in a **Federal Register** notice published on Tuesday, November 1, 2022, that announced a comment request with intent to prepare for a public scoping meeting.

FOR FURTHER INFORMATION CONTACT: Mr. Joseph Mulligan, GSA, 230 S. Dearborn St., Suite 3600, Chicago, IL 60604; email: *statestreet@gsa.gov;* telephone: 312–810–2326.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of November 1, 2022, in FR Doc. 2022–23721 on page 65773, in column one, correct ''Billing code 6820–A9–P'' to read ''Billing Code 6820–CF''.

William Renner,

Director, Facilities Management and Services Programs Division, U.S. General Services Administration.

[FR Doc. 2022–24219 Filed 11–4–22; 8:45 am]

BILLING CODE 6820–CF–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Award of a Single-Source Cooperative Agreement To Fund the Public Health Accreditation Board (PHAB)

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

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the award of approximately $935,000, with an expected total funding of approximately $4,675,000 over a five-

year period, to Public Health Accreditation Board (PHAB).

DATES: The period for this award will be July 1, 2023 through June 30, 2028.

FOR FURTHER INFORMATION CONTACT: Liza Corso, Center for State, Tribal, Local and Territorial Support, Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, GA 30329–4027 USA, Telephone: 1–800–CDC–INFO (1–800–232–4636), Email: *CSTLTSfeedback@cdc.gov.*

SUPPLEMENTARY INFORMATION: The single-source award will support the operations and continuous improvement of a national accreditation program for state, tribal, local, and territorial public health departments. Through this project, CDC will support the awardee to (1) provide education regarding accreditation; (2) improve and/or develop new products to ensure a relevant, current, and smoothly functioning program; (3) monitor emerging issues, foster innovation, and strengthen strategic partnerships to support and advance accreditation; (4) strengthen the evidence base for the use of accreditation to advance public health practice; and (5) develop and/or continuously improve accreditation standards, programs, and/or products for programmatic or focused areas of public health services.

PHAB is in a unique position to conduct this work, as it is widely recognized by health departments, national organizations, and federal agencies as the only national accrediting body for state, tribal, local, and territorial health departments. PHAB is a non-profit organization that has the infrastructure necessary to support the accreditation program, including staff, a heavily engaged Board of Directors, national consensus standards and measures developed with extensive input from the field, documentation guidance, and an assessment process. PHAB has continuously improved their standards and tools, including using a robust public vetting process to develop and release updated versions of the standards in 2014 and 2022; and launching the Pathways Recognition Program in 2022 for local, tribal, and territorial health departments who seek recognition for their performance improvement efforts and to facilitate accreditation readiness.

Summary of the Award

Recipient: Public Health Accreditation Board (PHAB).

Purpose of the Award: The purpose of this award is to support the operations and continuous improvement of a national accreditation program for state, tribal, local, and territorial public health departments. As of March 2022, 91% of the U.S. population is served by a PHAB-accredited health department; an increase from 58% of the U.S. population in April 2017. Continued support for the national accreditation program is critical.

Amount of Award: $935,000 in Federal Fiscal Year (FFY) 2023 funds, with a total estimated $4,675,000 for the five-year period of performance, subject to availability of funds.

Authority: This program is authorized under Section 317(k)(2) of the Public Health Service Act, [42 U.S.C. 241(a) and 247 b(k)(2), as amended].

Period of Performance: July 1, 2023 through June 30, 2028.

Dated: November 2, 2022.

Terrance Perry,

Chief Grants Management Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–24199 Filed 11–4–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–1572]

Agency Information Collection Activities: Proposed Collection; 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by January 6, 2023.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–1572 Home Health Agency Survey and Deficiencies Report

Under the 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 requires federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Home Health Agency Survey and Deficiencies Report; *Use:* This is a request to revise form CMS–1572 by adding fillable text or check blocks to each data field, thus converting it to a fillable .pdf format. A previous version of the CMS–1572 form had been in a fillable format. However, when it was revised in the past, it was placed into a non-fillable format. We also added a new selection to item #7. The CMS–1572 form is used by State Survey Agencies (SAs) when surveying Home Health Agencies (HHAs) and to collect information about an HHA. These regulations were created by CMS under the authority of sections 1861(o) and 1891 of the Social Security Act (''the Act'').

In the Medicare and Medicaid programs, CMS is responsible for developing Conditions of Participation (CoPs) that facilities must meet to become eligible to receive Medicare payments. State survey agencies (SAs) conduct on-site surveys of Home Health Agencies (HHAs) to ensure that HHA facilities are in compliance with these requirements.

Surveys of HHA providers are intended to ensure and strengthen patient health and safety, to enhance quality of care by emphasizing outcomes rather than process, to implement the Omnibus Reconciliation Act of 1987 (OBRA 87), and to achieve more effective compliance with Federal requirements. The CMS–1572 HHA survey form reflects this fundamental change and directs surveyors to observe and monitor the provision of care in the home setting. HHA surveyors use the CMS–1572 form to assist and direct them in evaluating important information relating to the quality of services provided HHAs in the home setting. Moreover, the CMS–1572 form represents a deficiency-based approach to evaluating and reporting compliance. *Form Number:* CMS–1572 (OMB control number: 0938–0355); *Frequency:* Yearly; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 3,833; *Total Annual Responses:* 3,833; *Total Annual Hours:* 1,917. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705.)

Dated: November 2, 2022.

William N. Parham, III

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–24230 Filed 11–4–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1469]

M10 Bioanalytical Method Validation and Study Sample Analysis; International Council for Harmonisation; 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 final guidance for industry entitled ''M10 Bioanalytical Method Validation and Study Sample Analysis.'' The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation. The guidance describes recommendations for method validation for bioanalytical assays for nonclinical and clinical studies that generate data to support regulatory submissions, including the procedures and processes that should be characterized for chromatographic and ligand-binding assays that are used to measure the parent and active metabolites of drugs administered in nonclinical and clinical subjects. The guidance is intended to provide industry with harmonized regulatory expectations for bioanalytical method validation of assays used to support regulatory submissions. The guidance replaces the draft guidance ''M10 Bioanalytical Method Validation'' issued on June 27, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on November 7, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2019–D–1469 for ''M10 Bioanalytical Method Validation and Study Sample Analysis.'' 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 this 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, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Brian Booth, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2186, Silver Spring, MD 20993–0002, 301–796–1508; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''M10 Bioanalytical Method Validation and Study Sample Analysis.'' The guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of June 27, 2019 (84 FR 30732), FDA published a notice announcing the availability of a draft guidance entitled ''M10 Bioanalytical Method Validation.'' The notice gave interested persons an opportunity to submit comments by September 25, 2019.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies on May 24, 2022.

This guidance provides recommendations on the validation of bioanalytical assays that support regulatory submissions. The final guidance describes the various elements of and recommendations for method validation for assays in nonclinical and clinical studies of new drugs and generic drugs and applies to chromatographic and ligand-binding assays for parent drug and active metabolites in biological matrices such as plasma, blood, or serum. This guidance finalizes the draft guidance of the same title issued in June 2019.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''M10 Bioanalytical Method Validation and Study Sample Analysis.'' 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 for investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information for review of new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information for review of biologics

license applications have been approved under OMB control number 0910–0338. The collections of information pertaining to Good Laboratory Practice Regulations have been approved under OMB control number 0910–0119. The collections of information pertaining to Good Clinical Practice have been approved under OMB control number 0910–0843.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: November 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–24113 Filed 11–4–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–1994 and FDA–2020–E–1995]

Determination of Regulatory Review Period for Purposes of Patent Extension; NOURIANZ

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for NOURIANZ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by January 6, 2023. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 8, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 6, 2023. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 6, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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 Nos. FDA–2020–E–1994 and FDA–2020–E–1995 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; NOURIANZ.'' Received comments, 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 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 § 10.20 (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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, NOURIANZ (istradefylline) indicated as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease experiencing ''off'' episodes. Subsequent to this approval, the USPTO received patent term restoration applications for NOURIANZ (U.S. Patent Nos. 7,727,993 and 7,727,994) from Kyowa Kirin Co., Ltd., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated February 8, 2021, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of NOURIANZ represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for NOURIANZ is 7,300 days. Of this time, 2,792 days occurred during the testing phase of the regulatory review period, while 4,508 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* September 3, 1999. The applicant claims October 6, 1999, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 3, 1999, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* April 25, 2007. FDA has verified the applicant's claim March 29, 2007, as the date the new drug application (NDA) for NOURIANZ (NDA 22075) was initially submitted. However, FDA records indicate that NDA 22075 was submitted on April 25, 2007.

3. *The date the application was approved:* August 27, 2019. FDA has verified the applicant's claims that NDA 22075 was approved on August 27, 2019.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket Nos. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–24217 Filed 11–4–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2066]

Agency Information Collection Activities; Proposed Collection; Comment Request; Certification of Identity for Freedom of Information Act and Privacy Act Requests

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with certain Freedom of Information and Privacy Act requests.

DATES: Either electronic or written comments on the collection of information must be submitted by January 6, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments 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 January 6, 2023. Comments received by mail/hand delivery/courier (for written/

paper submissions) will be considered timely if they are received on or before that date.

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–2016–N–2066 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Certification of Identity for Freedom of Information Act and Privacy Act Requests.'' Received comments, 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 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.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Certification of Identity; Form FDA 3975

OMB Control Number 0910–0832—Extension

This information collection supports Form FDA 3975 entitled ''Certification of Identity,'' which is used by FDA to identify an individual requesting a particular record under the Freedom of Information Act (FOIA) and the Privacy Act. The form is available on our website (at *https://www.fda.gov/media/107210/download*); although if an individual requests one, we will send it by mail or email. The form is required only if an individual makes a FOIA request or Privacy Act request for their own records but has not provided sufficient assurance of identity in the incoming request.

The FOIA grants the public a right to access Federal records not normally prepared for public distribution. The Privacy Act grants a right of access to members of the public who seek access to one's own records that are maintained in an Agency's system of records (*i.e.,* the records are retrieved by that individual's name or other personal identifier). The statutes overlap, and individuals who request their own records are processed under both statutes. The Agency may need to confirm that the individual making the FOIA or Privacy Act request is indeed the same person named in the Agency records. Respondents to the information collection are asked for certain information including name, citizenship

status, social security number, address, date of birth, place of birth, signature, and date of signature.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3975	24	1	24	0.17 (10 minutes)	4

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden.

Dated: November 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–24110 Filed 11–4–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–E–4324]

Determination of Regulatory Review Period for Purposes of Patent Extension; ANGELMED GUARDIAN SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ANGELMED GUARDIAN SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by January 6, 2023. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 8, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments 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 January 6, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2018–E–4324 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ANGELMED GUARDIAN SYSTEM.'' Received comments, 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 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 § 10.20 (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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device ANGELMED GUARDIAN SYSTEM. ANGELMED GUARDIAN SYSTEM is indicated for use in patients who have had prior acute coronary syndrome (ACS) events and who remain at high risk for recurrent ACS events. The ANGELMED GUARDIAN SYSTEM is indicated as an adjunct to patient recognized symptoms. The ANGELMED GUARDIAN SYSTEM detects potential ongoing ACS events, characterized by sustained ST segment changes, and alerts the patient to seek medical attention for those potential ACS events. An ANGELMED GUARDIAN SYSTEM alert is a more accurate predictor of ACS events when compared to patient recognized symptoms alone and demonstrates a reduced rate over time of patient presentations without ACS events (false positives) when compared to patient recognized symptoms alone. In the absence of symptoms, the ANGELMED GUARDIAN SYSTEM may identify asymptomatic ACS events and prompt the patient to seek medical attention. Subsequent to this approval, the USPTO received a patent term restoration application for ANGELMED GUARDIAN SYSTEM (U.S. Patent No. 6,609,023) from Angel Medical Systems, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 13, 2019, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of ANGELMED GUARDIAN SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ANGELMED GUARDIAN SYSTEM is 4,037 days. Of this time, 2,916 days occurred during the testing phase of the regulatory review period, while 1,121 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption for this device, under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), became effective:* March 23, 2007. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) for human tests to begin, as required under section 520(g) of the FD&C Act, became effective March 23, 2007.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* March 16, 2015. FDA has verified the applicant's claim that the premarket approval application (PMA) for ANGELMED GUARDIAN SYSTEM (PMA P150009) was initially submitted March 16, 2015.

3. *The date the application was approved:* April 9, 2018. FDA has verified the applicant's claim that PMA P150009 was approved on April 9, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,827 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–24216 Filed 11–4–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0350]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Retailer Training Programs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 7, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0745. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Tobacco Retailer Training Programs

OMB Control Number 0910–0745—Extension

Tobacco products are governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387u). FDA intends to issue regulations establishing standards for approved tobacco retailer training programs under section 906(d) of the FD&C Act (21 U.S.C. 387f(d)). In the interim, FDA published a guidance document entitled ''Tobacco Retailer Training Programs (Revised)'' (2018) that can be downloaded at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-retailer-training-programs.* The guidance is intended to assist tobacco retailers to voluntarily implement effective training programs for employees.

The guidance discusses recommended elements that should be covered in a training program, such as: (1) Federal laws restricting the access to, and the advertising and promotion of, cigarettes, smokeless, and covered tobacco products; (2) the health and economic effects of tobacco use, especially when the tobacco use begins at a young age; (3) written company policies against sales to youth and other restrictions on the access to, and the advertising and promotion of, tobacco products; (4) identification of the tobacco products sold in the retail establishment that are subject to the Federal laws and regulations prohibiting their sale to underage persons; (5) age verification methods; (6) practical guidelines for refusing sales; and (7) testing to ensure that employees have the required knowledge. The guidance recommends that retailers require current and new employees to take a written test prior to selling tobacco products and that refresher training be provided at least annually and more frequently as needed. The guidance recommends that retailers maintain certain written records documenting that all individual employees have been trained and that retailers retain these records for 4 years in order to be able to provide evidence of a training program during the 48-month time period covered by the civil money penalty schedules outlined in the law.

The guidance also recommends that retailers implement certain hiring and management practices as part of an effective retailer training program. The guidance suggests that applicants and current employees be notified both verbally and in writing of the importance of complying with laws prohibiting the sales of tobacco products to underage persons. In addition, FDA recommends that retailers implement an internal compliance check program and document the procedures and corrective actions for the program.

In the **Federal Register** of May 5, 2022 (87 FR 26766), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; guidance section IV	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Develop training program	79,700	1	79,700	16	1,275,200
Develop written policy against sales to youth and employee acknowledgement	79,700	1	79,700	1	79,700
Develop internal compliance check program	79,700	1	79,700	8	637,600
Total					1,992,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; guidance section IV	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Training program	79,700	4	318,800	0.25 (15 minutes)	79,700
Written policy against sales to youth and employee acknowledgement.	79,700	4	318,800	0.10 (6 minutes)	31,880
Internal compliance check program	79,700	2	159,400	0.5 (30 minutes)	79,700
Total					191,280

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents in tables 1 and 2 is based on data from the deeming rule Final Regulatory Impact Analysis,[1] which showed there are an estimated 362,273 retail establishments that currently sell tobacco products. The Agency reviewed these numbers again for this notice, and believe they are an accurate estimation. We assume that 75 percent of tobacco retailers already have some sort of age and identification verification training program in place. We expect that some of those retailer training programs already meet the elements in the guidance, some retailers would update their training program to meet the elements in the guidance, and other retailers would develop a training program for the first time. Thus, we estimate that two-thirds of tobacco retailers would develop a training program that meets the elements in the guidance (66 percent of 362,273 = 239,100; then annualized to 79,700).

We have adjusted our burden estimate and the number of respondents, which has resulted in a decrease to the currently approved burden and respondent count. This adjustment is based on available data estimating the number of retail establishments that sell tobacco products in the United States. Additionally, the burden chart was updated to reflect a change from an estimation over the course of 3 years to annualized burden.

Dated: November 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–24218 Filed 11–4–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0557]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarket Surveillance of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 7, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0449. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Postmarket Surveillance of Medical Devices—21 CFR Part 822

OMB Control Number 0910–0449—Extension

Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) authorizes FDA to require a manufacturer to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute. The PS regulation establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides instructions to manufacturers, so they know what information is required in a PS plan submission. FDA reviews PS plan submissions in accordance with 21 CFR 822.15 through 822.19 of the regulation, which describe the grounds for approving or disapproving a PS plan. In addition, the PS regulation provides instructions to manufacturers to submit interim and final reports in accordance with 21 CFR 822.38. Respondents to this collection of information are those manufacturers that require PS of their products.

In the **Federal Register** of May 27, 2022 (87 FR 32169), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 822.9 and 822.10; PS submission	5	1	5	120	600
§ 822.21; Changes to PS plan after approval	9	1	9	40	360
§ 822.28; Changes to PS plan for a device that is no longer marketed	1	1	1	8	8
§ 822.29; Waiver	0	0	0	40	0
§ 822.30; Exemption request	0	0	0	40	0
§ 822.38; Periodic reports	17	3	51	40	2,040
Total					3,008

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Explanation of Reporting Burden Estimate: The burden captured in table 1 is based on the data from FDA's internal tracking system. 21 CFR 822.26, 822.27, and 822.34 do not constitute information collection subject to review

[1] Deeming Tobacco Products to be Subject to the [Federal] Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act: Final Regulatory Impact Analysis, 2016 *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM500254.pdf.*

under the PRA because it entails no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument (see 5 CFR 1320.3(h)(1)).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 822.31; Manufacturer records	5	1	5	20	100
§ 822.32; Investigator records	15	1	15	5	75
Total					175

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Explanation of Recordkeeping Burden Estimate: FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically based surveillance plan, using three investigators. These estimates are based on FDA's knowledge and experience with PS.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. Our estimated burden for the information collection reflects an overall decrease of 4,780 hours and a corresponding decrease of 145 responses. We believe these adjustments more accurately reflect the current number of requests associated with postmarket surveillance of medical devices.

Dated: November 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–24232 Filed 11–4–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0776]

Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial; 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 final guidance entitled ''Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial; Guidance for Industry.'' The guidance document provides recommendations to sponsors interested in studying multiple versions of a cellular or gene therapy product in an early phase clinical trial for a single disease. Sponsors have expressed interest in gathering preliminary evidence of safety and activity using multiple versions of a cellular or gene therapy product in a single clinical trial, where each version of the product is distinct and is generally submitted to FDA in a separate investigational new drug application (IND). The guidance provides recommendations for conducting such studies, including how to organize and structure the INDs, submit new information, and report adverse events. The guidance announced in this notice finalizes the draft guidance of the same title dated September 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on November 7, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2021–D–0776 for ''Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial; Guidance for Industry.'' 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 Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jessica Gillum, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial; Guidance for Industry.'' The guidance document provides recommendations to sponsors interested in studying multiple versions of a cellular or gene therapy product in an early phase clinical trial for a single disease. Sponsors have expressed interest in gathering preliminary evidence of safety and activity using multiple versions of a cellular or gene therapy product in a single clinical trial, where each version of the product is distinct and is generally submitted to FDA in a separate IND. The objective of these early phase clinical studies is to guide which version(s) of the product to pursue for further development in later phase studies. Thus, these studies are not intended to provide primary evidence of effectiveness to support a marketing application and generally are not adequately powered to demonstrate a statistically significant difference in efficacy between the study arms. The guidance provides recommendations for conducting such studies, including how to organize and structure the INDs, submit new information, and report adverse events.

In the **Federal Register** of September 30, 2021 (86 FR 54207), FDA announced the availability of the draft guidance entitled ''Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early Phase Clinical Trial.'' FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. Changes to the guidance include clarifying how to continue the umbrella trial after a study arm has been closed and adding examples of changes that result in multiple versions of a cellular or gene therapy product. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance of the same title dated September 2021.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial.'' 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 and Form FDA 1572 have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: November 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–24112 Filed 11–4–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2671]

Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following virtual public meeting entitled ''Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023'' to allow supply chain stakeholders an opportunity to share their perspectives. The topics to be discussed are stakeholder experiences with implementation and overall readiness regarding implementation of enhanced drug distribution security requirements that will go into effect on November 27, 2023, standards for the interoperable data exchange of product tracing information, requests for product tracing information or verification from FDA for the purpose of investigating suspect or illegitimate products or for recalls, steps taken to build capacity for package-level tracing, pharmaceutical distribution supply chain best practices, and, in general, the impact that the Drug Supply Chain Security Act (DSCSA) requirements would have on public health, including patient safety and access to prescription drugs, and on

stakeholders, in terms of costs, benefits, and regulatory burden.

DATES: The public meeting will be held on December 7 and 8, 2022, from 10 a.m. to 3 p.m. eastern time and will take place virtually. Either electronic or written comments on this public meeting must be submitted by February 6, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held virtually and hosted by FDA.

You may submit comments as follows. Please note that late, untimely filed comments 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 February 6, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–N–2671 for ''Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023; Public Meeting; Request for Comments.'' Received comments, 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 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.

FOR FURTHER INFORMATION CONTACT: Kristle Green, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Silver Spring, MD 20993, 301–796–3130, *CDERODSIRPublicMeetings@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On November 27, 2013, the DSCSA (title II, Pub. L. 113–54) was signed into law. The DSCSA outlines critical steps to achieve electronic, interoperable tracing at the package level by 2023 to identify and trace certain prescription drugs as they are distributed within the United States. DSCSA requirements enhance FDA's ability to protect U.S. consumers from exposure to drugs that may be counterfeit, diverted, stolen, intentionally adulterated, or otherwise harmful by improving the detection and removal of potentially dangerous drugs from the drug supply chain.

Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee–1(g)(1)) imposed requirements for enhanced drug distribution security that go into effect on November 27, 2023. Section 582(i) of the FD&C Act directs FDA to hold public meetings to enhance the safety and security of the pharmaceutical distribution supply chain and provide opportunities for comment from members of the pharmaceutical distribution supply chain and other interested stakeholders. Since enactment of the law, FDA has held multiple public meetings that address specific topics as they relate to implementation of DSCSA requirements. As the capabilities of the pharmaceutical distribution supply chain have progressed and matured, this public meeting will be used to gather stakeholder perspectives on DSCSA implementation.

II. Topics for Discussion at the Public Meeting

- Stakeholder experiences with implementation and overall readiness regarding implementation of enhanced drug distribution security requirements that will go into effect on November 27, 2023.
- DSCSA standards for the interoperable data exchange of product tracing information for enhanced product tracing and verification.
- FDA requests to trading partners for product tracing information, verification for the purpose of investigations of suspect or illegitimate products, or recalls to support enhanced drug

distribution requirements under section 582(g) of the FD&C Act.

- Steps taken by the pharmaceutical distribution supply chain to build capacity for package-level tracing, including the ability of the healthcare system to maintain patient access to medicines, scalability of DSCSA requirements, and best practices.
- Technical capabilities and legal authorities, if any, needed to establish interoperable, electronic product tracing at the package level.
- General impact that the DSCSA requirements would have on public health, including patient safety and access to prescription drugs, and on stakeholders, in terms of costs, benefits, and regulatory burden.

If other topics are identified as appropriate, FDA will post these on the designated public meeting web page prior to the meeting.

III. Participating in the Public Meeting

Registration: This will be a virtual public meeting and there are no fees for this meeting. FDA may limit registration once the meeting capacity is reached. Individuals who wish to attend the general session of the public meeting must register by December 2, 2022, and provide the following information on the public meeting registration page: Your name, organization name, stakeholder type, email address, and telephone number to FDA at *https://dscsapublicmeeting2022.eventbrite.com.* Meeting information for virtual participation will be emailed by December 5, 2022, to those that registered.

If you need special accommodations due to a disability, please contact Kristle Green (see **FOR FURTHER INFORMATION CONTACT**) no later than 7 days before the public meeting.

Breakout Sessions: Any person interested in participating in small group discussions must register by November 28, 2022, following the instructions above, and indicate your request for breakout session participation. There will be no same-day registration for breakout sessions. FDA will organize breakout sessions based on registration and interest to help ensure varied stakeholder representation, including across the pharmaceutical distribution supply chain. FDA may limit the number of participants from each organization if interest exceeds breakout session capacity.

Request for Oral Presentations: Any person interested in presenting during the public meeting must register by November 28, 2022, following the instructions above, and indicate your request to present. There will be no same-day registration for oral presentations. FDA will do its best to accommodate requests for oral presentations. Individuals and organizations with common interests are encouraged to consolidate or coordinate their presentations and can submit a single request to present. Time allotted for each presentation will depend on the number of requests received and may be limited.

FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Other Issues for Consideration: FDA will provide a recording of the public meeting and materials from the meeting at *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa-implementation-and-readiness-efforts-2023-12072022* after the public meeting.

Dated: November 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–24212 Filed 11–4–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 Mental Health Special Emphasis Panel; Pathway to Independence Awards (K99/R00).

Date: December 2, 2022.

Time: 9:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Nicholas Gaiano, Ph.D., Review Branch Chief, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center/Room 6150/MSC 9606, 6001 Executive Boulevard, Bethesda, MD 20892–9606, 301–443–2742, *nick.gaiano@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 1, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–24115 Filed 11–4–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; NCI Genomic Data Commons (GDC) Data Submission Request Form (National Cancer Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide an opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Zhining Wang, Ph.D., Project Officer, Center for Cancer Genomics (CCG), National Cancer Institute, Building 31, Room 3A20, 31 Center Drive, Bethesda, MD 20814 or call non-toll-free number 301–402–1892 or Email your request, including your address to: *zhining.wang@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and suggestions from the public, and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the

function of the agency, including whether the information will have practical utility; (2) 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways 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.

Proposed Collection Title: NCI Genomic Data Commons (GDC) Data Submission Request Form, 0925–0752, Expiration Date 03/31/2023, EXTENSION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of the NCI Genomic Data Commons (GDC) Data Submission Request Form is to provide a vehicle for investigators to request the submission of their cancer genomic data into the GDC in support of data sharing. The purpose is also to provide a mechanism for the GDC Data Submission Review Committee to review and assess the data submission request for applicability to the GDC mission. The scope of the form involves obtaining information from investigators that: (1) would like to submit data about their study into the GDC, (2) are affiliated with studies that adhere to GDC data submission conditions. The benefits of the collection are that it provides the needed information for investigators to understand the types of studies and data that the GDC supports and that it provides a standard mechanism for the GDC to assess incoming data submission requests.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 50 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Investigator	200	1	15/60	50
Total	.....	200	.....	50

Dated: November 2, 2022.

Diane Kreinbrink,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2022–24186 Filed 11–4–22; 8:45 am]

BILLING CODE 4140–01–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: Center for Scientific Review Special Emphasis Panel; RFA: Countermeasures Against Chemical Threats Exploratory/Developmental Projects.

Date: December 5, 2022.

Time: 8:30 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: Jodie Michelle Fleming, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 812R, Bethesda, MD 20892, (301) 867–5309, *flemingjm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Microbial Vaccine Development.

Date: December 5–6, 2022.

Time: 10:00 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: Subhamoy Pal, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–0926, *subhamoy.pal@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Oncology.

Date: December 6–7, 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: Nywana Sizemore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6189, MSC 7804, Bethesda, MD 20892, 301–408–9916, *sizemoren@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Epigenomics of Neurodevelopment.

Date: December 6, 2022.

Time: 2:00 p.m. to 3:00 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: Mary G Schueler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7846, Bethesda, MD 20892, 301–915–6301, *marygs@csr.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: November 2, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–24204 Filed 11–4–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Sleep Disorders Research Advisory Board, December 01, 2022, 12 p.m. to December 01, 2022, 4 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD, 20892 which was

published in the **Federal Register** on November 01, 2022, 87 FR 65786.

Meeting is being amended to change the meeting time from 12 p.m. to 4 p.m. to 12 p.m. to 5 p.m. Also to change the agenda from, ''The purpose of this meeting is to update the Advisory Board and public stakeholders on the research agenda across NIH for the upcoming fiscal year, and the activities of professional societies.'' to ''The purpose of this meeting is to discuss with the Advisory Board timely research opportunities in sleep and circadian biology. Updates on the research agenda across the NIH for the upcoming fiscal year and the activities of professional societies will be provided to all stakeholders.'' The meeting is open to the public.

Dated: November 2, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–24203 Filed 11–4–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6331–N–08]

Public Interest De Minimis, Small Grants, and Minor Components Waiver of Build America, Buy America Provisions as Applied to Certain Recipients of HUD Federal Financial Assistance

AGENCY: Office of the Secretary, U.S. Department of Housing and Urban Development (HUD).

ACTION: Notice.

SUMMARY: In accordance with the Build America, Buy America Act (''BABA'' or ''the Act'') this notice advises that HUD is proposing a departmentwide public interest *de minimis,* Small Grants, and Minor Components waiver to the Buy America Domestic Content Procurement Preference (''Buy America Preference,'' or ''BAP'') as applied to the iron, steel, manufactured products, and construction materials requirement of the Act for recipients of Federal Financial Assistance. For the purposes of this proposed waiver, HUD is proposing to waive the application of the BAP for infrastructure projects whose total cost is an amount equal to or less than the Simplified acquisition threshold, which is currently $250,000. HUD is also proposing to waive the application of the BAP for all Small Grants of Federal Financial Assistance that are equal to or below the Simplified acquisition threshold, which is currently $250,000. Additionally, HUD is proposing to waive the application of the BAP for Minor Components of an infrastructure project, such that a cumulative total of no more than a total of 5 percent of the total cost of the iron, steel, manufactured products, and construction materials used in and incorporated into the infrastructure project, up to a maximum of $1 million. In accordance with the Act, HUD has found that such proposed De Minimis, Small Grants and Minor Components waivers are in the public interest. The waiver will assist HUD and its grantees and funding recipients in preventing immediate delays to critically important projects that serve to ensuring the safety and health of HUD constituents and continuing to provide economic opportunity through housing and community development projects. Moreover, this waiver will assist HUD in working to strengthen the housing market to bolster the economy and protect consumers, meet the need for quality affordable rental homes, utilize housing as a platform for improving quality of life, and build inclusive and sustainable communities free from discrimination.

DATES: HUD published this proposed waiver on its website on October 31, 2022. Comments on the proposed waiver set out in this document are due on or before November 15, 2022.

ADDRESSES: Interested persons are invited to submit comments on this proposed general applicability waiver. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

To receive consideration as public comments, comments must be submitted through one of two methods, specified below. All submissions must refer to the above docket number and title.

1. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.*

HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

2. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500.

No Facsimile Comments. Facsimile (FAX) comments will not be accepted.

3. *Public Inspection of Comments.* All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8:00 a.m. and 5:00 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the submissions must be scheduled by calling the Regulations Division at (202) 708–3055 (this is not a toll-free number).

FOR FURTHER INFORMATION CONTACT: Joseph Carlile, Department of Housing and Urban Development, 451 Seventh Street SW, Room 10226, Washington, DC 20410–5000, at (202) 402–7082 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* HUD encourages submission of questions about this document be sent to *BuildAmericaBuyAmerica@hud.gov.*

SUPPLEMENTARY INFORMATION:

I. Build America, Buy America

The Build America, Buy America Act (''BABA'' or ''the Act'') was enacted on November 15, 2021, as part of the Infrastructure Investment and Jobs Act (IIJA). Public Law 117–58. The Act establishes a domestic content procurement preference, the BAP, for Federal infrastructure programs. Section 70914(a) of the Act establishes that no later than 180 days after the date of enactment, HUD must ensure that none of the funds made available for infrastructure projects may be obligated by the Department unless it has taken steps to ensure that the iron, steel, manufactured products, and construction materials used in a project are produced in the United States. In section 70912, the Act further defines a project to include ''the construction, alteration, maintenance, or repair of infrastructure in the United States'' and includes within the definition of infrastructure those items traditionally included along with buildings and real property. Thus, starting May 14, 2022,

new awards of Federal Financial Assistance from a program for infrastructure, and any of those funds obligated by the grantee, are covered under BABA provisions of the Act, 41 U.S.C. 8301 note, unless covered by a waiver.

II. HUD's Progress in Implementation of the Act

Since the enactment of the Act, HUD has worked diligently to implement the BAP. Consistent with the requirements of section 70913 of the Act, HUD produced a report identifying and evaluating all of HUD's Federal Financial Assistance programs for compliance with the BAP on January 19, 2022, through **Federal Register** notice ''Identification of Federal Financial Assistance Infrastructure Programs Subject to the Build America, Buy America Provisions of the Infrastructure Investment and Jobs Act''. (87 FR 2894) In order to ensure orderly implementation of the BAP across HUD's programs, HUD published two general applicability waivers for HUD's programs on May 3, 2022. The first notice, ''General Applicability Waiver of Build America, Buy America Provisions as Applied to Recipients of HUD Federal Financial Assistance'' (87 FR 26219), extended the implementation date for the BAP until November 14, 2022, unless covered by a subsequent waiver. Thus, no funds obligated by HUD before November 14, 2022, are subject to the BAP. The second notice, ''General Applicability Waiver of Build America, Buy America Provisions as Applied to Tribal Recipients of HUD Federal Financial Assistance'' (87 FR 26221), extended the implementation date for the BAP for Federal Financial Assistance provided to Tribal recipients for a period of one year. Additionally, HUD published a Request for Information ''Request for Information Relating to the Implementation of the Build America, Buy America Act'' to gather additional information necessary to fully implement the BAP for HUD programs and to adequately prepare necessary Paperwork Reduction Act notices relating to such implementation. (June 1, 2022, 87 FR 33193)

Additional details on HUD's implementation of the BABA requirements can be found at *https://www.hud.gov/programoffices/generalcounsel/BABA.*

III. Waiver Authority

Under section 70914(b), HUD has authority to waive the application of a domestic content procurement preference when (1) application of the preference would be contrary to the public interest, (2) the materials and products subject to the preference are not produced in the United States at a sufficient and reasonably available quantity or satisfactory quality, or (3) inclusion of domestically produced materials and products would increase the cost of completing the Covered Activities by more than 25 percent. Section 70914(c) provides that a waiver under 70914(b) must be published by the agency with a detailed written explanation for the proposed determination and provide a public comment period of not less than 15 days.

IV. Public Interest in This General Applicability Waiver of Buy America Provisions

The Office of Management and Budget's April 18, 2022, memorandum, ''Initial Implementation Guidance on Application of Buy America Preference in Federal Financial Assistance Programs for Infrastructure'' (M–22–11) encourages agencies to consider whether it is in the public interest to waive application of a BAP to awards below the Simplified Acquisition Threshold. HUD is proposing this waiver not as an alternative to increasing domestic production, but as an important tool to implement the Buy American provisions in the most efficient manner in order to promote investment in HUD's domestic manufacturing base, strengthen critical supply chains, and position United States workers and businesses to compete and lead globally in the 21st century. HUD understands that advancing Made in America objectives is a continuous effort. HUD plans to move forward to implement the new requirements in a way that maximizes coordination and collaboration to support long-term investments in domestic production.

Through this notice, HUD is proposing to waive the application of the BAP for infrastructure projects whose total cost is an amount equal to or less than the 2 CFR 200.1 *Simplified acquisition threshold,* which is currently $250,000. HUD is also proposing to waive the application of the BAP for all Small Grants of Federal Financial Assistance that are equal to or below the 2 CFR 200.1 *Simplified acquisition threshold,* which is currently $250,000. HUD is also proposing to waive the application of the BAP for Minor Components of an infrastructure project, such that a cumulative total of no more than a total of 5 percent of the total cost of the iron, steel, manufactured products, and construction materials used in and incorporated into the infrastructure project, up to a maximum of $1 million.

For purposes of the Act, an infrastructure project involves the undertaking of any ''construction, alteration, maintenance, or repair'' of ''infrastructure,'' which includes, among other things, the ''structures, facilities and equipment'' of ''buildings and real property.''

In accordance with the Act, HUD has found that such proposed De Minimis, Small Grants and Minor Components waivers are in the public interest. Such waivers will allow HUD, grantees and funding recipients to focus their efforts on such critical projects. Proposing the waivers is not an alternative to increasing domestic production. It is actually a tool to promote investment in HUD's domestic manufacturing base in the long term. The waivers are in the interest of efficiency, to ease burdens for HUD grantees and funding recipients, will also allow HUD to focus, particularly in the early phases of BABA implementation, on key products, and critical supply chains where increased U.S. manufacturing can best advance our economic and national security. These waivers will allow HUD grantees and funding recipients to continue with projects. Without these waivers, HUD will likely lose grantee and funding recipient participation, be exposed to liabilities if HUD forces grantees and funding recipients to modify their current plans to come into compliance or delay critical activities to protect life, safety and property, and will negatively impact the most vulnerable Americans HUD seeks to serve.

For purposes of this waiver, HUD will evaluate the total cost of the infrastructure project as it would for purposes of the review contemplated under 24 CFR part 58, *i.e.,* by defining the scope consistent with 24 CFR 58.2(a)(4), as ''the activity, or a group of integrally related activities, designed by the recipient to accomplish, in whole or in part, a specific objective.'' HUD believes its grantees and recipients of Federal Financial Assistance that will be used for Covered Activities are familiar with this regulation and understand the proper application of the concept in connection with their activities, or as otherwise defined by HUD in a notice. However, in connection with the public housing program, evaluation of certain maintenance and repair activities within the definition of infrastructure projects under the Act is not appropriate using this standard. Therefore, for the purposes of determining the applicability of this waiver in connection with the maintenance and

repair of public housing, HUD will evaluate the infrastructure project as including the single relevant procurement contract for such maintenance or repairs, or, where applicable, the collection of procurements focused on the same specific objective (*e.g.,* construction of a resident service space) or limited scope of work (*e.g.,* lead based paint abatement).

In fiscal year 2022, HUD grantees will receive more than $15 billion through the Department's programs where infrastructure is an eligible activity and may be subject to the BAP. For example, Community Development Block Grant (CDBG) funds may be used for infrastructure projects (*e.g.,* water and sewer improvements, street improvements, neighborhood facilities) or non-infrastructure uses (*e.g.,* senior services, youth services, operation of food banks, administrative and planning expenses). HUD estimates that 40 percent of CDBG funds awarded in 2021 ($1.4 billion of $3.5 billion total) were used on infrastructure projects where the BAP could apply.

As HUD's previous Notice advised and as supported by several comments received during the comment period, many of HUD's programs may be subject to the BAP and have previously not required compliance with similar Buy American preferences. Because the potential application of BAP mandated by the Act is new to the majority of HUD's programs and Federal Financial Assistance, this waiver advances BABA by reducing the administrative burden to potential assistance recipients where the costs of compliance with BABA could distract from the focus on higher value BABA compliant items. Failure to provide recipients such flexibilities could delay the award for infrastructure projects as grantees and funding recipients must exert considerable effort accounting for the sourcing for miscellaneous, low-cost items. Moreover, HUD does not believe the waiver of the BAP for such awards will undermine the full and robust implementation of the Act or the ability of the agency to support the purposes behind the Act.

HUD expects to review this waiver every five years from the effective date of this waiver or more often as appropriate. No funds obligated by HUD or the grantee/funding recipient during the period of the waiver that would be exempted from compliance with BAP as a result of the waiver will be required to apply the BAP.

V. Impact of This Waiver on Other Federal Financial Assistance

Where the BAP or other BABA requirements are made applicable to projects of a grantee or funding recipient by another Federal agency, the grantee or funding recipient may not rely on this waiver as a waiver of any requirement imposed by the other Federal agency for the projects, nor is the grantee or funding recipient exempt from the application of those requirements in accordance with the requirements of the Federal agency providing such Federal Financial Assistance.

VI. Assessment of Cost Advantage of a Foreign-Sourced Product

Under OMB Memorandum M–22–11, ''Memorandum for Heads of Executive Departments and Agencies,'' published on April 18, 2022, agencies are expected to assess ''whether a significant portion of any cost advantage of a foreign-sourced product is the result of the use of dumped steel, iron, or manufactured products or the use of injuriously subsidized steel, iron, or manufactured products'' as appropriate before granting a public interest waiver.[1] HUD's analysis has concluded that this assessment is not applicable to this waiver, as this waiver is not based in the cost of foreign-sourced products. HUD will perform additional market research during the duration of the waiver to better understand the market to limit the use of waivers caused by dumping of foreign-sourced products.

VI. Solicitation of Comments on the Waiver

As required under section 70914 of the Act, HUD is soliciting comment from the public on the waiver announced in this Notice. In particular, HUD invites comments on whether the reliance on the Simplified acquisition threshold is an appropriate measure and if it is set at an appropriate level for purposes of the waiver. Additionally, HUD seeks comments on the percentage of costs excluded from coverage and whether there should be a cap on the total amount excluded from coverage. For example, should the total costs allowed to be excluded be limited only by the 5% exclusion, is the cap of $1 million appropriate or should it be capped at some other threshold?

Marcia L. Fudge,

Secretary.

[FR Doc. 2022–24296 Filed 11–3–22; 11:15 am]

BILLING CODE 4210–67–P

[1] See OMB Memorandum M–22–08, Identification of Federal Financial Assistance Infrastructure Programs Subject to the Build America, Buy America Provisions of the Infrastructure Investment and Jobs Act, *https://www.whitehouse.gov/wp-content/uploads/2021/12/M-22-08.pdf.*

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6331–N–05]

Public Interest Exigent Circumstances Waiver of Build America, Buy America Provisions as Applied to Certain Recipients of HUD Federal Financial Assistance

AGENCY: Office of the Secretary, U.S. Department of Housing and Urban Development (HUD).

ACTION: Notice.

SUMMARY: In accordance with the Build America, Buy America Act (''BABA'' or ''the Act'') this notice advises that HUD is proposing a departmentwide public interest waiver to the Buy America Domestic Content Procurement Preference (''Buy America Preference,'' or ''BAP'') for grantees and recipients of Federal Financial Assistance from HUD as applied to the iron, steel, manufactured products, and construction materials requirement of BABA in certain exigent circumstances. In accordance with the Act, HUD has found that this proposed departmentwide exigent circumstances waiver is in the public interest. The waiver will assist HUD and its grantees and funding recipients in preventing immediate delays to critically important projects that serve to ensuring the safety and health of HUD constituents and continuing to provide economic opportunity through housing and community development projects. Moreover, this waiver will assist HUD in working to strengthen the housing market to bolster the economy and protect consumers, meet the need for quality affordable rental homes, utilize housing as a platform for improving quality of life, and build inclusive and sustainable communities free from discrimination.

DATES: HUD published this proposed waiver on its website on October 31, 2022. Comments on the proposed waiver set out in this document are due on or before November 15, 2022.

ADDRESSES: Interested persons are invited to submit comments on this proposed general applicability waiver. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

To receive consideration as public comments, comments must be submitted through one of two methods, specified below. All submissions must refer to the above docket number and title.

1. Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.*

HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

2. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500.

No Facsimile Comments. Facsimile (FAX) comments will not be accepted.

3. Public Inspection of Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8:00 a.m. and 5:00 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the submissions must be scheduled by calling the Regulations Division at (202) 708–3055 (this is not a toll-free number).

FOR FURTHER INFORMATION CONTACT: Joseph Carlile, Department of Housing and Urban Development, 451 Seventh Street SW, Room 10226, Washington, DC 20410–5000, at (202) 402–7082 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* HUD encourages submission of questions about this document be sent to *BuildAmericaBuyAmerica@hud.gov.*

SUPPLEMENTARY INFORMATION:

I. Build America, Buy America

The Build America, Buy America Act (''BABA'' or ''the Act'') was enacted on November 15, 2021, as part of the Infrastructure Investment and Jobs Act (IIJA). Public Law 117–58. The Act establishes a domestic content procurement preference, the BAP, for Federal infrastructure programs. Section 70914(a) of the Act establishes that no later than 180 days after the date of enactment, HUD must ensure that none of the funds made available for infrastructure projects may be obligated by the Department unless it has taken steps to ensure that the iron, steel, manufactured products, and construction materials used in a project are produced in the United States. In section 70912, the Act further defines a project to include ''the construction, alteration, maintenance, or repair of infrastructure in the United States'' and includes within the definition of infrastructure those items traditionally included along with buildings and real property. Thus, starting May 14, 2022, new awards of Federal Financial Assistance from a program for infrastructure, and any of those funds obligated by the grantee, are covered under the BABA provisions of the Act, 41 U.S.C. 8301 note, unless covered by a waiver. Section 70912(4)(B) of the Act specifically exempts from the term Federal Financial Assistance certain assistance authorized under certain sections of the Robert T. Stafford Disaster Relief and Emergency Assistance Act or *pre and post disaster or emergency response expenditures.*

II. HUD's Progress in Implementation of the Act

Since the enactment of the Act, HUD has worked diligently to implement the BAP. Consistent with the requirements of section 70913 of the Act, HUD produced a report identifying and evaluating all of HUD's Federal Financial Assistance programs for compliance with the BAP on January 19, 2022, by **Federal Register** notice ''Identification of Federal Financial Assistance Infrastructure Programs Subject to the Build America, Buy America Provisions of the Infrastructure Investment and Jobs Act''. (87 FR 2894) In order to ensure orderly implementation of the BAP across HUD's programs, HUD published two general applicability waivers for HUD's programs on May 3, 2022. The first notice, ''General Applicability Waiver of Build America, Buy America Provisions as Applied to Recipients of HUD Federal Financial Assistance'' (87 FR 26219), extended the implementation date for the BAP until November 14, 2022, unless covered by a subsequent waiver. Thus, no funds obligated by HUD before November 14, 2022, are subject to the BAP. The second notice, ''General Applicability Waiver of Build America, Buy America Provisions as Applied to Tribal Recipients of HUD Federal Financial Assistance'' (87 FR 26221), extended the implementation date for the BAP for Federal Financial Assistance provided to Tribal recipients for a period of one year. Additionally, HUD published a Request for Information ''Request for Information Relating to the Implementation of the Build America, Buy America Act'' to gather additional information necessary to fully implement the BAP for HUD programs and to adequately prepare necessary Paperwork Reduction Act notices relating to such implementation. (June 1, 2022, 87 FR 33193)

Additional details on HUD's implementation of the BABA requirements can be found at *https://www.hud.gov/program_offices/general_counsel/BABA.*

III. Waiver Authority

Under section 70914(b), HUD has authority to waive the application of a domestic content procurement preference when (1) application of the preference would be contrary to the public interest, (2) the materials and products subject to the preference are not produced in the United States at a sufficient and reasonably available quantity or satisfactory quality, or (3) inclusion of domestically produced materials and products would increase the cost of the overall project by more than 25 percent. Section 70914(c) provides that a waiver under 70914(b) must be published by the agency with a detailed written explanation for the proposed determination and provide a public comment period of not less than 15 days.

IV. Public Interest in This General Applicability Waiver of Buy America Provisions

HUD is proposing this waiver not as an alternative to increasing domestic production, but as an important tool to implement the Buy American provisions in the most efficient manner in order to promote investment in HUD's domestic manufacturing base, strengthen critical supply chains, and position United States workers and businesses to compete globally in the 21st century. HUD understands that advancing Made in America objectives is a continuous effort. HUD plans to move forward to implement the new requirements in a way that maximizes

coordination and collaboration to support long-term investments in domestic production.

HUD recognizes that there are exigent circumstances, particularly with respect to the conduct of maintenance and other rehabilitation and repair activities in connection with affordable housing and community development projects, that warrant the exclusion from the application of the BAP in the public interest. Specifically, where an award for Federal Financial Assistance is being utilized to repair or conduct maintenance of infrastructure within the meaning of the Act in exigent circumstances, the ability to quickly respond and address the need is critical to ensuring the protection of life, safety and property of residents and community members. This ability to immediately respond to such situations could be compromised if the grantee or recipient is required to navigate the complex BAP requirements for such an activity in the midst of the exigent circumstances.[1] Such a waiver will allow HUD grantees and funding recipients to focus their efforts on such critical projects. Proposing the waiver is not an alternative to increasing domestic production. It is actually a tool to promote investment in our domestic manufacturing base in the long term. The waiver is in the interest of efficiency, to ease burdens for grantees and recipients, avoid unnecessary costs, and avoid delays to projects that are critical and time sensitive. The waiver will also allow HUD to focus, particularly in the early phases of BABA implementation, on key products and critical supply chains where increased U.S. manufacturing can best advance HUD's economic and national security. This waiver will also allow recipients to continue with projects. Without this waiver, HUD will likely lose grantee and funding recipient participation, be exposed to liabilities if HUD forces grantees and funding recipients to modify their current plans to come into compliance or delay critical activities to protect life, safety and property, and will negatively impact the most vulnerable Americans HUD seeks to serve.

For example, if a public housing development is damaged by a boiler malfunction in the middle of the winter, the need to repair the damaged structure and replace the boiler is of immediate concern in protecting the life, safety, and property of the residents of that public housing development. Additionally, for example, if an emergency or fire exit door is damaged and becomes unusable, the need to repair the exit door is of immediate concern to protecting the life, safety and property of the residents of that public housing development. Included within the scope of exigent circumstances are the remediation of defects impacting housing quality standards that existing HUD policy requires to be completed within 30 days or less. The potential consequences and impact of incidents meeting these standards can endanger the life, safety or property of residents and the community, and necessitate urgent action to remediate the issue. Thus, for purposes of this waiver, HUD will consider exigent circumstances to include circumstances where undertaking the BAP covered activity without delay is necessary to protect life, safety or provide necessary security to residents or community members, or to prevent the destruction of property. The waiver of BAP will apply provided such remediation is carried out within the time period required by HUD policy.

In fiscal year 2022, HUD grantees will receive more than $15 billion through the Department's programs where infrastructure is an eligible activity and may be subject to the BAP. For example, Community Development Block Grant (''CDBG'') funds may be used for infrastructure projects (*e.g.,* water and sewer improvements, street improvements, neighborhood facilities) or non-infrastructure uses (*e.g.,* senior services, youth services, operation of food banks, administrative and planning expenses). HUD estimates that 40 percent of CDBG funds awarded in 2021 ($1.4 billion of $3.5 billion total) were used on infrastructure projects where the BAP could apply. HUD does not currently track funds used on infrastructure projects for an exigent circumstance, but estimates that in an average year, less than 1 percent of annual CDBG funds are used for urgent needs activities.

HUD believes that full compliance with the BAP in exigent circumstances will create undue hardship due to the anticipated burdensome delays to ensure compliance with the BAP and, as noted, could jeopardize the life, health and safety of residents and community members unnecessarily for funds being utilized in exigent circumstances. As a result, HUD has determined that it is not in the public interest to impose the BAP on projects completing covered infrastructure activities in exigent circumstances.

HUD expects to review this waiver every five years from the effective date of this waiver or more often as appropriate. Funds obligated by HUD during the time period this waiver is effective will not be required to apply the BAP when funds are expended by the grantee or funding recipient in connection with exigent circumstances as described in this waiver.

V. Impact of This Waiver on Other Federal Financial Assistance

Where the BAP or other BABA requirements are made applicable to projects of a grantee or funding recipient by another Federal agency, the grantee or funding recipient may not rely on this waiver as a waiver of any requirement imposed by the other Federal agency for the projects, nor is the grantee or funding recipient exempt from the application of those requirements in accordance with the requirements of the Federal agency providing such Federal Financial Assistance.

VI. Assessment of Cost Advantage of a Foreign-Sourced Product

Under OMB Memorandum M–22–11, ''Memorandum for Heads of Executive Departments and Agencies,'' published on April 18, 2022, agencies are expected to assess ''whether a significant portion of any cost advantage of a foreign-sourced product is the result of the use of dumped steel, iron, or manufactured products or the use of injuriously subsidized steel, iron, or manufactured products'' as appropriate before granting a public interest waiver.[2] HUD's analysis has concluded that this assessment is not applicable to this waiver, as this waiver is not based in the cost of foreign-sourced products. HUD will perform additional market research during the duration of the waiver to better understand the market to limit the

[1] Please note that section 70912(4)(B) of the Act excludes ''pre and post disaster or emergency response expenditures from inclusion within the definition of Federal Financial Assistance subject to the BAP. The Office of Management and Budget's April 18, 2022, memorandum, ''Initial Implementation Guidance on Application of Buy America Preference in Federal Financial Assistance Programs for Infrastructure'' (M–22–11) confirms that pre and post disaster or emergency response expenditures'' includes those expenditures ''that are (1) authorized by statutes other than the Stafford Act, 42 U.S.C. 5121 *et seq.,* and (2) made in anticipation of or response to an event or events that qualify as an ''emergency'' or ''major disaster'' within the meaning of the Stafford Act, *id.* section 5122(1), (2).'' As a result, HUD's provision of Federal Financial Assistance through specific emergency and disaster recovery grants, (*e.g.,* CDBG–DR grants), which are appropriated by Congress in in response to an emergency or disaster within the meaning of the Stafford Act are statutorily excluded from the applicability of BAP.

[2] See OMB Memorandum M–22–08, Identification of Federal Financial Assistance Infrastructure Programs Subject to the Build America, Buy America Provisions of the Infrastructure Investment and Jobs Act, *https://www.whitehouse.gov/wp-content/uploads/2021/12/M-22-08.pdf.*

use of waivers caused by dumping of foreign-sourced products.

VII. Solicitation of Comments on the Waiver

As required under section 70914 of the Act, HUD is soliciting comment from the public on the public interest waiver announced in this Notice. In particular, HUD invites comments on the definition of exigent circumstances that serves as the foundation for the application of the waiver, including the types of activities undertaken in response to such circumstances that should be considered within the scope of this waiver. HUD also invites comments on the process through which grantees or funding recipients may demonstrate or document reliance on this waiver.

Marcia L. Fudge,

Secretary.

[FR Doc. 2022–24340 Filed 11–3–22; 4:15 pm]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[234.LLID957000.L14400000. BJ0000.241A00]

Notice of Filing of Plats of Survey, Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of surveys.

SUMMARY: The Bureau of Land Management (BLM) has officially filed the plats of survey of the lands described below in the BLM, Idaho State Office, Boise, Idaho, on the dates specified below:

Boise Meridian, Idaho

T. 2 S., R. 4 W., Sections 2 and 11, accepted September 14, 2022.

T. 33 N., R. 3 E., Section 33, accepted September 15, 2022.

T. 1 S., R. 3 E., Section 21, accepted September 16, 2022.

T. 23 N., R. 1 E., Section 27, accepted September 20, 2022.

T. 5 S., R. 7 E., Sections 23, 24, 25, 26 and 35, accepted September 21, 2022.

T. 13 N., R. 5 W., Sections 24, 25 and 36, accepted September 22, 2022.

T. 13 N., R. 4 W., Section 30, accepted September 22, 2022.

ADDRESSES: A copy of the plats may be obtained from the Public Room at the BLM, Idaho State Office, 1387 S Vinnell Way, Boise, Idaho 83709, upon required payment.

FOR FURTHER INFORMATION CONTACT: Monte L. King, Branch of Cadastral Survey, BLM, 1387 South Vinnell Way, Boise, Idaho 83709–1657; (208) 373–3984; email: *mking@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 7–1–1 (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.

SUPPLEMENTARY INFORMATION: The plat, in two sheets, of the dependent resurvey of portions of the north boundary and subdivisional lines and the subdivision of sections 2 and 11, Township 2 South, Range 4 West, Boise Meridian, Idaho, Group Number 1460, was accepted September 14, 2022.

The plat, in one sheet, incorporating the field notes of the dependent resurvey of portions of the south boundary and subdivisional lines and the subdivision of section 33, Township 33 North, Range 3 East, Boise Meridian, Idaho, Group Number 1472, was accepted September 15, 2022.

The plat, in one sheet, incorporating the field notes of the dependent resurvey of a portion of the subdivisional lines, Township 1 South, Range 3 East, Boise Meridian, Idaho, Group Number 1490, was accepted September 16, 2022.

The plat, in one sheet, incorporating the field notes of the dependent resurvey of a portion of the subdivisional lines and the subdivision of section 27, Township 23 North, Range 1 East, Boise Meridian, Idaho, Group Number 1498, was accepted September 20, 2022.

The plat, in one sheet, incorporating the field notes of the dependent resurvey of portions of the south and east boundaries, and subdivisional lines and the subdivision of sections 23, 24, 25, 26 and 35, Township 5 South, Range 7 East, Boise Meridian, Idaho, Group Number 1541, was accepted September 21, 2022.

The plat, in one sheet, incorporating the field notes of the dependent resurvey of portions of the south boundary, east boundary, and subdivisional lines and the subdivision of sections 24, 25, and 36, Township 13 North, Range 5 West, Boise Meridian, Idaho, Group Number 1499, was accepted September 22, 2022.

The plat, in one sheet, incorporating the field notes of the dependent resurvey of a portion of the subdivisional lines and the subdivision of section 30, Township 13 North, Range 4 West, Boise Meridian, Idaho, Group Number 1501, was accepted September 22, 2022.

A person or party who wishes to protest one or more plats of survey identified above must file a written notice of protest with the Chief Cadastral Surveyor for Idaho, BLM within 30 calendar days from the date of this publication at the address listed in the **ADDRESSES** section of this notice. The protest must identify the plat(s) of survey that the person or party wishes to protest and contain all reasons and evidence in support of the protest. A protest is considered filed on the date it is received by the Chief Cadastral Surveyor for Idaho during regular business hours; if received after regular business hours, a protest will be considered filed the next business day.

Before including your address, phone number, email address, or other personal identifying information in a protest, you should be aware that the documents you submit, including your personal identifying information, may be made publicly available in their entirety at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 U.S.C., Chapter 3).

Monte L. King,

Acting Chief Cadastral Surveyor for Idaho.

[FR Doc. 2022–24147 Filed 11–4–22; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming

Commission Fee Rate and Fingerprint Fees

AGENCY: National Indian Gaming Commission, Interior.

ACTION: Notice.

SUMMARY: Notice is hereby given that the National Indian Gaming Commission has adopted its annual fee rates of 0.00% for tier 1 and 0.08% (.0008) for tier 2, which maintain the current fee rates. These rates shall apply to all assessable gross revenues from each gaming operation under the jurisdiction of the Commission. If a tribe has a certificate of self-regulation, the fee rate on Class II revenues shall be 0.04% (.0004) which is one-half of the annual fee rate. The annual fee rates are effective November 1, 2022 and will remain in effect until new rates are adopted. The National Indian Gaming Commission has also adopted its fingerprint processing fee of $45 per card which represents an increase of

$10 per card. The fingerprint processing fee is effective November 1, 2022 and will remain in effect until the Commission adopts a new rate.

FOR FURTHER INFORMATION CONTACT: Yvonne Lee, National Indian Gaming Commission, 1849 C Street NW, Mail Stop #1621, Washington, DC 20240; telephone (202) 632–7003; fax (202) 632–7066.

SUPPLEMENTARY INFORMATION: The Indian Gaming Regulatory Act (IGRA) established the National Indian Gaming Commission, which is charged with regulating gaming on Indian lands.

Commission regulations (25 CFR 514) provide for a system of fee assessment and payment that is self-administered by gaming operations.

Pursuant to those regulations, the Commission is required to adopt and communicate assessment rates and the gaming operations are required to apply those rates to their revenues, compute the fees to be paid, report the revenues, and remit the fees to the Commission. All gaming operations within the jurisdiction of the Commission are required to self-administer the provisions of these regulations, and report and pay any fees that are due to the Commission. Even though the industry's Gross Gaming Revenues showed a significant increase in FY21 (basis for FY23's fee calculation), it is necessary for the Commission to maintain the fee rate to ensure that the agency has sufficient funding to fully meet its statutory and regulatory responsibilities as the gaming industry continues to emerge from the pandemic. In addition, it is critical for the Commission to maintain constantly an adequate transition carryover balance to cover any cash flow variations.

Pursuant to 25 CFR 514, the Commission must also review annually the costs involved in processing fingerprint cards and set a fee based on fees charged by the Federal Bureau of Investigation and costs incurred by the Commission. Commission costs include Commission personnel, supplies, equipment & infrastructure costs, and postage to submit the results to the requesting tribe. The number of fingerprint cards submitted to the NIGC for processing has decreased significantly during the pandemic. The fingerprint processing fee increase is a result of spreading the fixed costs allocated to fingerprint processing over less number of cards processed. In addition, FY23 costs reflects the Commission's continued commitment to take necessary measures to comply with the Federal Bureau of Investigation Criminal Justice Information Services (FBI CJIS) requirements. These measures are not only required, but critical to ensure the NIGC and participating tribes can continue to use the FBI criminal history report information (CHRI) to determine a key employee or primary management official's eligibility for a gaming license.

Dated: November 1, 2022.

Edward Simermeyer,

Chairman.

Dated: November 1, 2022.

Jean Hovland,

Vice Chair.

[FR Doc. 2022–24134 Filed 11–4–22; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034810; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Robert S. Peabody Institute of Archaeology, Andover, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Robert S. Peabody Institute of Archaeology intends to repatriate a cultural item that meets the definition of an unassociated funerary object and has a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural item was removed from Westchester County, NY.

DATES: Repatriation of the cultural item in this notice may occur on or after December 7, 2022.

ADDRESSES: Ryan J. Wheeler, Robert S. Peabody Institute of Archaeology, Phillips Academy, 180 Main Street, Andover, MA 01810, telephone (978) 749–4490, email *rwheeler@andover.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Robert S. Peabody Institute of Archaeology. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by the Robert S. Peabody Institute of Archaeology.

Description

The one cultural item was removed from Westchester County, NY. The one unassociated funerary objects is a birdstone. At an unknown date, the birdstone (catalog no. 29526) was removed by F.G. Hillman from a site in Port Chester, NY, and in 1908, it was acquired by the Robert S. Peabody Institute of Archaeology. Hillman was a dealer in natural history specimens, Native American objects, antiques, books, stamps, and coins.

Cultural Affiliation

The cultural items in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: anthropological, archeological, geographical, historical, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Robert S. Peabody Institute of Archaeology has determined that:

- The one cultural item described above is reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and is believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- There is a relationship of shared group identity that can be reasonably traced between the cultural item and the Delaware Nation, Oklahoma; Delaware Tribe of Indians; and the Stockbridge Munsee Community, Wisconsin.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on

or after December 7, 2022. If competing requests for repatriation are received, the Robert S. Peabody Institute of Archaeology must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The Robert S. Peabody Institute of Archaeology is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, 10.10, and 10.14.

Dated: October 26, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–24228 Filed 11–4–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034808; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of Defense, Defense Health Agency, National Museum of Health and Medicine, Silver Spring, MD

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the U.S. Department of Defense, Defense Health Agency, National Museum of Health and Medicine has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were removed from the vicinity of Waimea in Kauai County, HI.

DATES: Repatriation of the human remains in this notice may occur on or after December 7, 2022.

ADDRESSES: Mr. Brian F. Spatola, Curator of Anatomical Division, National Museum of Health and Medicine, U.S. Army Garrison Forest Glen, 2500 Linden Lane, Silver Spring, MD 20910, telephone (301) 319–3353, email *brian.f.spatola.civ@healthl.mil.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the National Museum of Health and Medicine. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the National Museum of Health and Medicine.

Description

At an unknown date, human remains representing, at minimum, one individual were removed from the vicinity of Waimea in Kauai County, HI. The human remains consist of an adult cranium that was collected by Valdemar Knudsen. Initially, these human remains were donated to the Smithsonian Institution. In February of 1869, they were transferred to the Army Medical Museum (today the National Museum of Health and Medicine). The cranium exhibits a healed depression fracture to the frontal bone. No known individual was identified. No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: anthropological, geographical, historical, and archival.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the National Museum of Health and Medicine has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native Hawaiian ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Native Hawaiian organization Hui Iwi Kuamo'o.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES.** Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after December 7, 2022. If competing requests for repatriation are received, the National Museum of Health and Medicine must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The National Museum of Health and Medicine is responsible for sending a copy of this notice to the Native Hawaiian organization identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: October 26, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–24226 Filed 11–4–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034802; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: U.S. Department of the Interior, Bureau of Indian Affairs, Washington, DC

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of the Interior, Bureau of Indian Affairs (BIA), in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects, sacred objects, and objects of cultural patrimony. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the BIA. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes,

or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the BIA at the address in this notice by December 7, 2022.

ADDRESSES: Tamara Billie, NAGPRA Coordinator, Bureau of Indian Affairs, 1001 Indian School Road NW, Mailbox 44—Suite 345, Albuquerque, NM 87104, telephone (505) 879–9711, email *tamara.billie@bia.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the U.S Department of the Interior, Bureau of Indian Affairs, Washington, DC, that meet the definition of unassociated funerary objects, sacred objects, and objects of cultural patrimony under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

All 376 cultural items listed in this notice were removed at an unknown date or dates from various sites located on the Wind River Indian Reservation, in Fremont County, WY, and at an unknown date or dates, these cultural items came into the possession of Theodore Sowers. In 1995, Sowers' daughters transferred these cultural items to Sowers' alma mater, the University of Denver. The 376 cultural items include 25 associated funerary objects, one sacred object, and 350 objects of cultural patrimony.

The 25 unassociated funerary objects are one ammunition belt (DU ID#1995.1.91), one arrow shaft (DU ID#1995.1.73), one awl (DU ID#1995.1.84), four fragments of beadwork (DU ID#1995.1.77 A–B and 1995.1.78 A–B), one bridle (DU ID#1995.1.83), two Sun Dance brooches (DU ID#1995.1.88–89), one choker (DU ID#1995.1.76), one earring (DU ID#1995.1.74), two gaming sticks (DU ID#1995.1.82 A–B), one necklace (DU ID#1995.1.79), two pouch fragments (DU ID#1995.1.75 and 1995.1.80), one riding crop (DU ID#1995.1.93), one saddle (DU ID#1995.1.92 A–D), one saddle horn (DU ID#1995.1.90), two scrapers (DU ID#1995.1.85–86), one pipe stem (DU ID#1995.1.87), and two tools (DU ID#1995.1.81 A–B). Museum records indicate that these 25 unassociated funerary objects were removed from a burial.

The one sacred object is a Sun Dance whistle (DU ID #1995.1.72). This determination is based on information presented during consultation with Eastern Shoshone Tribal Historic Preservation Office (THPO) staff and a Cultural/Spiritual Representative in March of 2019.

The 350 objects of cultural patrimony are 23 utilized lithic flakes (DU ID#WY WR.1), one steatite jar (DU ID#2879), 20 tools (DU ID#1995.1.283–288 and 1995.1.308–321), one stone core (DU ID#1995.1.1259), one unworked stone (DU ID#1995.1.595), seven fern fossils (DU ID#1995.1.1826–1832), two fossils (DU ID#1995.1.1835 and 1995.1.1837), one stone knife (DU ID#1995.1.210), three pieces of petrified wood (1995.1.1833–1834 and 1995.1.1836), four stone scrapers (DU ID#1995.1.209, 1995.1.217, 1995.1.221, and 1995.1.223), two stone choppers (DU ID#1995.1.739–740), four stone cores (DU ID#1995.1.733–736), 23 utilized lithic flakes (DU ID#1995.1.741–763), 18 stone knives (DU ID#1995.1.715–732), two stone manos (DU ID#1995.1.737–738), 45 stone scrapers (DU ID#1995.1.670–714), 19 stone tools (DU ID#1995.1.289–307), one stone abrader (DU ID#1995.1.936), eight stone bifaces (DU ID#1995.1.887–888, 1995.1.891, and 1995.1.893–897), eight stone choppers (DU ID#1995.1.819, 1995.1.928–933, and 1995.1.938), one coprolite (DU ID#1995.1.937), two stone cores (DU ID#1995.1.934–935), four stone drills (DU ID#1995.1.808, 1995.1.905–907), nine lithic flakes (DU ID#1995.1.913–914, 1995.1.918, 1995.1.921–923, and 1995.1.925–927), four utilized lithic flakes (DU ID#1995.912, 1995.1.919–920, and 1995.1.924), 36 stone knives (DU ID#1995.1.810–818. 1995.1.822–841, 1995.1.889–890, 1995.1.892, 1995.1.898–900, and 1995.1.909), three stone projectile points (DU ID#1995.1.768–770), two rocks coated in red ochre (DU ID#1995.1.939–940), one lot of stone scrapers (DU ID#1995.1.776–786, 1995.1.788–807, 1995.1.820–821, 1995.1.842, 1995.1.885–886, 1995.1.901–904, 1995.1.908, 1995.1.911, and 1995.1.915–917), one sinker (DU ID#1995.1.809), one stone uniface (1995.1.910), one stone knife (DU ID#1995.1.765), one stone projectile point (DU ID#1995.1.767), two stone scrapers (DU ID#1995.1.764 and 1995.1.766), two lithic flakes (DU ID#1995.1.772–773), one stone projectile point (DU ID#1995.1.771), three stone scrapers (DU ID#1995.1.774–775 and 1995.1.787), two stone knives (DU ID#1995.1.874 and 1995.1.878), 40 stone scrapers (DU ID#1995.1.843–873, 1995.1.875–877, and 1995.1.879–884), six stone choppers (DU ID#1995.1.1279–1284), one stone core (DU ID#1995.1.1278), 11 stone knives (DU ID#1995.1.1276–1277, 1995.1.207–208, 1995.1.211–212, 1995.1.222, 1995.1.224–225, and 1995.1.228), and 23 stone scrapers (DU ID#1995.1.1262–1274, 1995.1.206, 1995.1.213–216, 1995.1.218–220, and 1995.1.226–227). This determination is based on information presented during consultation with Eastern Shoshone Tribal Historic Preservation Office (THPO) staff and a Cultural/Spiritual Representative in March of 2019.

Based on information in the possession of the BIA, which includes information obtained during consultation, the items listed in this notice are culturally affiliated with the Eastern Shoshone Tribe of the Wind River Reservation, Wyoming (*previously* listed as Shoshone Tribe of the Wind River Reservation, Wyoming). This Indian Tribe has been living on the Wind River Mountain range and its environs for some 12,000 years.

Determinations Made by the U.S Department of the Interior, Bureau of Indian Affairs

Officials of the U.S. Department of the Interior, Bureau of Indian Affairs have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), 25 of the cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(3)(C), one of the cultural items described above is a specific ceremonial object needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.
- Pursuant to 25 U.S.C. 3001(3)(D), 350 of the cultural items described above have ongoing historical, traditional, or cultural importance central to the Native American group or

culture itself, rather than property owned by an individual.

• Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects, sacred objects, and objects of cultural patrimony and the Eastern Shoshone Tribe of the Wind River Reservation, Wyoming (*previously* listed as Shoshone Tribe of the Wind River Reservation, Wyoming).

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Tamara Billie, NAGPRA Coordinator, Bureau of Indian Affairs, 1001 Indian School Road NW, Mailbox 44—Suite 345, Albuquerque, NM 87104, telephone (505) 879–9711, email *tamara.billie@bia.gov,* by December 7, 2022. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects, sacred object, and objects of cultural patrimony to the Eastern Shoshone Tribe of the Wind River Reservation, Wyoming (*previously* listed as Shoshone Tribe of the Wind River Reservation, Wyoming) may proceed.

The U.S. Department of the Interior, Bureau of Indian Affairs, with assistance from the Denver Museum is responsible for notifying the Eastern Shoshone Tribe of the Wind River Reservation, Wyoming (*previously* listed as Shoshone Tribe of the Wind River Reservation, Wyoming) that this notice has been published.

Dated: October 26, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–24221 Filed 11–4–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034805; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Beloit College, Logan Museum of Anthropology, Beloit, WI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: Beloit College, Logan Museum of Anthropology, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to Beloit College, Logan Museum of Anthropology. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Beloit College, Logan Museum of Anthropology at the address in this notice by December 7, 2022.

FOR FURTHER INFORMATION CONTACT: Nicolette B. Meister, Beloit College, Logan Museum of Anthropology, 700 College Street, Beloit, WI 53511, telephone (608) 363–2305, email *meistern@beloit.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of Beloit College, Logan Museum of Anthropology, Beloit, WI, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

On an unknown date, six cultural items were removed from Elliot Mound, No. 3, in Sacramento County, CA. Museum catalog information states the items most likely belong to the Horatio Nelson Rust Collection. A native of Amherst, Massachusetts, Horatio Nelson Rust (1826–1906) was a lifelong antiquarian and amateur archeologist who began collecting archeological and ethnographic items as a traveling salesman on the East Coast. He accepted artifacts for trade or payment, and contracted the sale or collection of artifacts from institutions in the East. In 1880, Rust moved to California, where he served as a United States Indian Agent. In 1892, Rust sold approximately 3,000 items to Frank Granger Logan. In 1894, Logan donated the Rust Collection to the Logan Museum of Anthropology. The six unassociated funerary objects (catalog number 4902) are one lot of coiled basketry fragments; one lot of loose weave net fragments; one lot of compact weave net fragments; one lot of twisted cordage fragments; one bundle of twisted threads; and one lot of woven blanket fragments.

Based on archeological, anthropological, geographical, ethnohistoric, ethnographic, linguistic, and oral traditional information, the Sacramento Valley and Delta regions, where Elliot Mound No. 3 is located, are home to Nisenan-speaking groups, of which Wilton Rancheria, California is one.

Determinations Made by Beloit College, Logan Museum of Anthropology

Officials of Beloit College, Logan Museum of Anthropology have determined that:

• Pursuant to 25 U.S.C. 3001(3)(B), the six cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.

• Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Wilton Rancheria, California.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Nicolette B. Meister, Beloit College, Logan Museum of Anthropology, 700 College Street, Beloit, WI 53511, telephone (608) 363–2305, email *meistern@beloit.edu,* by December 7, 2022. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects to the Wilton Rancheria, California may proceed.

Beloit College, Logan Museum of Anthropology is responsible for notifying the Wilton Rancheria, California that this notice has been published.

Dated: October 26, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–24225 Filed 11–4–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034803; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of the Interior, Bureau of Indian Affairs, Washington, DC

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the U.S. Department of the Interior, Bureau of Indian Affairs (BIA), has completed an inventory of human remains and has determined that there is no cultural affiliation between the human remains and any Indian Tribe. The human remains were removed from San Juan County, NM.

DATES: Disposition of the human remains and associated funerary objects in this notice may occur on or after December 7, 2022.

ADDRESSES: Tamara Billie, NAGPRA Coordinator, Bureau of Indian Affairs, 1001 Indian School Road NW, Mailbox 44—Suite 345, Albuquerque, NM 87104, telephone (505) 879–9711, email *tamara.billie@bia.gov.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the BIA. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the BIA.

Description

In 1944, human remains (catalog numbers DU 6014 and DU 6056) representing, at minimum, one individual were removed from near Shiprock, in San Juan County, NM, possibly by Dr. E.B. Renaud, founder of the University of Denver Department of Anthropology, and were subsequently housed at the University of Denver Museum of Anthropology. No known individual was identified. No associated funerary objects are present.

Tribal Land

The human remains in this notice were removed from a known geographic location. At the time of removal, this location was the tribal land of one or more Indian Tribes.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes, the U.S. Department of the Interior, Bureau of Indian Affairs has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- No relationship of shared group identity can be reasonably traced between the human remains and any Indian Tribe.
- The human remains described in this notice were removed from the tribal land of the Navajo Nation, Arizona, New Mexico, & Utah.

Requests for Disposition

Written requests for disposition of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for disposition may be submitted by:

1. Any one or more of the Indian Tribes identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization, or who shows that the requestor is a tribal land Indian Tribe.

Disposition of the human remains and associated funerary objects described in this notice to a requestor may occur on or after December 7, 2022. If competing requests for disposition are received, the U.S. Department of the Interior, Bureau of Indian Affairs must determine the most appropriate requestor prior to disposition. Requests for joint disposition of the human remains and associated funerary objects are considered a single request and not competing requests. The U.S. Department of the Interior, Bureau of Indian Affairs is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9 and 10.11.

Dated: October 26, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–24223 Filed 11–4–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034801; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of the Interior, National Park Service, Colonial National Historical Park, Yorktown, VA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of the Interior, National Park Service, Colonial National Historical Park has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations and has determined that there is a cultural affiliation between the human remains and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to Colonial National Historical Park. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Colonial National Historical Park at the address in this notice by December 7, 2022.

FOR FURTHER INFORMATION CONTACT: Jerri Marr, Superintendent, Colonial National Historical Park, P.O. Box 210, Yorktown, VA 23690, telephone (757) 898–2400, email *jerri_marr@nps.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the U.S. Department of the Interior, National Park Service, Colonial National Historical Park, Yorktown, VA. The

human remains were removed from unknown locations in Central Virginia.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the Superintendent, Colonial National Historical Park.

Consultation

A detailed assessment of the human remains was made by Colonial National Historical Park professional staff in consultation with representatives of the Monacan Indian Nation.

History and Description of the Remains

At unknown dates, human remains representing, at minimum, three individuals were removed from unknown sites in Central Virginia by Colonel Wirt Robinson. In the late 19th and early 20th centuries, Colonel Robinson collected human remains and artifacts from multiple Virginia counties, including Amherst, Appomattox, Buckingham, Campbell, and Nelson. In 1940, the collection was purchased from Colonel Robinson's widow by the National Park Service and placed with Colonial National Historical Park's Jamestown museum collection. During the study, evaluation, and cataloging of the collection by the University of Virginia, several human remains were discovered. No known individuals were identified. No associated funerary objects are present.

In 2000, the Wirt Robinson Collection was loaned to the Monacan Indian Nation and analyzed by Dr. Jeffrey Hantman of the University of Virginia. Dr. Hantman, an authority on Monacan history and material culture, wrote that ''There can be no more appropriate place for this collection than with the Monacan Indian Nation.'' In 2002, osteologist Debra Gold of St. Cloud State University concluded that the 14 human bones and one human tooth represented two adults and one juvenile. In 2008, the artifacts, none of which were determined to be associated funerary objects, were deaccessioned and transferred to the Monacan Indian Nation.

All of the Virginia counties from which the human remains and artifacts were removed have been identified as Monacan ancestral territory.

Determinations Made by the U.S. Department of the Interior, National Park Service, Colonial National Historical Park

Officials of the U.S. Department of the Interior, National Park Service, Colonial National Historical Park have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of three individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Monacan Indian Nation.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Jerri Marr, Superintendent, Colonial National Historical Park, P.O. Box 210, Yorktown, VA 23690, telephone (757) 898–2400, email *jerri_marr@nps.gov,* by December 7, 2022. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Monacan Indian Nation may proceed.

The U.S. Department of the Interior, National Park Service, Colonial National Historical Park is responsible for notifying the Monacan Indian Nation that this notice has been published.

Dated: October 26, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–24220 Filed 11–4–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–34788; 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 October 22, 2022, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by November 22, 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 October 22, 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.

Key: State, County, Property Name, Multiple Name (if applicable), Address/Boundary, City, Vicinity, Reference Number.

ALABAMA

Etowah County

Noojin House and Bellevue-Mineral Springs Hotel Site, 326 Bellevue Dr., Gadsden, SG100008433

FLORIDA

Wakulla County

Panacea Mineral Springs, Coastal Hwy., US 98, Panacea, SG100008423

IOWA

Polk County

Firestone District Office and Warehouse, 1775 East Euclid St., Des Moines, SG100008431

MASSACHUSETTS

Bristol County

S. Gourse & Sons Block, 162–170 Pleasant St., Fall River, SG100008429

Suffolk County

Charlotte Street-Esmond Street Historic District, 682–754 Blue Hill Ave., 50 and 64

Bradshaw, 12–62 Charlotte, 9–71 Esmond,12–16 and 206 McLellan Sts., Boston, SG100008419
Dudley Terrace-Dudley Street Historic District, 2–12 Dudley Terr., 713, 715–723, and 722–726 Dudley Street, Boston, SG100008435

Worcester County

Pierce, Sylvester K., House, 4 West Broadway, Gardner, SG100008420
Main Street and Murray Avenue Historic District, 718 and 720 Main St., 87 and 91 Murray Ave., Worcester, SG100008421

MONTANA

Deer Lodge County

Driver's Saloon and Café, (Black Montana's Heritage Places MPS), 104–106 East Commercial Ave., Anaconda, MP100008428

Mineral County

Swanson Homestead, Approx.12 miles south of Superior, Superior vicinity, SG100008425

Ravalli County

Como School, Jct. of Old Darby Rd. and US 93, Darby vicinity, SG100008424

WASHINGTON

Island County

Haller, Colonel Granville & Henrietta, House, 1 NE Front St., Coupeville, SG100008426
In the interest of preservation, a SHORTENED comment period has been requested for the following resource:

NEW MEXICO

Santa Fe County

El Rancho de las Golondrinas, 334 Los Pinos Rd., Santa Fe vicinity, SG100008430
Comment period: 3 days
Additional documentation has been received for the following resources:

ALABAMA

Baldwin County

Jenkins Farm and House (Additional Documentation), 29040 Jenkins Farm Rd., Loxley, AD16000862

COLORADO

Denver County

East High School (Additional Documentation), 1545 Detroit St., Denver, AD06000660

WEST VIRGINIA

Berkeley County

Downtown Martinsburg Historic District (Additional Documentation), (Berkeley County MRA), Roughly bounded by West Race, Water, Stephen, and Charles Sts., Martinsburg, AD80004416

Authority: Section 60.13 of 36 CFR part 60

Dated: October 25, 2022.

Sherry A. Frear,

Chief, National Register of Historic Places/ National Historic Landmarks Program.

[FR Doc. 2022–24138 Filed 11–4–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034809; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: University of Denver Museum of Anthropology, Denver, CO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The University of Denver Museum of Anthropology, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the University of Denver Museum of Anthropology. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the University of Denver Museum of Anthropology at the address in this notice by December 7, 2022.

FOR FURTHER INFORMATION CONTACT: Anne Amati, University of Denver Museum of Anthropology, 2000 E Asbury Avenue, Denver, CO 80208, telephone (303) 871–2687, email *anne.amati@du.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the University of Denver Museum of Anthropology, Denver, CO, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

At an unknown date, two cultural items were removed from an unknown site in Alabama. At an unknown date, the cultural items came into the possession of Fallis F. Rees. In 1968, Mr. Rees donated his collection, including these items, to the University of Denver. The two unassociated funerary objects are two jars (DU #s 4139 and 4140).

Geographical and historical evidence support a cultural affiliation of these objects with the Indian Tribes that have a legacy of occupation in the state of Alabama. Based on information provided by The Choctaw Nation of Oklahoma during consultation, these objects are unassociated funerary objects.

Determinations Made by the University of Denver Museum of Anthropology

Officials of the University of Denver Museum of Anthropology have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the two cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Cherokee Nation; Coushatta Tribe of Louisiana; Eastern Band of Cherokee Indians; Eastern Shawnee Tribe of Oklahoma; Seminole Tribe of Florida (*previously* listed as Seminole Tribe of Florida (Dania, Big Cypress, Brighton, Hollywood, & Tampa Reservations)); Shawnee Tribe; The Chickasaw Nation; The Choctaw Nation of Oklahoma; The Muscogee (Creek) Nation; and the Thlopthlocco Tribal Town (hereafter referred to as ''The Tribes'').

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with

information in support of the claim to Anne Amati, University of Denver Museum of Anthropology, 2000 E Asbury Avenue, Denver, CO 80208, telephone (303) 871–2687, email *anne.amati@du.edu,* by December 7, 2022. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects to The Choctaw Nation of Oklahoma on behalf of The Tribes may proceed.

The University of Denver Museum of Anthropology is responsible for notifying The Tribes that this notice has been published.

Dated: October 26, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–24227 Filed 11–4–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034804; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Beloit College, Logan Museum of Anthropology, Beloit, WI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: Beloit College, Logan Museum of Anthropology has completed an inventory of human remains and associated funerary objects in consultation with the appropriate Indian Tribes or Native Hawaiian organizations and has determined that there is a cultural affiliation between the human remains and associated funerary objects, and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to Beloit College, Logan Museum of Anthropology. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Beloit College, Logan Museum of Anthropology at the address in this notice by December 7, 2022.

FOR FURTHER INFORMATION CONTACT: Nicolette B. Meister, Beloit College, Logan Museum of Anthropology, 700 College Street, Beloit, WI 53511, telephone (608) 363–2305, email *meistern@beloit.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of Beloit College, Logan Museum of Anthropology, Beloit, WI. The human remains and associated funerary objects were removed from Sacramento County, CA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Beloit College, Logan Museum of Anthropology professional staff in consultation with representatives of the Buena Vista Rancheria of Me-Wuk Indians of California; Federated Indians of Graton Rancheria, California; Greenville Rancheria (*previously* listed as Greenville Rancheria of Maidu Indians of California); Ione Band of Miwok Indians of California; Pechanga Band of Indians (*previously* listed as Pechanga Band of Luiseno Mission Indians of the Pechanga Reservation, California); Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California; United Auburn Indian Community of the Auburn Rancheria of California; Wilton Rancheria, California; and the Yocha Dehe Wintun Nation, California (*previously* listed as Rumsey Indian Rancheria of Wintun Indians of California) (hereafter referred to as ''The Consulted Tribes'').

History and Description of the Remains

On an unknown date, human remains representing, at minimum, three individuals were removed from ''likely'' Elliot Mound, Sacramento County, CA. The human remains (31121; 31127) and associated funerary objects were obtained by Albert Green Heath (1888–1953). Heath was an avid collector and dealer of Native American items who traveled throughout North America buying, trading, and selling Native American items. Heath's large collection came to be known as the Museum of Amerind Arts or the Museum of American Indian Art. In 1955, Beloit College, Logan Museum of Anthropology purchased the Albert Green Heath collection. The human remains belong to three individuals of undetermined age and sex. No known individuals were identified. The 29 associated funerary objects are one lot of glass beads (31122); three bone pipes (31123.1; 31123.2; 31123.3); two stone beads (31124.1; 31124.2); one bone fish gorge (31125); four bone whistles or flutes (31128.1; 31128.2; 31128.3; 31128.4); one lot of bone beads or tubes (31129.1; 31129.2; 31129.3; 31129.4; 31129.5; 31129.7; 31129.8); five bone awls (31130.1; 31130.2; 31130.3; 31130.4; 31130.5); eight bone pendants (31131.1; 31131.2; 31131.3; 31131.4; 31131.5; 31131.6; 31131.7; 31131.8); two obsidian projectile points (31132.1; 31132.2); one bone bead (31206); and one lot of strung shell beads (with a stone bead added on each end of the string (31126) and a bone bead or tube (31129.6)). This last object is currently missing from the museum's collections.

Determinations Made by Beloit College, Logan Museum of Anthropology

Officials of Beloit College, Logan Museum of Anthropology have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of three individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 29 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Bridgeport Indian Colony (*previously* listed as Bridgeport Paiute Indian Colony of California); Buena Vista Rancheria of Me-Wuk Indians of California; California Valley Miwok Tribe, California; Cher-Ae Heights Indian Community of the Trinidad Rancheria, California; Chicken Ranch Rancheria of Me-Wuk Indians of

California; Federated Indians of Graton Rancheria, California; Ione Band of Miwok Indians of California; Jackson Band of Miwuk Indians (*previously* listed as Jackson Rancheria of Me-Wuk Indians of California); Middletown Rancheria of Pomo Indians of California; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California; United Auburn Indian Community of the Auburn Rancheria of California; and the Wilton Rancheria, California (hereafter referred to as ''The Tribes'').

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Nicolette B. Meister, Beloit College, Logan Museum of Anthropology, 700 College Street, Beloit, WI 53511, telephone (608) 363–2305, email *meistern@beloit.edu,* by December 7, 2022. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Tribes may proceed.

Beloit College, Logan Museum of Anthropology is responsible for notifying The Consulted Tribes and The Tribes that this notice has been published.

Dated: October 26, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–24224 Filed 11–4–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034811; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Robert S. Peabody Institute of Archaeology, Andover, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Robert S. Peabody Institute of Archaeology intends to repatriate certain cultural items that meet the definition of unassociated funerary objects and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural items were removed from Lowndes and Tishomingo Counties, MS.

DATES: Repatriation of the cultural items in this notice may occur on or after December 7, 2022.

ADDRESSES: Ryan J. Wheeler, Robert S. Peabody Institute of Archaeology, Phillips Academy, 180 Main Street, Andover, MA 01810, telephone (978) 749–4490, email *rwheeler@andover.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Robert S. Peabody Institute of Archaeology. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by the Robert S. Peabody Institute of Archaeology.

Description

The two cultural items were removed from Lowndes and Tishomingo Counties, MS. The two unassociated funerary objects are one pottery vessel and one stone pipe. The pottery vessel (catalog no. 39044) was removed by Clarence B. Moore in 1901 from Burial Mound 2 at Chowder Springs Landing (22Lo555) in Lowndes County, MS. It was transferred to the Robert S. Peabody Institute of Archaeology at some point after that. The stone pipe (catalog no. 35775) was removed from Tishomingo County, MS, by Warren K. Moorehead in 1902, during an expedition for the Robert S. Peabody Institute of Archaeology.

Cultural Affiliation

The cultural items in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: anthropological, archeological, geographical, historical, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Robert S. Peabody Institute of Archaeology has determined that:

- The two cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from specific burial sites of Native American individuals.
- There is a relationship of shared group identity that can be reasonably traced between the cultural items and The Chickasaw Nation.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after December 7, 2022. If competing requests for repatriation are received, the Robert S. Peabody Institute of Archaeology must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The Robert S. Peabody Institute of Archaeology is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, 10.10, and 10.14.

Dated: October 26, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–24229 Filed 11–4–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[OMB Control Number 1010–0176; Docket ID: BOEM–2017–0016]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Renewable Energy and Alternate Uses of Existing Facilities on the Outer Continental Shelf

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Ocean Energy Management (BOEM) is proposing this information collection request (ICR) to renew the Office of Management and Budget (OMB) Control Number 1010–0176.

DATES: Comments must be received by OMB no later than December 7, 2022.

ADDRESSES: Submit your written comments on this ICR to the OMB's desk officer for the Department of the Interior at *www.reginfo.gov/public/do/PRAMain.* From the *www.reginfo.gov/public/do/PRAMain* landing page, find this information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments by parcel delivery to the BOEM Information Collection Clearance Officer, Anna Atkinson, Bureau of Ocean Energy Management, 45600 Woodland Road, Sterling, Virginia 20166; or by email to *anna.atkinson@boem.gov.* Please reference OMB Control Number 1010–0006 in the subject line of your comments. You may also comment by searching the docket number BOEM–2017–0016 at *http://www.reginfo.gov/public/do/PRAMain.*

FOR FURTHER INFORMATION CONTACT: Anna Atkinson by email at *anna.atkinson@boem.gov* or by telephone at 703–787–1025. 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.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, BOEM provides the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps BOEM assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand BOEM's information collection requirements and provide the requested data in the desired format.

Title of Collection: ''30 CFR part 585, Renewable Energy and Alternate Uses of Existing Facilities on the Outer Continental Shelf.''

Abstract: The ICR addresses the paperwork requirements in the regulations under ''30 CFR part 585, Renewable Energy and Alternate Uses of Existing Facilities on the Outer Continental Shelf [OCS]'' issued pursuant to the OCS Lands Act, as amended (43 U.S.C. 1331 *et seq.*). The OCS Lands Act at subsection 8(p) (43 U.S.C. 1337(p)) authorizes the Secretary of the Interior to issue leases, easements, or rights-of way on the OCS for activities that produce or support production, transportation, or transmission of energy from sources other than oil and gas, including renewable energy. Subsection 8(p) directs the Secretary to issue any necessary regulations to carry out the OCS renewable energy program. The Secretary delegated this authority to BOEM. BOEM issued regulations for OCS renewable energy activities at 30 CFR part 585; this notice concerns the reporting and recordkeeping elements required by these regulations.

Respondents are parties interested in obtaining a lease or grant for renewable energy activities on the OCS; lessees and grantees submitting plans for commercial and noncommercial renewable energy projects on the OCS, and, if such plans are approved, constructing, operating, maintaining, and decommissioning those projects; and applicants for, or holders of, rights-of-use and easement for alternate uses of existing facilities on the OCS. BOEM must ensure that these activities are carried out in a manner that provides for, among other things, safety, protection of the environment, and consideration of other OCS users. In order to execute its duties, BOEM requires information regarding potential purchasers of leases, grants, and rights-of-way; their proposed activities; their financial assurance instruments to ensure accrued obligations are met; and their payments to the U.S. Treasury.

BOEM uses forms to collect information to ensure proper and efficient administration of OCS renewable energy leases and grants and to document the financial responsibility of lessees and grantees. Forms BOEM–0002, BOEM–0003, BOEM–0004, and BOEM–0006 are used, respectively, by renewable energy entities on the OCS to assign a grant interest, assign a lease interest, relinquish a lease or grant, and designate an operator. Form BOEM–0005 is used to document a surety's guarantee of lessees' and grantees' performance. BOEM maintains the submitted forms as official lease and grant records.

OMB Control Number: 1010–0176.

Form Number:

- BOEM–0002, ''Outer Continental Shelf (OCS) Renewable Energy Assignment of Grant;''
- BOEM–0003, ''Assignment of Record Title Interest in Federal OCS Renewable Energy Lease;''
- BOEM–0004, ''Outer Continental Shelf (OCS) Renewable Energy Lease or Grant Relinquishment Application;''
- BOEM–0005, ''Outer Continental Shelf (OCS) Renewable Energy Lessee's, Grantee's, and Operator's Bond;'' and
- BOEM–0006, ''Outer Continental Shelf (OCS) Renewable Energy Lease or Grant Designation of Operator.''

Type of Review: Extension of a currently approved information collection.

Respondents/Affected Public: Companies interested in renewable energy-related uses on the OCS and holders of leases and grants under 30 CFR part 585.

Total Estimated Number of Annual Responses: 265 responses.

Total Estimated Number of Annual Burden Hours: 18,783 hours.

Respondent's Obligation: Mandatory or required to obtain or retain a benefit.

Frequency of Collection: On occasion or annually.

Total Estimated Annual Non-Hour Burden Cost: $3,816,000 non-hour costs. The non-hour cost burdens consist of service fees and payments to a contractor for drafting BOEM-required documents, preparing and conducting site-specific studies, and writing reports to evaluate potential causes of harm to natural resources.

Estimated Reporting and Recordkeeping Hour Burden: The estimated annual hour burden for this collection is 18,783 hours. In calculating the burden, BOEM recognized that some of its required information collections are incurred by respondents in the normal course of their activities, like compiling and maintaining business records. BOEM considers some information collection activities to be usual and customary business practices

and excluded those activities from its account in estimating the burden.

A **Federal Register** notice with a 60-day public comment period on this proposed ICR was published on September 2, 2022 (87 FR 54250). BOEM did not receive any comments during the 60-day comment period.

BOEM is again soliciting comments on the proposed ICR. BOEM is especially interested in public comments addressing the following issues: (1) is the collection necessary to the proper functions of BOEM; (2) what can BOEM do to ensure that this information is processed and used in a timely manner; (3) is the burden estimate accurate; (4) how might BOEM enhance the quality, utility, and clarity of the information to be collected; and (5) how might BOEM minimize the burden of this collection on the respondents, including minimizing the burden through the use of information technology?

Public Comment Notice: Comments submitted in response to this notice are a matter of public record and will be available for public review on *www.reginfo.gov.* You should be aware that your entire comment—including your address, phone number, email address, or other personally identifiable information included in your comment—may be made publicly available. Even if BOEM withholds your information in the context of this ICR, your comment is subject to the Freedom of Information Act (FOIA). If your comment is requested under the FOIA, your information will only be withheld if BOEM determines that a FOIA exemption to disclosure applies. BOEM will make such a determination in accordance with the Department of the Interior's (DOI) FOIA regulations and applicable law.

In order for BOEM to consider withholding from disclosure your personally identifiable information, you must identify, in a cover letter, any information contained in your comments that, if released, would constitute a clearly unwarranted invasion of your personal privacy. You must also briefly describe any possible harmful consequence of the disclosure of information, such as embarrassment, injury, or other harm.

Note that BOEM will make available for public inspection all comments on *www.reginfo.gov,* in their entirety, submitted by organizations and businesses or by individuals identifying themselves as representatives of organizations or businesses.

BOEM protects proprietary information in accordance with FOIA (5 U.S.C. 552), DOI's implementing regulations (43 CFR part 2), and 30 CFR 585.113.

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 authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Karen Thundiyil,

Chief, Office of Regulations, Bureau of Ocean Energy Management.

[FR Doc. 2022–24195 Filed 11–4–22; 8:45 am]

BILLING CODE 4310–MR–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1269]

Certain Electrolyte Containing Beverages and Labeling and Packaging Thereof; Notice of Commission Final Determination To Issue a Limited Exclusion Order; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to issue a limited exclusion order (''LEO'') barring entry of certain electrolyte containing beverages and labeling and packaging thereof that are imported by or on behalf of the following defaulting respondents (all of Mexico): Carbonera Los Asadores de C.V.; Comercial Treviño de Reynosa, S.A. de C.V.; Distribuidora Mercatto S.A. de C.V.; H & F Tech International S.A. de C.V.; Leticia Angélica Saenz Fernandez; Yoselen Susana Martinez Tirado; Grupo Comercial Lux del Norte S.A. de C.V.; and Caribe Agencia Express, S.A. de C.V. (collectively, the ''Defaulting Respondents''). The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Houda Morad, 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: On July 6, 2021, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based on a complaint filed by CAB Enterprises, Inc. of Houston, Texas and Sueros y Bebidas Rehidratantes, S.A. de C.V. of Mexico (collectively, ''Complainants''). *See* 86 FR 35532–33 (July 6, 2021). The complaint, as supplemented, alleges a violation of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain electrolyte containing beverages and labeling and packaging thereof by reason of infringement of U.S. Trademark Registration Nos. 4,222,726; 4,833,885; 4,717,350; and 4,717,232 (collectively, ''the Asserted Trademarks''). *See id.* In addition to the Defaulting Respondents, the notice of investigation (''NOI'') names the following respondents (all of Mexico): Flexicompuestos S.A. de C.V. (''Flexicompuestos''); Comercializadora Degu S.A. de C.V.; MPC Foods S.A. de C.V.; Myrna Guadalupe Perez Martinez; Comercializadora Embers S.A. de C.V.; and Manuel Bautista Nogales (''Nogales'') (collectively, ''the Terminated Respondents''). *See id.* The Office of Unfair Import Investigations (''OUII'') is also a party to the investigation. *See id.*

The Commission previously found the Defaulting Respondents in default pursuant to Commission Rule 210.16 (19 CFR 210.16) for failure to respond to the complaint and notice of investigation and to orders to show cause why they should not be found in default for failing to respond to the complaint and NOI issued by the presiding administrative law judge (''ALJ''). *See* Order No. 8 (Sept. 14, 2021), *unreviewed by* Comm'n Notice (Oct. 6, 2021); Order No. 19 (Apr. 7, 2022), *unreviewed by* Comm'n Notice (Apr. 26, 2022).

On April 18, 2022, Complainants filed a declaration under Commission Rule 210.16 (19 CFR 210.16) requesting the immediate entry of a limited exclusion order against the Defaulting Respondents. Complainants also indicated pursuant to 19 CFR 210.16(c)(2) that they are not seeking issuance of a general exclusion order or cease and desist orders.

On May 27, 2022, the Commission issued a notice seeking written submissions from the parties, the public, and interested government

agencies on the issues of remedy, the public interest, and bonding. *See* 87 FR 33831–32 (June 3, 2022) (''Remedy Notice''). On June 10, 2022 (and as corrected on June 23, 2022), Complainants filed a submission in response to the Commission's Remedy Notice. On the same day, respondents Flexicompuestos and Nogales also filed a submission in response to the Commission's Remedy Notice. OUII filed a submission in response to the Commission's Remedy Notice on June 10, 2022, and a response to the parties' submissions on June 17, 2022.

On June 28, 2022, the Commission terminated the investigation as to the Terminated Respondents, including Flexicompuestos and Nogales, based on Complainant's withdrawal of the complaint as to those respondents. *See* Order No. 21 (June 1, 2022), *unreviewed by* Comm'n Notice (June 28, 2022). Accordingly, only the Defaulting Respondents remain in the investigation.

When the conditions in section 337(g)(1)(A)–(E) (19 U.S.C. 1337(g)(1)(A)–(E)) have been satisfied, section 337(g)(1) and Commission Rule 210.16(c) (19 CFR 210.16(c)) direct the Commission, upon request, to issue a limited exclusion order or a cease and desist order or both against a respondent found in default, based on the allegations regarding a violation of section 337 in the Complaint, which are presumed to be true, unless after consideration of the public interest factors in section 337(g)(1), it finds that such relief should not issue.

Having examined the record of this investigation, including the parties' submissions in response to the Remedy Notice, the Commission has determined pursuant to subsection 337(g)(1) that the appropriate remedy in this investigation is an LEO prohibiting the unlicensed entry of certain electrolyte containing beverages and labeling and packaging thereof that infringe Complainants' Asserted Trademarks and that are imported by or on behalf of the Defaulting Respondents. The Commission has determined that the public interest factors enumerated in subsection 337(g)(1) do not preclude the issuance of the LEO. The Commission has further determined that the bond during the period of Presidential review pursuant to section 337(j) (19 U.S.C. 1337(j)) shall be in the amount of 100 percent of the entered value of the imported articles that are subject to the LEO. The investigation is terminated.

The Commission's vote for this determination took place on November 2, 2022.

The authority for the Commission's determination is contained in 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).

While temporary remote operating procedures are in place in response to COVID–19, the Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 CFR 201.16(a), 210.7(a)(1)), the Commission orders that the Complainant(s) complete service for any party/parties without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

By the order of the Commission.

Issued: November 2, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–24243 Filed 11–4–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—The Institute of Electrical and Electronics Engineers, Inc.

Notice is hereby given that, on March 29, 2022 pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), The Institute of Electrical and Electronics Engineers, Inc. (''IEEE'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing additions or changes to its standards development activities. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, 65 new standards have been initiated and 44 existing standards are being revised. More detail regarding these changes can be found at:

https://standards.ieee.org/about/sasb/sba/june2021/

https://standards.ieee.org/about/sasb/sba/nov2021/

https://standards.ieee.org/about/sasb/sba/feb2022/

https://standards.ieee.org/about/sasb/sba/mar2022/

The following pre-standards activities associated with IEEE Industry Connections Activities were launched or renewed:

https://standards.ieee.org/about/bog/smdc/june2021/

https://standards.ieee.org/about/bog/cag/approvals/mar2022/

On September 17, 2004, IEEE filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on November 3, 2004 (69 FR 64105).

The last notification was filed with the Department on December 16, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on March 11, 2022 (87 FR 14041).

Catherine Reilly,

Counsel for Civil Operations, Antitrust Division.

[FR Doc. 2022–24119 Filed 11–4–22; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—The Digital Dollar Project, Inc.

Notice is hereby given that, on July 21, 2022 pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''). The Digital Dollar Project, Inc. (''DDP'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, BDO UNIBANK INC., Mandaluyong City, PHILIPPINES; Digital Asset Holdings, LLC, New York, NY; H–E–B, San Antonio, TX; Indigenous Nations Tribal Reserve (INTR), Norman, OK; Elijah's Heart, Franklin, TN; and National Bankers Association, Washington, DC have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open and DDP intends to file additional written notifications disclosing all changes in membership.

On June 9, 2022, the Digital Dollar Project filed its original notification pursuant to Section 6(a) of the Act.

The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on August 1, 2022 (87 FR 4007).

Catherine Reilly,

Counsel for Civil Operations, Antitrust Division.

[FR Doc. 2022–24126 Filed 11–4–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Advanced Fluids for Electrified Vehicles

Notice is hereby given that, on September 21, 2022, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Advanced Fluids for Electrified Vehicles (''AFEV'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, John Deere, Moline, IL, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and AFEV intends to file additional written notifications disclosing all changes in membership.

On June 16, 2021, AFEV filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on August 16, 2021 (86 FR 45751).

The last notification was filed with the Department on August 26, 2022. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on September 15, 2022 (87 FR 56703).

Catherine Reilly,

Counsel for Civil Operations, Antitrust Division.

[FR Doc. 2022–24122 Filed 11–4–22; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research And Production Act of 1993—Z-Wave Alliance, Inc.

Notice is hereby given that, on September 2, 2022, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (the ''Act''), Z-Wave Alliance, Inc. (the ''Joint Venture'') filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Specifically, Control & More, Riyadh, SAUDI ARABIA; Good Energy Solutions, Inc., Lawrence, KS; Smart AT For You, Teneriffe, AUSTRALIA; and iGuard Home Solutions Inc., Seattle, WA have joined as parties to the venture.

Also, Power and Data Engineering, Alfords Point, AUSTRALIA; Vodafone Group Services GmbH, Dusseldorf, GERMANY; Sybersense IOT, Millcreek, UT; Head Enterprises Queensland Pty Ltd, Springwood, AUSTRALIA; ImaGenius, Saugus, MA; Animus Home AB, Lund, SWEDEN; HomeControl AS, Oslo, NORWAY; SoftAtHome, Colombes, FRANCE; iHomeFuture, Dubai, UNITED ARAB EMIRATES; Arvitech Controls S.A., Guayaquil, ECUADOR; ContractOne, Shenzhen, PEOPLE'S REPUBLIC OF CHINA; Polynhome, Paris, FRANCE; Anhui Geniatech INC., LTD, Hefei, PEOPLE'S REPUBLIC OF CHINA; I feel, Tikva, ISRAEL; Pamex Inc., Chino, CA; A1 Smarthome Inc., Calgary, CANADA; Blaze Automation Inc., Princeton, NJ; Essence Group (Essence Security International Ltd.), Herzliya, ISRAEL; Shenzhen Saykey Technology Co., Ltd, Shenzhen, PEOPLE'S REPUBLIC OF CHINA; Webee Corporation, Sunnyvale, CA; ZNET CO., LTD, Nagoya, JAPAN; Complete Electrical Academy, Clifton, VA; Ubitech Limited, Tsuen Wan, HONG KONG–CHINA; Fantem Technologies (Shenzhen) Co., Ltd., Shenzhen City, PEOPLE'S REPUBLIC OF CHINA; and Sensurance, San Antonio, TX have withdrawn as parties to the venture.

No other changes have been made in either the membership or the planned activity of the venture. Membership in this venture remains open, and the Joint Venture intends to file additional written notifications disclosing all changes in membership.

On November 19, 2020, the Joint Venture filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on December 1, 2020 (85 FR 77241).

The last notification was filed with the Department on June 20, 2022. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 30, 2022 (87 FR 53004).

Catherine Reilly,

Counsel for Civil Operations, Antitrust Division.

[FR Doc. 2022–24118 Filed 11–4–22; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Electromagnetic Security Consortium, Inc.

Notice is hereby given that, on September 2, 2022, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.,* (the ''Act''), the Electromagnetic Security Consortium, Inc. filed written notifications simultaneously with the Department of Justice and the Federal Trade Commission disclosing (1) the identities of the parties to Electromagnetic Security Consortium, Inc. and (2) the nature and objectives of Electromagnetic Security Consortium, Inc. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to section 6(b) of the Act, the identities of the members of Electromagnetic Security Consortium, Inc. are the following companies: Acqusight, Amissville, VA; Coffee County Kansas, Burlington, KS; Conductive Group, Heber, UT; EXCEL SERVICES CORPORATION, Rockville, MD; Gtegrity, Inc., Millersville, MD; HLM Associates, Strasburg, VA; LBA Group Inc., Greenville, NC; Midgard Education Publishing, LLC, Pompano Beach, FL; MindShare Resource Solutions, Renton, WA; Montana State University, Bozeman, MT; Niles Expanded Metals & Plastics, Niles, OH; Palmer's Contracting Group, Warrenton, VA; Palmer's Security Solutions, Manassas, VA; RESA Power, Bedford, NH; RF Defense, Owings Mills, MD;

SCIF Consultant, LLC, Quitman, TX; Signals Defense, Owings Mills, MD; Victory Systems, LLC, Zebulon, NC; and Willis Mechanical, Inc., Norcross, GA.

Electromagnetic Security Consortium, Inc. was formed as a Delaware non-stock member corporation. Electromagnetic Security Consortium, Inc.'s general area of planned activity is to develop, qualify, and deploy technologies that mitigate both environmental and man-made electromagnetic threats, and undertake such further activities as may from time to time be appropriate to further such purposes and achieve such goals.

Membership in Electromagnetic Security Consortium, Inc. remains open and Electromagnetic Security Consortium, Inc. intends to file additional written notifications disclosing all changes in membership.

Catherine Reilly,

Counsel for Civil Operations, Antitrust Division.

[FR Doc. 2022–24127 Filed 11–4–22; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Advanced Media Workflow Association, Inc.

Notice is hereby given that, on September 15, 2022, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Advanced Media Workflow Association, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Amazon Web Services, Houston, TX, has been added as a party to this venture.

Also, Railroad 19, Saratoga, NY, has withdrawn as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Advanced Media Workflow Association, Inc. intends to file additional written notifications disclosing all changes in membership.

On March 28, 2000, Advanced Media Workflow Association, Inc. filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on June 29, 2000 (65 FR 40127).

The last notification was filed with the Department on June 27, 2022. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on August 1, 2022 (87 FR 47007).

Catherine Reilly,

Counsel for Civil Operations, Antitrust Division.

[FR Doc. 2022–24121 Filed 11–4–22; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—ASTM International Standards

Notice is hereby given that on May 23, 2022 pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), ASTM International (''ASTM'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing additions or changes to its standards development activities. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, ASTM has provided an updated list of current, ongoing ASTM activities originating between March 11, 2022- and May 18, 2022 designated as Work Items. A complete listing of ASTM Work Items, along with a brief description of each, is available at *http://www.astm.org.*

On September 15, 2004, ASTM filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on November 10, 2004 (69 FR 65226). The last notification with the Department was filed on December 14, 2021. A notice was filed in the **Federal Register** on March 11, 2022 (87 FR 14043).

Catherine Reilly,

Counsel for Civil Operations, Antitrust Division.

[FR Doc. 2022–24120 Filed 11–4–22; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to The National Cooperative Research and Production Act of 1993—Southwest Research Institute—Cooperative Research Group on ROS-Industrial Consortium Americas

Notice is hereby given that, on September 1, 2022, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Southwest Research Institute—Cooperative Research Group on ROS-Industrial Consortium-Americas (''RIC-Americas'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Fluor Marine Propulsion, LLC, West Mifflin, PA; and L5Automation Inc., La Canada, CA, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and RIC-Americas intends to file additional written notifications disclosing all changes in membership.

On April 30, 2014, RIC-Americas filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 9, 2014 (79 FR 32999).

The last notification was filed with the Department on May 18, 2022. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on June 13, 2022 (87 FR 35793).

Catherine Reilly,

Counsel for Civil Operations, Antitrust Division.

[FR Doc. 2022–24128 Filed 11–4–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

[OMB Number 1125–0012]

Agency Information Collection Activities; Proposed eCollection; eComments Requested; Revision of a Currently Approved Collection; Request for New Recognition, Renewal of Recognition, Extension of Recognition of a Non-Profit Religious, Charitable, Social Service, or Similar Organization (Form EOIR–31)

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Executive Office for Immigration Review (EOIR), Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** on August 15, 2022, allowing for a 60-day comment period.

DATES: The comment period for the notice published at 87 FR 50123 on August 15, 2022 is extended. Comments are encouraged and will be accepted for an additional 30 days until December 7, 2022.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2500, Falls Church, VA 22041, telephone: (703) 305–0289. Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- 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;
- 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;
- Enhance the quality, utility, and clarity of the information to be collected; and/or
- 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 submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a currently approved collection.

2. *The Title of the Form/Collection:* Request for New Recognition, Renewal of Recognition, Extension of Recognition of a Non-profit Religious, Charitable, Social Service, or Similar Organization.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form EOIR–31. The applicable component within the Department of Justice is the Office of Legal Access Programs, Executive Office for Immigration Review.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Non-profit organizations seeking new recognition, renewal of recognition, or extension of recognition to be recognized as legal service providers by the Office of Legal Access Programs of the Executive Office for Immigration Review (EOIR).

Abstract: This information collection will allow an organization to request, renew, and extend recognition of the organization to appear before EOIR and/or the Department of Homeland Security. This information collection is necessary to determine whether an organization meets the eligibility requirements for recognition. Requests can be made using a fillable pdf. application or electronic submission.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 131 respondents will complete the form annually for initial recognition with an average of 2 hours per response, for a total of 262 hours. It is estimated that 190 respondents will complete the form annually for renewal of recognition with an average of 7 hours per response, with a total of 1,330 hours.

6. *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 1,592 total annual burden hours associated with this collection.

If additional information is required contact: Robert Houser, Department Clearance Officer, Policy and Planning Staff, Office of the Chief Information Officer, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, Suite 3E.206, Washington, DC 20530.

Dated: October 28, 2022.

Robert Houser,

Department Clearance Officer, Policy and Planning Staff, Office of the Chief Information Officer, U.S. Department of Justice.

[FR Doc. 2022–23888 Filed 11–4–22; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF JUSTICE

[OMB 1125–0007]

Agency Information Collection Activities; Proposed eCollection; eComments Requested; Revision of a Currently Approved Collection; Immigration Practitioner Complaint Form.

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Executive Office for Immigration Review, Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** on August 25, 2022, allowing for a 60-day comment period.

DATES: The comment period for the notice published at 87 FR 52417 on August 25, 2022 is extended. Comments are encouraged and will be accepted until December 7, 2022.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg

Pike, Suite 2500, Falls Church, VA 22041, telephone: (703) 305–0289. Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20530 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Executive Office for Immigration Review, including whether the information will have practical utility;
- 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;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- 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 submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a currently approved collection.

2. *The Title of the Form/Collection:* Immigration Practitioner Complaint Form.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form EOIR–44. The applicable component within the Department of Justice is the Office of General Counsel, Executive Office for Immigration Review.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals who wish to file a complaint against an immigration practitioner authorized to appear before the Board of Immigration Appeals and the immigration courts. Abstract: The information on this form will be used to determine whether the Office of the General Counsel of the Executive Office for Immigration Review should conduct a preliminary disciplinary inquiry, request additional information from the complainant, refer the matter to a state bar disciplinary authority or other law enforcement agency, or take no further action.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 125 respondents will complete the form annually, with an average of 2 hours per response.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated public burden associated with this collection is 250 hours. It is estimated that respondents will take 2 hours to complete the form. The burden hours for collecting respondent data sum to 250 hours (125 respondents × 2 hours = 250 hours).

If additional information is required contact: Robert Houser, Department Clearance Officer, Policy and Planning Staff, Office of the Chief Information Officer, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, Suite 3E.206, Washington, DC 20530.

Dated: October 28, 2022.

Robert Houser,

Department Clearance Officer, Policy and Planning Staff, Office of the Chief Information Officer, U.S. Department of Justice.

[FR Doc. 2022–23890 Filed 11–4–22; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Post Enrollment Data Collection for Job Corps Participants

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employment Training Administration (ETA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before December 7, 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.

Comments are invited on: (1) 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; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The 2014 Workforce Innovation Opportunity Act (WIOA) required the Office of Job Corps to collect and report specific post enrollment outcomes for eligible Job Corps participants beginning in Program Year (PY) 2016. The WIOA performance reporting requirements, which replaced those of the 1998 Workforce Investment Act (WIA), are designed to provide a common set of metrics to be reported by similar programs. To collect the necessary information to meet the new WIOA reporting requirements, the Office of Job Corps revised its post enrollment data collection system (PEDC) in 2019, which primarily collects data through survey instruments. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on February 24, 2022 (87 FR 10391).

This information collection is subject to the PRA. 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 the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3)

years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–ETA.

Title of Collection: Post Enrollment Data Collection for Job Corps Participants.

OMB Control Number: 1205–0426.

Affected Public: Individuals or households; private sector—businesses or other for-profits and not-for-profit institutions.

Total Estimated Number of Respondents: 49,200.

Total Estimated Number of Responses: 93,400.

Total Estimated Annual Time Burden: 21,538 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D).)

Dated: October 31, 2022.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2022–24177 Filed 11–4–22; 8:45 am]

BILLING CODE 4510–FT–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Emergency Mine Evacuation

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Mine Safety and Health Administration (MSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before December 7, 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.

Comments are invited on: (1) 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; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Nora Hernandez by telephone at 202–693–8633, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: MSHA requires each operator of an underground coal mine to submit a Mine Emergency Evacuation and Firefighting Program of Instruction to the MSHA District Manager for approval. Upon approval by the MSHA District Manager, the operator uses the approved instruction program to implement programs for training miners to respond appropriately to mine emergencies. MSHA uses the plans to ensure that the operator's program will provide the required training and drills to all miners. MSHA requires the operators to certify the training and drills for each miner at the completion of each quarterly drill, annual expectations training, or other training, and that a copy be provided to the miner upon request. These certifications are used by MSHA, operators, and miners as evidence that the required training has been completed. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on June 17, 2022 (87 FR 36538).

This information collection is subject to the PRA. 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 the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–MSHA.

Title of Collection: Emergency Mine Evacuation.

OMB Control Number: 1219–0141.

Affected Public: Businesses or other for-profits institutions.

Total Estimated Number of Respondents: 155.

Total Estimated Number of Responses: 867,338.

Total Estimated Annual Time Burden: 372,761 hours.

Total Estimated Annual Other Costs Burden: $62,186.

(Authority: 44 U.S.C. 3507(a)(1)(D).)

Nora Hernandez,

Departmental Clearance Officer.

[FR Doc. 2022–24178 Filed 11–4–22; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petition for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of a petition for modification submitted to the Mine Safety and Health Administration (MSHA) by the party listed below.

DATES: All comments on the petition must be received by MSHA's Office of Standards, Regulations, and Variances on or before December 7, 2022.

ADDRESSES: You may submit comments identified by Docket No. MSHA–2022–054 by any of the following methods:

1. *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments for MSHA–2022–054.

2. *Fax:* 202–693–9441.

3. *Email: petitioncomments@dol.gov.*

4. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452.

Attention: S. Aromie Noe, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect copies of the petition and comments during normal business hours at the address listed above. Before visiting MSHA in person,

call 202–693–9455 to make an appointment, in keeping with the Department of Labor's COVID–19 policy. Special health precautions may be required.

FOR FURTHER INFORMATION CONTACT: S. Aromie Noe, Office of Standards, Regulations, and Variances at 202–693–9440 (voice), *Petitionsformodification@dol.gov* (email), or 202–693–9441 (fax). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and title 30 of the Code of Federal Regulations (CFR) part 44 govern the application, processing, and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. The application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, sections 44.10 and 44.11 of 30 CFR establish the requirements for filing petitions for modification.

II. Petition for Modification

Docket Number: M–2022–012–M.

Petitioner: Nyrstar Tennessee Mines—Gordonsville, LLC, 120 Zinc Mine Circle, Gordonsville, Tennessee, 38563.

Mine: Middle Tennessee Mine, MSHA ID No. 40–00864, located in Smith County, Tennessee.

Regulation Affected: 30 CFR 57.11052(d), Refuge areas.

Modification Request: The petitioner requests a modification of 30 CFR 57.11052(d) to permit the use of the refuge chamber's internal air supply, versus the use of a compressed air line, to provide air for the underground refuge chamber.

The petitioner states that:

(a) The application of 30 CFR 57.11052(d) requiring the use of a compressed air line would be unsafe under the conditions present at the mine.

(b) The mine is an underground zinc mine utilizing both random room and pillar mining and longitudinal long-hole stoping. In both methods, a single development drift is driven through waste rock adjacent to the ore body. When this drift reaches planned elevations, level accesses are developed to provide entry points to the ore body for exploration and later ore production. Once the level development and exploration are completed at a planned elevation, the ore is extracted either perpendicular (random room and pillar mining) or parallel to the strike of the ore (longitudinal stoping).

(c) The mine has been in operation since 1968, and the petitioner has operated the Mine since 2009. During the second quarter of 2022, the mine typically had 25 stopes associated with production, and approximately 15 main development drifts in which exploration and development were occurring. The precise number of stopes and drifts may vary slightly from one month to the next.

(d) There are 22 to 33 miners working in the mine.

(e) There are five active refuge chambers located throughout the mine. The locations are subject to change depending on the mining direction.

(f) Each refuge chamber is a self-contained chamber with its own sources for electrical power, breathable air, water, food, and a lavatory. Designed to physically shield miners following an underground emergency, each refuge chamber can provide electrical power and breathable air to eight occupants for a minimum of 48 hours.

(g) The refuge chambers are compliant with the following parameters of 30 CFR part 7 Subpart L:

(1) Breathable air provided via compressed oxygen or compressed air;

(2) Oxygen supply rate at 1.32 cubic feet per hour per person;

(3) Compressed air supply rate at 12.5 cubic feet per minute per person.

(h) In addition to medical grade oxygen cylinders and compressed air cylinders, each refuge chamber has been supplied with a compressed air line with an Ingersoll-Rand 80 gallon electric compressor outside of the chamber for more than 15 years.

(i) A monitoring/diversion system will be installed to prevent any compressed air from entering the 29 South Refuge Chamber in case the compressed air carbon monoxide level reaches or exceeds 10 parts per million (PPM). The other refuge chambers do not require the installation of this diversion system. If the petition is granted, the diversion system will not be used.

(j) Underground operations take place in a dynamic environment. Exploration and development areas are dominated by self-propelled mobile equipment and blasting activities.

(k) The refuge chambers must be relocated from time to time. The connection of air lines must be considered when positioning the refuge chambers

(l) Damage to the refuge chamber puts miners at risk as it may not function as intended. Each time a refuge chamber is relocated, there is a potential that it will be damaged. Similarly, if a compressed air line needs to be run and connected at each new location, there is a chance that the line or the connections will be damaged. Potential damage to the refuge chamber, the external air line, and the compressor increases each time a chamber and the components are moved, disconnected, rerouted, reconnected, and tested. The risk of damaging the lines and connectors is eliminated by relying on the refuge chamber's medical grade oxygen cylinders.

(m) Oxygen discharged from damaged or leaking air lines could fuel a potential fire, making the compressed air lines more of a potential hazard than a source of breathable air. Removing compressed air lines removes this hazard.

(n) The air compressors are vulnerable to power failure and damage. However, the compressed medical oxygen cylinders and compressed air cylinders are secured within the refuge chamber and are not subject to damage or power failure. The medical grade oxygen cylinders will at all times guarantee miners no less than the same measure of protection afforded by the standard with no diminution of safety to miners.

The petitioner proposes the following alternative method:

(a) Using the self-contained refuge chamber's internal air supply that provides a minimum of a 48-hour internal air supply for up to 8 miners.

(b) Securing medical grade oxygen cylinders and compressed air cylinders within the refuge chamber so they are not subject to damage or power failure.

The petitioner asserts that the alternative method proposed will at all times guarantee no less than the same measure of protection afforded the miners under the mandatory standard.

Song-ae Aromie Noe,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2022–24179 Filed 11–4–22; 8:45 am]

BILLING CODE 4520–43–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Expectations for Representatives Appearing Before the Office of Workers' Compensation Programs

AGENCY: Office of Workers' Compensation Programs, Labor.

ACTION: Notice of expectations of conduct.

SUMMARY: The Office of Workers' Compensation Programs (OWCP) is adopting a set of expectations regarding the conduct of representatives who interact with OWCP staff. The intent is to respond to inappropriate behavior on the part of a small percentage of representatives who participate in the benefit programs administered by OWCP.

DATES: The set of expectations was signed October 6, 2022.

FOR FURTHER INFORMATION CONTACT: Nancy Griswold, Deputy Director, OWCP at *Griswold.Nancy.J@dol.gov;* (202) 604–5776.

SUPPLEMENTARY INFORMATION: The Office of Workers' Compensation Programs (OWCP) administers benefit programs for workers covered by the Black Lung Benefits Act, Longshore and Harbor Workers' Compensation Act, Federal Employees' Compensation Act, and the Energy Employees Occupational Illness Compensation Program Act. Public servants who process benefits claims within each of these programs are required to interact with the public on a daily basis. While the vast majority of individuals who interact with Federal workers during the processing of claims do so in an appropriate manner, there have been recurring instances of improper and abusive conduct directed at OWCP's employees by a small minority of individuals representing parties/claimants. Because such inappropriate conduct can interfere with claims processing and impair the decision-making process, OWCP has adopted a set of expectations for the behavior of individuals who interact with its employees. Moreover, OWCP has a responsibility to prohibit discrimination against or harassment of any OWCP employee because of race, color, sex (including sexual harassment and pregnancy, and related conditions), sexual orientation, gender identity, ethnicity or national origin, religion, age, genetic information, disability, or in retaliation for engaging in protected Equal Employment Opportunity (EEO) activity (collectively, protected characteristics). OWCP is issuing these expectations both in response to instances of improper and abusive conduct but also to generally clarify and ensure a common understanding of how party/claimant representatives should conduct themselves in dealings with OWCP. In doing so, OWCP seeks to maintain an environment of civility that will facilitate the claims process and improve the working environment for its employees.

OWCP adopts this set of expectations under Secretary's Order 10–2009, 74 FR 58834.

Expectations for Representatives Appearing Before the Office of Workers' Compensation Programs

(a)*Purpose and scope.* OWCP strives to treat all claimants, parties and their representatives with courtesy and respect, and prohibit discrimination and/or harassment against their employees based on protected characteristics. We expect that claimants, parties and their representatives will extend that same courtesy and respect to OWCP employees.

In light of this expectation, all attorneys and other persons acting on behalf of a party/claimant should both provide competent assistance to the party/claimant and recognize OWCP's authority to lawfully administer the process. In particular, we expect all representatives to adhere to the following guidelines.

(b) *Expectations of Affirmative Conduct.* OWCP expects that a representative will:

(1) Be truthful in their dealings with claimants, other parties, and with OWCP and its programs.

(2) Act with reasonable promptness to assist the party/claimant with obtaining the information or evidence that must be submitted under OWCP's regulations and forwarding the information or evidence to OWCP for consideration as soon as practicable.

(3) Assist the party/claimant in complying, as soon as practicable, with OWCP's requests for information or evidence at any stage of the administrative decision-making process in their claim.

(4) Aid in the efficient, fair, and orderly conduct of the administrative decision-making process by:

(i) Providing competent representation. Competent representation requires the knowledge, skill, thoroughness, and preparation reasonably necessary for the representation.

(ii) Acting with reasonable diligence and promptness in representing a party/claimant. This includes providing prompt and responsive answers to OWCP's requests for information concerning a claim.

(iii) Communicating promptly with the party/claimant, including reasonably informing them of all matters concerning the representation, consulting with them on an ongoing basis while representing them, and responding to their reasonable requests for information.

(5) For business conducted with OWCP electronically, conducting such business at the times and in the manner prescribed by OWCP.

(6) Ensuring that all of the representative's employees, assistants, partners, contractors, and any other person assisting the representative on claims for which the representative has been appointed, are aware that they are expected to comply with these guidelines.

(c) *Unacceptable Conduct.* Engaging in disrespectful and obstructive behavior does not benefit parties/claimants and interferes with proper administration of the claims process. We therefore expect that a representative will not:

(1) Undertake representation in any matter when they are legally barred from doing so.

(2) Communicate with OWCP or other parties or representatives in a threatening or disrespectful manner. OWCP may restrict the communication methods of a representative who does not meet this expectation.

(3) In any manner or by any means, threaten, coerce, intimidate, deceive or knowingly mislead a party/claimant or prospective party/claimant regarding the availability of benefits or other rights under the relevant Act.

(4) Willfully misleading the party/claimant or prospective party/claimant about the representative's services and qualifications.

(5) Knowingly make or present false or misleading oral or written statements, evidence, assertions, or representations about a material fact or law.

(6) Through their own actions or omissions, unreasonably delay or cause to be delayed the processing of a claim.

(7) Divulge the party/claimant's confidential information outside of the claims adjudication process without their consent.

(8) Attempt to influence, directly or indirectly, the outcome of a decision, determination or other administrative action by:

(i) Threatening harm (either physical or otherwise) to a presiding official, OWCP employee, or other person who is or may reasonably be expected to be

involved in the administrative decision-making process; or

(ii) Offering anything of value to a presiding official, OWCP employee, or other person who is or may reasonably be expected to be involved in the administrative decision-making process.

OWCP will report any such threats or offers to appropriate authorities.

(9) Engage in actions or behavior that impede the fair and orderly conduct of administrative proceedings, including:

(i) Repeatedly being absent from, or persistently tardy at, scheduled proceedings without good cause;

(ii) Disrupting proceedings or obstructing the adjudicative process by:

(A) Directing threatening or intimidating language, gestures or actions at any person involved in the process.

(B) Providing misleading information or misrepresenting facts that affect how OWCP processes a claim, such as the place of residence or mailing address of a party/claimant.

(C) Communicating with OWCP staff or adjudicators outside the normal course of business or other prescribed procedures in an attempt to inappropriately influence the processing or outcome of a claim.

(10) Refusing to comply with any of our rules or regulations.

(11) Requesting or assisting another person to violate our rules or regulations.

(12) Advising any party/claimant or person not to comply with any of our rules or regulations.

(13) Engage in actions, behavior, or conduct that is discriminatory or harassing, and based on protected characteristics.

Signed at Washington, DC, on October 6, 2022.

Christopher J. Godfrey,

Director, Office of Workers' Compensation Programs.

[FR Doc. 2022–22630 Filed 11–4–22; 8:45 am]

BILLING CODE 4510–CR–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (22–089)]

Planetary Science Advisory Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Planetary Science Advisory Committee. The meeting will be held for the purpose of soliciting, from the scientific community and other persons, scientific and technical information relevant to program planning.

DATES: Monday, December 5, 2022, 10:00 a.m. to 6:00 p.m., Eastern Time; and Tuesday, December 6, 2022, 10:00 a.m. to 6:00 p.m., Eastern Time.

ADDRESSES: Virtual meeting via telephone and WebEx.

FOR FURTHER INFORMATION CONTACT: Ms. KarShelia Kinard, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–2355 or *karshelia.kinard@nasa.gov.*

SUPPLEMENTARY INFORMATION: As noted above, this meeting will be available telephonically and via WebEx.

For Monday, December 5, the WebEx information for attendess is: *https://nasaenterprise.webex.com/nasaenterprise/j.php?MTID=mecbc5b9797e7620ff4bf243759dbc18c.* The Webinar number is 2760 894 5087 and the password is P@C-psd-1205 (71207731 from phones). To join by telephone call, use U.S. Toll +1–929–251–9612 (Access code: 276 089 45087).

For Tuesday, December 6, the WebEx information for attendees is: *https://nasaenterprise.webex.com/nasaenterprise/j.php?MTID=m3fd0d89e8c8864d864ae6d339f2efadd.* The Webinar number is 2763 772 4826 and the password is P@C-psd-1206 (71207731 from phones). To join by telephone call, use U.S. Toll +1–929–251–9612 (Access code: 276 377 24826).

Accessibility: Captioning will be provided for this meeting. We are committed to providing equal access to this meeting for all participants. If you need alternative formats or other reasonable accommodations, please contact Ms. KarShelia Kinard, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–2355 or *karshelia.kinard@nasa.gov.*

The agenda for the meeting includes the following topics:

—Planetary Science Division Update
—Planetary Science Division Research and Analysis Program Update

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Carol Hamilton,

Acting Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2022–24231 Filed 11–4–22; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2023–006]

Freedom of Information Act (FOIA) Advisory Committee Meeting

AGENCY: Office of Government Information Services (OGIS), National Archives and Records Administration (NARA).

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: We are announcing an upcoming Freedom of Information Act (FOIA) Advisory Committee meeting in accordance with the Federal Advisory Committee Act and the second United States Open Government National Action Plan.

DATES: The meeting will be on December 1, 2022, from 10 a.m. to 12:30 p.m. EST. You must register by 11:59 p.m. EST November 29, 2022, to attend.

ADDRESSES: This meeting will be held virtually. We will send access instructions for the meeting to those who register according to the instructions below.

FOR FURTHER INFORMATION CONTACT: Kirsten Mitchell, Designated Federal Officer for this committee, by email at *foia-advisory-committee@nara.gov,* or by telephone at 202.741.5770.

SUPPLEMENTARY INFORMATION:

Agendas and meeting materials: We will post all meeting materials, including the agenda, at *https://www.archives.gov/ogis/foia-advisory-committee/2022-2024-term.*

This meeting will be the third of the 2022–2024 committee term. The purpose of the meeting will be to hear from a panel discussing complex FOIA requests and litigation, and to hear reports from each of the three subcommittees.

Procedures: This virtual meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. app. 2). If you wish to offer oral public comments during the public comments periods of the meetings, you must register in advance through Eventbrite *https://foiaac-mtg-dec-1-2022.eventbrite.com.* You must provide an email address so that we can provide you with information to access the meeting online. Public comments will be limited to three minutes per individual. We will also live-stream the meeting on the National Archives YouTube channel, *https://www.youtube.com/user/usnationalarchives,* and include a captioning option. To request additional accommodations (*e.g.,* a transcript),

email *foia-advisory-committee@nara.gov* or call 202.741.5770. Members of the media who wish to register, those who are unable to register online, and those who require special accommodations, should contact Kirsten Mitchell (contact information listed above).

Tasha Ford,

Committee Management Officer.

[FR Doc. 2022–24202 Filed 11–4–22; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Proposed Collection: Comment Request

ACTION: Notice.

SUMMARY: The National Endowment for the Arts, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the National Endowment for the Arts, on behalf of the Federal Council on the Arts and the Humanities, is soliciting comments concerning renewal of the Application for International Indemnification. A copy of this collection request can be obtained by contacting the office listed below in the address section of this notice.

DATES: Written comments must be submitted to the office listed in the address section below within 60 days from the date of this publication in the **Federal Register**.

ADDRESSES: Send comments to Patricia Loiko, National Endowment for the Arts, via email (*loikop@arts.gov*).

SUPPLEMENTARY INFORMATION: The National Endowment for the Arts is particularly interested in comments which:

- 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;
- 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;
- Enhance the quality, utility and clarity of the information to be collected; and
- 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 the electronic submissions of responses.

Dated: November 1, 2022.

Bonita Smith,

Director, Office of Administrative Services and Contracts National Endowment for the Arts.

[FR Doc. 2022–24153 Filed 11–4–22; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Proposed Collection: Comment Request

ACTION: Notice.

SUMMARY: The National Endowment for the Arts, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the National Endowment for the Arts, on behalf of the Federal Council on the Arts and the Humanities, is soliciting comments concerning renewal of the Application for Domestic Indemnification. A copy of this collection request can be obtained by contacting the office listed below in the address section of this notice.

DATES: Written comments must be submitted to the office listed in the address section below within 60 days from the date of this publication in the **Federal Register**.

ADDRESSES: Send comments to Patricia Loiko, National Endowment for the Arts, via email (*loikop@arts.gov*).

SUPPLEMENTARY INFORMATION: The National Endowment for the Arts is particularly interested in comments which:

- 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;
- 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;
- Enhance the quality, utility and clarity of the information to be collected; and
- 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 the electronic submissions of responses.

Dated: November 1, 2022.

Bonita Smith,

Director, Office of Administrative Services and Contracts, National Endowment for the Arts.

[FR Doc. 2022–24159 Filed 11–4–22; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

Meeting of National Council on the Humanities

AGENCY: National Endowment for the Humanities; National Foundation on the Arts and the Humanities.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, notice is hereby given that the National Council on the Humanities will meet to advise the Chair of the National Endowment for the Humanities (NEH) with respect to policies, programs and procedures for carrying out her functions; to review applications for financial assistance under the National Foundation on the Arts and Humanities Act of 1965 and make recommendations thereon to the Chair; and to consider gifts offered to

NEH and make recommendations thereon to the Chair.

DATES: The meeting will be held on Thursday, November 17, 2022, from 11 a.m. until 2:30 p.m., and Friday, November 18, 2022, from 11 a.m. until adjourned.

ADDRESSES: The meeting will be held by videoconference originating at Constitution Center, 400 7th Street SW, Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 7th Street, SW, 4th Floor, Washington, DC 20506; (202) 606–8322; *evoyatzis@neh.gov.*

SUPPLEMENTARY INFORMATION: The National Council on the Humanities is meeting pursuant to the National Foundation on the Arts and Humanities Act of 1965 (20 U.S.C. 951–960, as amended). The following Committees of the National Council on the Humanities will convene by videoconference on November 17, 2022, from 11 a.m. until 2:30 p.m., to discuss specific grant applications and programs before the Council:

Challenge Programs;
Digital Humanities;
Education Programs;
Federal/State Partnership;
Preservation and Access;
Public Programs; and
Research Programs.

The plenary session of the National Council on the Humanities will convene by videoconference on November 18, 2022, at 11 a.m. until 2 p.m. The agenda for the plenary session will be as follows:

A. Minutes of Previous Meetings
B. Reports
  1. Introduction of New Council member
  2. Farewell Remarks from Former Council member
  3. Chair's Remarks
  4. Reports on Policy and General Matters
C. Challenge Programs
D. Digital Humanities
E. Education Programs
F. Federal/State Partnership
G. Preservation and Access
H. Public Programs
I. Research Programs

The National Council will then convene in executive session by videoconference on November 18, 2022, from 2:10 p.m. to 3:40 p.m.

This meeting of the National Council on the Humanities will be closed to the public pursuant to sections 552b(c)(4), 552b(c)(6), and 552b(c)(9)(B) of title 5, U.S.C., as amended, because it will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, and discussion of certain information, the premature disclosure of which could significantly frustrate implementation of proposed agency action. I have made this determination pursuant to the authority granted me by the Chair's Delegation of Authority to Close Advisory Committee Meetings dated April 15, 2016.

Dated: November 1, 2022.

Samuel Roth,

Attorney-Advisor, National Endowment for the Humanities

[FR Doc. 2022–24116 Filed 11–4–22; 8:45 am]

BILLING CODE 7536–01–P

NATIONAL SCIENCE FOUNDATION

Proposal Review; Notice of Meetings

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces its intent to hold proposal review meetings throughout the year. The purpose of these meetings is to provide advice and recommendations concerning proposals submitted to the NSF for financial support. The agenda for each of these meetings is to review and evaluate proposals as part of the selection process for awards. The review and evaluation may also include assessment of the progress of awarded proposals. These meetings will primarily take place at NSF's headquarters, 2415 Eisenhower Avenue, Alexandria, VA 22314.

These meetings will be closed to the public. The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act. NSF will continue to review the agenda and merits of each meeting for overall compliance of the Federal Advisory Committee Act.

These closed proposal review meetings will not be announced on an individual basis in the **Federal Register**. NSF intends to publish a notice similar to this on a quarterly basis. For an advance listing of the closed proposal review meetings that include the names of the proposal review panel and the time, date, place, and any information on changes, corrections, or cancellations, please visit the NSF website: *https://www.nsf.gov/events/advisory.jsp.* This information may also be requested by telephoning, 703/292–8687.

Dated: November 1, 2022.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2022–24152 Filed 11–4–22; 8:45 am]

BILLING CODE 7555–01–P

PENSION BENEFIT GUARANTY CORPORATION

Proposed Submission of Information Collection for OMB Review; Comment Request; Annual Financial and Actuarial Information Reporting

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of intent to request extension of OMB approval of information collection.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) intends to request that the Office of Management and Budget (OMB) extend approval, without modifications, under the Paperwork Reduction Act, of a collection of information contained in its regulation on Annual Financial and Actuarial Information Reporting. This notice informs the public of PBGC's intent and solicits public comment on the collection of information.

DATES: Comments must be submitted on or before January 6, 2023.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Email: paperwork.comments@pbgc.gov.* Refer to OMB control number 1212–0049 in the subject line.
- *Mail or Hand Delivery:* Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101.

Commenters are strongly encouraged to submit public comments electronically. PBGC expects to have limited personnel available to process public comments that are submitted on paper through mail. Until further notice, any comments submitted on paper will be considered to the extent practicable.

All submissions received must include the agency's name (Pension Benefit Guaranty Corporation, or PBGC) and refer to OMB control number 1212–0049. All comments received will be posted without change to PBGC's website, *http://www.pbgc.gov,* including

any personal information provided. Do not submit comments that include any personally identifiable information or confidential business information.

Copies of the collection of information may be obtained by writing to Disclosure Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101, or calling 202–229–4040 during normal business hours. If you are deaf or hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

FOR FURTHER INFORMATION CONTACT: Melissa Rifkin (*rifkin.melissa@pbgc.gov*), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101. (If you are deaf or hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.)

SUPPLEMENTARY INFORMATION: Section 4010 of the Employee Retirement Income Security Act of 1974 (ERISA) and PBGC's regulation on Annual Financial and Actuarial Information Reporting (29 CFR part 4010) require each member of a controlled group to submit financial and actuarial information to PBGC under certain circumstances. Section 4010 specifies that each controlled group member must provide PBGC with certain financial information, including audited (if available) or (if not) unaudited financial statements. Section 4010 also specifies that the controlled group must provide PBGC with certain actuarial information necessary to determine the liabilities and assets for all PBGC-covered plans.

PBGC's 4010 regulation specifies the items of identifying, financial, and actuarial information that filers must submit under section 4010, through PBGC's e-filing portal. Computer-assisted analysis of this information helps PBGC to anticipate possible major demands on the pension insurance system and to focus PBGC resources on situations that pose the greatest risks to that system. Because other sources of information are usually not as current as the section 4010 information and do not reflect a plan's termination liability, the section 4010 filing plays a major role in PBGC's ability to protect participant and premium-payer interests.

PBGC estimates that 400 controlled groups will submit filings under part 4010 each year. The total estimated annual hourly and cost burdens of the information collection are 800 hours and $11,080,000.

The collection of information has been approved under OMB control number 1212–0049 (expires March 31, 2023). PBGC intends to request that OMB extend its approval, without modifications, for another 3 years. 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.

PBGC is soliciting public comments to—

- 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;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodologies and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- 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 submission of responses.

Issued in Washington, DC, by:

Hilary Duke,

Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2022–24233 Filed 11–4–22; 8:45 am]

BILLING CODE 7709–02–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2023–31 and CP2023–30]

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:* November 9, 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:

Table of Contents

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.

[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).

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2023–31 and CP2023–30; *Filing Title:* USPS Request to Add Priority Mail & First-Class Package Service Contract 224 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 1, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* November 9, 2022.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2022–24187 Filed 11–4–22; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96205; File No. SR–PEARL–2022–43]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 2614, Orders and Order Instructions and Rule 2618, Risk Settings and Trading Risk Metrics To Enhance Existing Risk Controls

November 1, 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 October 19, 2022, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''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

The Exchange is filing a proposed rule change to enhance its existing risk controls and provide Equity Members [3] additional risk controls when trading equity securities on the Exchange's equity trading platform (referred to herein as ''MIAX Pearl Equities'').

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 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 purpose of the proposed rule change is to enhance certain existing risk controls and provide Equity Members additional risk controls when trading equity securities on MIAX Pearl Equities. To help Equity Members manage their risk, the Exchange currently offers Limit Order Price Protection and other risk controls that authorize the Exchange to take automated action if a designated limit for an Equity Member is breached. Such risk controls provide Equity Members with enhanced abilities to manage their risk when trading on the Exchange. The Exchange now proposes to amend Limit Order Price Protection under Exchange Rule 2614(a)(1)(I) and amend Exchange Rule 2618 to enhance certain existing risk controls and provide additional optional risk controls to Equity Members. Each of these changes are described below.

Limit Order Price Protection

Limit Order Price Protection is set forth under Exchange Rule 2614(a)(1)(I) and provides for the cancellation of Limit Orders priced too far away from a specified reference price at the time the order first becomes eligible to trade. A Limit Order entered before Regular Trading Hours [4] that becomes eligible to trade during Regular Trading Hours will be subject to Limit Order Price Protection at the time Regular Trading Hours begins.[5]

Exchange Rule 2614(a)(1)(I)(i) provides that a Limit Order to buy (sell) will be rejected if it is priced at or above (below) the greater of a specified dollar value and percentage away from the following: (1) the PBO for Limit Orders to buy, the PBB for Limit Orders to sell; (2) if the PBO or PBB is unavailable, the consolidated last sale price disseminated during the Regular Trading Hours on trade date; (3) if the PBO, PBB, and a consolidated last sale price are unavailable, the prior day's Official Closing Price identified as such by the primary listing exchange, adjusted to account for events such as corporate actions and news events. Exchange Rule 2614(a)(1)(I)(iii) provides that Limit Order Price Protection will not be applied if the prices listed above are unavailable. Equity Members have requested that Limit Order Price Protection also not be applied when the prior day's Official Closing Price is to be used when the PBO, PBB, and a consolidated last sale price are unavailable and a trading halt has been declared by the primary listing market during that trading day. The Exchange understands that Equity Members believe the Official Closing Price does not appropriately relate to the current trading behavior of the security in such a scenario and Equity Members would prefer Limit Order Price Protection not be applied since it may result in their Limit Order being unnecessarily rejected. The Exchange, therefore, proposes to amend Exchange Rule 2614(a)(1)(I)(iii) to provide that Limit Order Price Protection would not be applied when a regulatory halt has been declared by the primary listing market during that trading day and the Exchange would have applied the prior day's Official Closing Price because the PBO, PBB, and a consolidated last sale price are unavailable.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Equity Member'' is a Member authorized by the Exchange to transact business on MIAX Pearl Equities. *See* Exchange Rule 1901.

[4] The term ''Regular Trading Hours'' means the time between 9:30 a.m. and 4:00 p.m. Eastern Time. *See* Exchange Rule 1901.

[5] Further, a Limit Order in a security that is subject to a trading halt becomes first eligible to trade when the halt is lifted and continuous trading has resumed. *See Exchange Rule* 2614(a)(1)(I)(iii).

Exchange Rule 2614(a)(1)(I)(ii) provides Equity Members the ability to customize their specified dollar and percentages on a per session [6] basis. If an Equity Member does not provide the Exchange specified dollar values or percentages for their order(s), default specified dollar and percentages established by the Exchange will be applied.[7] Equity Members have expressed the need for additional flexibility by being able to customize their dollar and percentage thresholds on a per Market Participant Identifier (''MPID'') basis, rather than only on a per session basis. Equity Members requested this flexibility so that they can customize their dollar and percentage thresholds individually for each of their MPIDs based on their risk appetite. Therefore, the Exchange proposes to amend Exchange Rule 2614(a)(1)(I)(ii) to also allow Equity Members to customize the specified dollar and percentages on a per MPID basis.

Per-Order Risk Controls

The Exchange offers Equity Members the ability to establish certain risk control parameters that assist Equity Members in managing their market risk on a per order basis. These optional risk controls are set forth under Exchange Rule 2618(a)(1) and offer Equity Members protection from entering orders outside of certain size and price parameters, and selected order type and modifier combinations, as well as protection from the risk of duplicative executions. The Exchange also permits Equity Members to block new orders, to cancel all open orders, block both new orders and cancel all open orders, and automatically cancel all orders to the extent the Equity Member loses its connection to MIAX Pearl Equities.[8] The risk controls are available to all Equity Members, but are particularly useful to Market Makers, who are required to continuously quote in the Equity Securities to which they are assigned.

As an initial matter, the Exchange proposes to amend Exchange Rule 2618(a)(5) and (6) to incorporate the risk controls set forth under Exchange Rule 2618(a)(1). Exchange Rule 2618(a)(5) currently provides that for the risk settings identified in Exchange Rule 2618(a)(2) (discussed below), both the Equity Member and the Clearing Member (if allocated such responsibility pursuant to Exchange Rule 2618(a)(4)) may enable alerts to signal when the Equity Member is approaching designated limits. Equity Members are also able to enable alerts for risk settings set forth under Exchange Rule 2618(a)(1) and the Exchange proposes to codify this option in Exchange Rule 2618(a)(5). Therefore, Exchange Rule 2618(a)(5) would provide that for the risk settings identified in Exchange Rule (a)(1), the Equity Member may enable alerts to signal when the Equity Member is approaching designated limits provided for in the applicable risk control.

Exchange Rule 2618(a)(6) currently provides that if a risk setting identified in Exchange Rule 2618(a)(2) is breached, the Exchange will automatically block new orders submitted and cancel open orders until such time that the applicable risk control is adjusted to a higher limit by the Equity Member or Clearing Member with the responsibility of establishing and adjusting the risk settings identified in paragraph (a)(2). The same is true for risk settings set forth under Exchange Rule 2618(a)(1) and the Exchange proposes to codify this option in Exchange Rule 2618(a)(6) by adding references to Exchange Rule 2618(a)(1) and providing that the Exchange will automatically block new orders submitted and cancel open orders based on the applicable risk control. Whether the Exchange automatically blocks new orders or cancels open orders would depend on the nature of the applicable risk control. For example, the Exchange would block an order if it was an order type that the Equity Member instructed the Exchange to block pursuant to Exchange Rule 2618(a)(1)(C) or was entered in a Principal capacity and to be blocked pursuant to proposed Exchange Rule 2618(a)(1)(E). The Exchange would cancel an order in a security resting on the MIAX Pearl Equities Book where, for purposes of the cumulative risk controls under Exchange Rule 2618(a)(2), an order is entered in a security that breaches the threshold selected by the Equity Member and the Equity Member instructed the Exchange to cancel the resting orders.[9] The Exchange provides an internet-facing portal via its website that Equity Members access using unique login credentials. The online portal provides self-service functions to Equity Members.[10] Equity Members may use the Exchange's online portal to establish or adjust risk controls set forth under Exchange Rule 2618(a)(1) and (2) and may establish or adjust those controls at the beginning of each trading day or intra-day.

The Exchange also proposes to amend Exchange Rule 2618(a)(1) to provide additional optional per order risk controls to Equity Members.[11] The proposed controls would relate to the entry of orders placed in a Principal or Riskless Principal capacity, the size of an order as compared to the average daily volume (''ADV'') of the security, orders in securities on the Equity Member's restricted securities list, and controls related to the frequency at which orders and/or Cancel/Replace messages are entered. Specifically, Exchange Rule 2618(a)(1)(E) would provide for the prevention of the entry of orders placed in a Principal or Riskless Principal capacity. An Equity Member would be able to instruct the Exchange to reject any orders marked with the capacity of Principal or Riskless Principal or convert such orders to an Agency capacity. In such case, only orders with a capacity of Agency would be accepted. This control is similar to existing controls, such as controls to block an order type or modifier under Exchange Rule 2618(a)(1)(C), because both instruct the Exchange to reject an order that includes certain specific characteristics, such as an order modifier, or in this case, a specific capacity. This proposed risk setting may also assist Equity Members in complying with Exchange Rule 2603, which requires Equity Members to ''input accurate information into the System, including, but not limited to, whether the Equity Member acted in a Principal, Agent, or Riskless Principal capacity for each order entered'' by preventing the entry of an order in a Principal capacity where it seeks to only enter orders in an Agency capacity.

Exchange Rule 2618(a)(1)(F) would provide for controls preventing the entry of an order or order modification request with a size that exceeds the

[6] ''Sessions'' is a defined group of connections to the Exchange's System.

[7] The default specified dollar and percentages are posted to the Exchange's website here: *https://www.miaxequities.com/system-configuration/pearl-equities.*

[8] *See* Exchange Rule 2618(a)(7)(a) (proposed herein to be renumbered as Exchange Rule 2618(a)(7)(A)). The Exchange also proposes to renumber Exchange Rule 2618(a)(7)(b) as Exchange Rule 2618(a)(7)(B).

[9] In such case, the Exchange would also reject the order that breaches the threshold selected by the Equity Member.

[10] *See* Member Firm Portal User Manual, *available at https://www.miaxoptions.com/sites/default/files/knowledge-center/2022-06/MIAX_Exchanges_Member_Firm_Portal_User_Manual_05262022.pdf* (last visited October 13, 2022).

[11] The Exchange also proposes to amend Exchange Rule 2618 to replace all references to the term ''User'' with ''Equity Member'' to ensure consistent terminology is used within the Rule. This is a non-substantive change since the risk controls under Exchange Rule 2618 are only available to Equity Members and, therefore, this proposed change does not alter the operation or application of Exchange Rule 2618.

ADV[12] of the security multiplied by a percentage selected by the Equity Member when the ADV of the security is greater than a specified minimum ADV selected by the Equity Member[13] When opting into this protection, the Equity Member would need to configure an ADV percentage and ''minimum ADV'' for the security. A minimum ADV is required in the security for the control to be applied. For example, an Equity Member may indicate that for any securities with an ADV of 3,000 shares or less, the ADV check should not be applied. The Equity Member sets the minimum ADV, but the ADV percentage only applies if the ADV in the security is higher than the minimum ADV selected by the Equity Member. Pursuant to amended Exchange Rule 2618(a)(6), the Exchange would automatically block new orders or order modification requests until such time that this risk control is adjusted to a higher limit by the Equity Member. Another example, assume the ADV in security ABCD is 2,000 shares and the Equity Member sets a custom percentage of 10% and a minimum ADV of 1,500 shares. In such case, the risk control would be applied as 1,500 < 2,000 with an ADV check threshold of 200 shares (10% × 2,000 = 200 shares). The Equity Member then submits an order for 200 shares and that order is accepted by the Exchange. However, the Exchange would reject an order where that Equity Member entered an order for greater than 200 shares.

Exchange Rule 2618(a)(1)(G) would provide controls related to orders in securities on the Equity Member's restricted securities list. Generally speaking, a restricted list is a current list of securities in which the Equity Member prohibits proprietary, employee and certain solicited customer transactions in a security. This control would instruct the Exchange to reject any order in a security that is included on the Equity Member's restricted securities list pursuant to amended Exchange Rule 2618(a)(6).[14] Lastly, Exchange Rule 2618(a)(1)(H) would provide for controls related to the frequency at which orders and/or Cancel/Replace messages are entered and that instruct the Exchange to reject an order or Cancel/Replace message that are entered at a pace that exceeds a certain frequency.[15] In such case, the Equity Member sets the time window in which the Exchange will count the number of order or Cancel/Replace messages that are received. The Exchange would prevent the entry of new orders or Cancel/Replace messages until a certain amount of time selected by the Equity Member has passed or the Equity Member has reset this control. Pursuant to amended Exchange Rule 2618(a)(5), an Equity Member may enable alerts to signal when the Equity Member is approaching designated frequency limits. This control is similar to existing controls, such as controls to block an order type or modifier under Exchange Rule 2618(a)(1)(C), because both instruct the Exchange to reject an order that includes certain specific characteristics, such as an order modifier, or in this case, is entered within a certain time of an earlier order or Cancel/Replace message.

Currently, Equity Members are able to customize thresholds applicable to the current risk controls under Exchange Rule 2618(a)(1) on a per session or indirectly on a firm level basis[16] and the Exchange proposes to codify this optionality under Exchange Rule 2618(a)(3) by adding a reference to Exchange Rule 2618(a)(1). The Exchange also proposes to now allow Equity Members further flexibility by allowing them to customize thresholds applicable to the current risk controls and the new risk controls described above and set forth under Exchange Rule 2618(a)(1) on a MPID basis. Equity Members have requested this added flexibility so that they may separately manage their order flow at a more granular level.

Exchange Rule 2618(a)(3) currently provides, in sum, that either an Equity Member or its Clearing Member may establish and adjust limits for the risk settings provided in Exchange Rule 2618(a)(2) (described below). Exchange Rule 2618(a)(3)(A) further provides that these limits or thresholds may be set at the MPID, session, or firm level.[17] Exchange Rule 2618(a)(3) does not currently include the risk settings under Exchange Rule 2618(a)(1). Therefore, the Exchange proposes to amend Exchange Rule 2618(a)(3) to include the risk settings under Exchange Rule 2618(a)(1) to codify that they may be set at the firm or session level and to further provide that they may also be set at the MPID level by including the following sentence: ''[a]n Equity Member may set limits for the risk settings provided in paragraph (a)(1) of this Rule 2618.'' Exchange Rule 2618(a)(3)(B) also provides that such limits may be established or adjusted before the beginning of a trading day or during the trading day. This is currently true for the controls under Exchange Rule 2618(a)(1) and adding reference to this rule above to Exchange Rule 2618(a)(3) would codify this functionality and add this additional specificity to the Rule.

The level at which the limits for a certain control could be set would depend on the nature of the control. Specifically, Equity Members are or would be able to set risk settings on a session and/or MPID level for the controls listed under Exchange Rule 2618(a)(1)(A), (B), and (C), and proposed Exchange Rule 2618(a)(1)(E), (F), and (G). Controls to prohibit the entry of duplicative orders under Exchange Rule 2618(a)(1)(D) may only be able to be set at the session level, but due to the nature of the check, the controls would also monitor for duplicative orders sent from the same MPID. Controls related to the frequency of orders and Cancel/Replace messages under proposed Exchange Rule 2618(a)(1)(H) may be set at the session, firm, and MPID level.

Cumulative Risk Controls

Exchange Rule 2618(a)(2) sets forth the specific cumulative risk settings the Exchange offers and include Gross Notional Trade Value and Net Notional Trade Value. Gross Notional Trade Value is a pre-established maximum daily dollar amount for purchases and sales across all symbols, where both purchases and sales are counted as positive values. Net Notional Trade Value is a pre-established maximum daily dollar amount for purchases and sales across all symbols, where purchases are counted as positive values and sales are counted as negative values. For purposes of calculating the Gross Notional Trade Value and Net Notional Trade Value, only executed orders are included.[18]

[12] The ADV would be calculated over the prior 20 trading days and would account for trading days with an early close.

[13] This control is based on Interpretations and Policies .01(g) of EDGX Rule 11.10 and EDGA Rule 11.10.

[14] This control is based on Interpretations and Policies .01(d) of EDGX Rule 11.10 and EDGA Rule 11.10.

[15] This control is based on Interpretations and Policies .01(f) of EDGX Rule 11.10 and EDGA Rule 11.10. Rejection of orders under Exchange Rule 2618(a)(1)(H) is provided for in Exchange Rule 2618(a)(6).

[16] *See* Section 9 of the MIAX Pearl Equities Exchange User Manual *available at MIAX_Pearl_Equities_User_Manual_June_2022.pdf (miaxoptions.com)* (last visited September 19, 2022); *and* Section 1 of the MIAX Pearl Equities Exchange Port Attributes document *available at https://www.miaxoptions.com/sites/default/files/page-files/MIAX_PEARL_Equities_Port_Attributes_v2.0.pdf* (last visited September 19, 2022). The Exchange does not currently expressly permit Equity Members to set the controls listed under Exchange Rule 2614(a)(1) on a firm level basis. However, Equity Members may achieve firm level settings for controls listed under Exchange Rule 2614(a)(1) by setting all of their MPID and session level settings to the same threshold.

[17] *Id.*

[18] The Exchange also proposes to amend the descriptions of Gross Notional Trade Value and Net

Based on Equity Member demand, the Exchange proposes to adopt the following two additional cumulative risk controls that take into account open, unexecuted orders, Gross Notional Open Value and Net Notional Open Value. Proposed Exchange Rule 2618(a)(2)(C) would provide that the Gross Notional Open value is a pre-established maximum daily dollar amount for open buy and sell orders across all symbols, where both open orders to buy and sell are counted as positive values. For purposes of calculating the Gross Notional Open Value, only unexecuted orders are included. Proposed Exchange Rule 2618(a)(2)(D) would provide that the Net Notional Open Value is a pre-established maximum daily dollar amount for open buy and sell orders across all symbols, where open orders to buy are counted as positive values and open orders to sell are counted as negative values. For purposes of calculating the Net Notional Open Value, only unexecuted orders are included, just like the Gross Notional Open Value risk control.

For both the Gross Notional Open Value and Net Notional Open Value risk settings, the open orders calculation would only include Limit Orders resting on the MIAX Pearl Equities Book and Limit Orders that have been routed to an away exchange for execution. Limit Orders and Pegged Orders will be included at their limit price. Market Orders would not be included. Both the Gross Notional Open Value and Net Notional Open Value risk settings are completely optional and would not be applied where the Equity Member does not set the applicable threshold.

Exchange Rule 2618(a)(4) provides that an Equity Member that does not self-clear may allocate and revoke [19] the responsibility of establishing and adjusting the Gross Notional Trade Value and Net Notional Trade Value settings to a Clearing Member [20] that clears transactions on behalf of the Equity Member, if designated in a manner prescribed by the Exchange. The Exchange proposes that the same would be true for the new Gross Notional Open Value and Net Notional Open Value settings.

By way of background, Exchange Rule 2620(a) allows Clearing Members an opportunity to manage their risk of clearing on behalf of other Equity Members, if authorized to do so by the Equity Member trading on the Exchange. Such functionality is designed to help Clearing Members better monitor and manage the potential risks that they assume when clearing for Equity Members of the Exchange. An Equity Member may allocate or revoke the responsibility of establishing and adjusting the risk settings identified in paragraph (a)(2) of Exchange Rule 2618 to its Clearing Member in a manner prescribed by the Exchange. By allocating such responsibility, an Equity Member cedes all control and ability to establish and adjust such risk settings to its Clearing Member unless and until such responsibility is revoked by the Equity Member. Because the Equity Member is responsible for its own trading activity, the Exchange will not provide a Clearing Member authorization to establish and adjust risk settings on behalf of an Equity Member without first receiving consent from the Equity Member. The Exchange considers an Equity Member to have provided such consent if it allocates the responsibility to establish and adjust risk settings to its Clearing Member in a manner prescribed by the Exchange.

Exchange Rule 2618(a)(3) provides that either an Equity Member or its Clearing Member, if allocated such responsibility pursuant to Exchange Rule 2618(a)(4), may establish and adjust limits for the risk settings provided in Exchange Rule 2618(a)(2). An Equity Member or Clearing Member may establish and adjust limits for the risk settings in a manner prescribed by the Exchange. This includes use of the Exchange's online portal. The online portal page also provides a view of all applicable limits for each Equity Member, which will be made available to the Equity Member and its Clearing Member, as currently discussed in Exchange Rule 2618(a)(4).

Trading Collar

In addition to the optional risk control parameters described above, the Exchange also prevents all incoming orders, including those marked ISO, from executing at a price outside the Trading Collar price range and is described in Exchange Rule 2618(b). The Trading Collar prevents buy orders from trading or routing at prices above the collar and prevents sell orders from trading or routing at prices below the collar. The Trading Collar price range is calculated using the greater of numerical guidelines for clearly erroneous executions under Exchange Rule 2621 or a specified dollar value established by the Exchange.

Exchange Rule 2618(b)(1) provides that the Trading Collar price range is calculated based on a Trading Collar Reference Price and sets forth a sequence of prices to determine the Trading Collar Reference Price to be used if a certain reference price is unavailable. The Exchange first utilizes the consolidated last sale price disseminated during the Regular Trading Hours on the trade date as the Trading Collar Reference Price. If not available, the prior day's Official Closing Price identified as such by the primary listing exchange, adjusted to account for events such as corporate actions and news events is used. If neither are available to use as the Trading Collar Reference Price, the Exchange suspends the Trading Collar function in the interest of maintaining a fair and orderly market in the impacted security. The Exchange calculates the Trading Collar price range for a security by applying the Numerical Guideline and reference price to the Trading Collar Reference Price. The result is added to the Trading Collar Reference Price to determine the Trading Collar Price for buy orders, while the result is subtracted from the Trading Collar Reference Price to determine the Trading Collar Price for sell orders. Exchange Rule 2618(b)(1) further provides that upon entry, any portion of an order to buy (sell) that would execute at a price above (below) the Trading Collar Price is cancelled.

Like proposed above for Limit Order Price Protection, Equity Members have requested that the Trading Collar not be applied when the prior day's Official Closing Price is to be used when the a consolidated last sale price is unavailable and a regulatory halt has been declared by the primary listing market during that trading day. The Exchange understands that Equity Members believe the Official Closing Price does not appropriately relate to the current trading behavior of the security in such a scenario and Equity Members would prefer the Trading Collar not be applied since it may result in their order being unnecessarily rejected. The Exchange, therefore,

Notional Trade Value under Exchange Rules 2618(a)(2) to replace the unnecessary phrase ''which refers to'' with the word ''is''. These changes do not alter the operation of either risk control.

[19] As discussed below, if an Equity Member revokes from its Clearing Member the responsibility of establishing and adjusting the risk settings identified in paragraph (a)(2), the settings applied by the Equity Member would be applicable.

[20] The term ''Clearing Member'' refers to a Member that is a member of a Qualified Clearing Agency and clears transactions on behalf of another Member. *See* Exchange Rule 2620(a). Exchange Rule 2620(a) also outlines the process by which a Clearing Member shall affirm its responsibility for clearing any and all trades executed by the Equity Member designating it as its Clearing Firm, and provides that the rules of a Qualified Clearing Agency shall govern with respect to the clearance and settlement of any transactions executed by the Equity Member on the Exchange.

proposes to amend Exchange Rule 2618(b)(1) to provide that upon entry, an order priced outside the Trading Collar would not be rejected when a trading halt has been declared by the primary listing market during that trading day and the Exchange would have applied the prior day's Official Closing Price because the consolidated last sale price is unavailable. In such case, the Exchange would accept such Limit Order and post it on the MIAX Pearl Equities Book at its limit price.[21]

* * * * *

The Exchange does not guarantee that the risk settings in this proposal are sufficiently comprehensive to meet all of an Equity Member's risk management needs. Pursuant to Rule 15c3–5 under the Act,[22] a broker-dealer with market access must perform appropriate due diligence to assure that controls are reasonably designed to be effective, and otherwise consistent with the rule.[23] Use of the Exchange's risk settings included in Exchange Rule 2618 will not automatically constitute compliance with Exchange or federal rules and responsibility for compliance with all Exchange and SEC rules remains with the Equity Member.

Implementation

Due to the technological changes associated with this proposed change, the Exchange will issue a trading alert publicly announcing the implementation date of the proposed enhancements to its risk controls set forth herein. The Exchange anticipates that the implementation date will be in the fourth quarter of 2022.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[24] in general, and furthers the objectives of Section 6(b)(5),[25] 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 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.

Specifically, the Exchange believes the proposed amendments will remove impediments to and perfect the mechanism of a free and open market and a national market system because they provide additional functionality for an Equity Member to manage its risk. The Exchange notes that all of the proposed changes, risk settings, and related functionality are entirely optional. The Exchange believes that the proposed risk settings under Exchange Rule 2618(a)(1) and (2) are designed to protect investors and the public interest because the proposed additional functionality is a form of risk mitigation that will aid Equity Members and Clearing Members in minimizing their financial exposure and reduce the potential for disruptive, market-wide events. In turn, the introduction of such risk management functionality could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system. The proposed rule change would provide an additional option for Equity Members seeking to further tailor their risk management capability while transacting on the Exchange.

Risk Controls Under Exchange Rule 2618(a)(1)

The proposed risk settings under Exchange Rule 2618(a)(1) promote just and equitable principles of trade because they would provide Equity Members with additional protections to manage trading risk and market exposure. Certain of the proposed additional risk settings are available on other equity exchanges [26] or similar to existing risk settings. Specifically, proposed Exchange Rule 2618(a)(1)(E) regarding the entry of orders in a Principal or Riskless Principal capacity is similar to existing controls, such as controls to block an order type or modifier under Exchange Rule 2618(a)(1)(C), because it instructs the Exchange to reject an order that includes certain specific characteristics, such as an order modifier, or in this case, is entered with a specific capacity. Further the proposed controls under Exchange Rule 2618(a)(1)(F), (G), and (H) are based on the rules of other national securities exchange. For example, proposed Exchange Rule 2618(a)(1)(F) provides for the prevention of the entry of an order or order modification request with a size that exceeds the average daily trading volume of the security is based on Interpretations and Policies .01(g) of EDGX Rule 11.10 and EDGA Rule 11.10. Proposed Exchange Rule 2618(a)(1)(G) regarding the entry of orders in securities on an Equity Member's restricted list is based on Interpretations and Policies .01(d) of EDGX Rule 11.10 and EDGA Rule 11.10. Finally, proposed Exchange Rule 2618(a)(1)(H) regarding the frequency of orders and Cancel/Replace messages is based on Interpretations and Policies .01(f) of EDGX Rule 11.10 and EDGA Rule 11.10.

The Exchange believes amending Exchange Rule 2618(a)(3) to incorporate the risk controls under Exchange Rule 2618(a)(1) promotes just and equitable principles of trade because it simply codifies an Equity Member's ability to customize thresholds applicable to the current risk controls under Exchange Rule 2618(a)(1) on a per session or indirectly on a firm level basis.[27] This proposed change would also allow Equity Members to customize thresholds applicable to the current risk controls and the new risk controls described above and set forth under Exchange Rule 2618(a)(1) on a MPID basis. Doing so would provide Equity Members with finer granularity with which they may set and customize such thresholds and manage order flow.

The Exchange's proposal to amend Exchange Rule 2618(a)(5) and (6) to incorporate the risk controls set forth under Exchange Rule 2618(a)(1) also promotes just and equitable principles of trade because it simply codifies existing behavior and provides additional specificity within each Rule. Incorporating Exchange Rule 2618(a)(1) within Exchange Rule 2618(a)(5) fosters cooperation and coordination with persons facilitating transactions in securities because it will codify and make clear that the Exchange will provide alerts when an Equity Member's trading activity reaches certain thresholds under the risk protections set forth under Exchange Rule 2618(a)(1). Likewise, incorporating Exchange Rule 2618(a)(1) within Exchange Rule 2618(a)(6) will also codify and make clear that the Exchange will automatically block new orders submitted and cancel open orders until such time that the applicable risk control is adjusted to a higher limit by the Equity Member. Both these changes would provide greater clarity within the Exchange's rules and avoid potential investor confusion.

[21] In such case, a Limit Order would continue to be subject to the Exchange's applicable re-pricing processes. *See* Exchange Rule 2614(a)(1)(E)–(H).

[22] 17 CFR 240.15c3–5.

[23] *See* Division of Trading and Markets, Responses to Frequently Asked Questions Concerning Risk Management Controls for Brokers or Dealers with Market Access, *available at https://www.sec.gov/divisions/marketreg/faq-15c-5-risk-management-controls-bd.htm.*

[24] 15 U.S.C. 78f(b).

[25] 15 U.S.C. 78f(b)(5).

[26] *See supra* notes 13–15.

[27] *See supra* note 16.

Proposed Gross Notional Open Value and Net Notional Open Value Risk Controls

The proposed Gross Notional Open Value and Net Notional Open Value risk controls under Exchange Rule 2618(a)(2) would further permit Equity Members and Clearing Members who have a financial interest in the risk settings of Equity Members to better monitor and manage their potential risks, including those assumed by Clearing Members, thereby providing Equity Members and Clearing Members with greater control and flexibility over setting their own risk tolerance and exposure. In addition, the proposed additional risk settings under Exchange Rule 2618(a)(2) could provide Clearing Members, who have assumed certain risks of Equity Members, greater control over risk tolerance and exposure on behalf of their correspondent Equity Members, if allocated responsibility pursuant to Exchange Rule 2618(a)(4), while also providing an alert system under Exchange Rule 2618(a)(5) that ensures that both Equity Members and Clearing Members are aware of developing issues. As such, the Exchange believes that the proposed risk settings would provide additional means to address potentially market-impacting events, helping to ensure the proper functioning of the market. To the extent a Clearing Member might reasonably require an Equity Member to provide access to its risk settings as a prerequisite to continuing to clear trades on the Equity Member's behalf, the Exchange's sharing of those risk settings directly reduces the administrative burden on participants on the Exchange, including both Clearing Members and Equity Members. Moreover, providing Clearing Members with the ability to see the risk settings established for Equity Members for which they clear fosters efficiencies in the market and removes impediments to and perfects the mechanism of a free and open market and a national market system. The Exchange believes that the proposed new risk settings under Exchange Rule 2618(a)(2) are consistent with the Act, particularly Section 6(b)(5),[28] because they would foster cooperation and coordination with persons engaged in facilitating transactions in securities and more generally, will protect investors and the public interest, by allowing Equity Members and Clearing Members to better monitor their risk exposure and by fostering efficiencies in the market and removing impediments to and perfect the mechanism of a free and open market and a national market system.

In addition, the proposed Gross Notional Open Value and Net Notional Open Value risk controls under proposed Exchange Rule 2618(a)(2)(C) and (D), respectively, are similar to credit controls measuring gross and net exposure provided for in Exchange Rules 2618(a)(1)(A) and (a)(2)(A) and (B). Further, like the Exchange's existing credit controls measuring gross and net exposure, the proposed risk setting would also be based on a notional execution value. Proposed Gross Notional Open Value and Net Notional Open Value risk controls under proposed Exchange Rule 2618(a)(2)(C) and (D) are also reasonably designed to provide Equity Members and Clearing Members (if allocated responsibility pursuant to Exchange Rule 2618(a)(4)) additional opportunity to monitor and manage the potential risks of an execution that exceeds their certain risk appetite, as well as to provide Clearing Members with greater control over their risk tolerance and exposure on behalf of their correspondent Equity Members.

Limit Order Price Protection and Trading Collar Changes

Allowing Equity Members to customize their Limit Order Price Protection dollar and percentage thresholds on a per MPID basis, rather than only on a per session basis under Exchange Rule 2614(a)(1)(I)(ii) provides Equity Members additional flexibility to customize those thresholds in a manner consistent with their risk appetite and behavior. The proposal promotes just and equitable principles of trade because it would allow Equity Members to set their risk thresholds comprehensively and across various level settings, including the more granular MPID level, if they chose to do so, as well as prevent the unnecessary rejection of orders in certain market scenarios.

The proposal to not apply Limit Order Price Protection and Trading Collar when the prior day's Official Closing Price is to be used when the PBO, PBB, (for Limit Order Price Protection) and a consolidated last sale price are unavailable and a trading halt has been declared by the primary listing market during that trading day also promotes just and equitable principles of trade because in such a scenario, the Exchange believes the Official Closing Price does not appropriately relate to the current trading behavior of the security and may result in their order being unnecessarily rejected. Equity Members are free to not enter orders during such times and enter such orders later when Limit Order Price Protection and Trading Collars are in effect.

Replacing ''User'' With ''Equity Member''

The proposal to amend Exchange Rule 2618 to replace all references to the term ''User'' with ''Equity Member'' removes impediments to and perfects the mechanism of a free and open market and a national market system because it would ensure consistent terminology is used within the Rule, thereby avoiding potential investor confusion. This is a non-substantive change since the risk controls under Exchange Rule 2618 are only available to Equity Members and, therefore, this proposed change does not alter the operation or application of Exchange Rule 2618.

* * * * *

Finally, the Exchange believes that the proposed rule change does not unfairly discriminate among the Exchange's Members because use of the risk settings is optional and are not a prerequisite for participation on the Exchange. The proposed risk settings are completely voluntary and, as they relate solely to optional risk management functionality, no Member is required or under any regulatory obligation to utilize them.

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. In fact, the Exchange believes that the proposal may have a positive effect on competition because it would allow the Exchange to offer additional risk management functionality that is comparable to functionality that has been adopted by other national securities exchanges.[29] Further, by providing Equity Members and their Clearing Members additional means to monitor and control risk, the proposed rule may increase confidence in the proper functioning of the markets and contribute to additional competition among trading venues and broker-dealers. Rather than impede competition, the proposal is designed to facilitate more robust risk management by Equity Members and Clearing Members, which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system. The proposal would impose no burden on intra-market competition because use of the proposed risk settings is optional and

[28] 15 U.S.C. 78f(b)(5).

[29] *See supra* notes 13–15.

each risk setting is available to all Equity Members equally.

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 [30] and Rule 19b–4(f)(6) [31] 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–2022–43 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–2022–43. 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 a.m. and 3 p.m. Copies of such 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–2022–43 and should be submitted on or before November 28, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–24146 Filed 11–4–22; 8:45 am]

BILLING CODE 8011–01–P

[30] 15 U.S.C. 78s(b)(3)(A).

[31] 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.

[32] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96199; File No. SR–ISE–2022–24]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Pricing Schedule at Options 7, Section 6 To Adopt a New Qualified Contingent Cross Rebate Program and Increase the Crossing Fee Cap

November 1, 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 October 24, 2022, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') 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 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 amend the Exchange's Pricing Schedule at Options 7, Section 6.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/ise/rules,* 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 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's Pricing Schedule at Options 7, Section 6 to: (1) adopt a new Qualified Contingent Cross (''QCC'') [3] rebate program, and (2) increase the Crossing Fee Cap.

The Exchange initially filed the proposed pricing changes on October 3, 2022 (SR–ISE–2022–21). On October 14, 2022, the Exchange withdrew that filing and submitted SR–ISE–2022–22. On October 24, 2022, the Exchange withdrew that filing and submitted this filing.

QCC Rebate

Background

Today, the Exchange offers a QCC and Solicitation Rebate program in Options 7, Section 6.A whereby Members using QCC and/or other solicited orders executed in the Solicitation [4] or Facilitation [5] Mechanisms (together with QCC, collectively, ''Current Solicited Orders'') receive rebates for each originating contract side in all symbols traded on the Exchange. Once a Member reaches a certain volume threshold in Current Solicited Orders during a month, the Exchange provides rebates to that Member for all of its eligible Current Solicited Order traded contracts for that month.[6] Members receive the rebate for all Current Solicited Orders except for Current Solicited Orders between two Priority Customers.[7]

Today, the volume threshold and corresponding QCC and Solicitation Rebates in Section 6.A are as follows:

Originating contract sides	Rebate
0 to 99,999	$0.00
100,000 to 199,999	($0.05)
200,000 to 499,999	($0.07)
500,000 to 749,999	($0.09)
750,000 to 999,999	($0.10)
1,000,000+	($0.11)

Volume resulting from all Current Solicited Orders is aggregated in determining the applicable volume tier as set forth above. For Members that achieve the highest volume threshold of 1,000,000 or more originating contract sides, the Exchange also currently provides an additional rebate of $0.01 per originating contract side on Current Solicited Orders that qualify for the QCC and Solicitation Rebate program if the Member achieves in a given month: (i) combined Current Solicited Order volume of more than 1,750,000 originating contract sides and (ii) Priority Customer Complex Tiers 6 or higher in Section 4 (the ''note * incentive'').[8] In addition, the Exchange provides an additional rebate of $0.01 per originating contract side that is applied to each QCC and Solicitation Rebate volume tier where the Member receives the rebate (*i.e.,* tier 2 or higher) if the Member also achieves Priority Customer Complex Tier 2 or higher in a given month (the ''note &'' incentive). Thus, qualifying Members may receive up to $0.06 in the second QCC and Solicitation Rebate volume tier, $0.08 in the third tier, $0.10 in the fourth tier, $0.11 in the fifth tier, and $0.13 in the sixth and highest tier (*i.e.,* the $0.11 base rebate, the $0.01 note * incentive, and the $0.01 note & incentive).

Proposal

To further encourage QCC order flow, the Exchange now proposes to adopt a new QCC Rebate program in Section 6.B. As a result of this change, the Exchange will no longer provide the Section 6.A rebates, as described above, for QCC orders. With the proposed changes, the Exchange will continue to provide the Section 6.A rebates for solicited orders executed in the Solicited Order Mechanism or Facilitation Mechanism (''Amended Solicited Orders''). In addition, executed QCC volume will continue to be combined with executed Amended Solicited Order volume to count towards the Section 6.A rebate tiers described above; however, the Section 6.A rebates will only be provided to the Amended Solicited Orders as the Exchange will pay the new QCC Rebates in Section 6.B to QCC orders under this proposal.

To effectuate the foregoing changes, the Exchange first proposes to update all references to the ''QCC and Solicitation Rebate'' in Section 6.A to the ''Solicitation Rebate.'' The Exchange also proposes to amend the first paragraph of Section 6.A to provide that Members using the QCC and/or other solicited orders executed in the Solicited Order Mechanism or Facilitation Mechanism will receive rebates for solicited orders executed in the Solicited Order Mechanism or Facilitation Mechanism (*i.e.,* Amended Solicited Orders) according to the table in Section 6.A for each originating contract side in all symbols traded on the Exchange. Volume associated with QCC executions will be aggregated in calculating the Solicitation Rebate volume tiers in Section 6.A, but Members that execute QCC volume will receive the QCC Rebate in Section 6.B.

The Exchange also proposes to update each instance in Section 6.A where the current language refers to Amended Solicited Order volume to add a reference to QCC volume as well, and to make clear in the second paragraph of Section 6.A that the volume aggregation in Section 6.A would include *combined* QCC and Amended Solicited Order volume (as is the case today). The Exchange further proposes a corrective change in the second paragraph of Section 6.A to replace the reference to QCC and Solicitation volume totals with QCC and Amended Solicited Order volume totals to use correct terminology.

Next, the Exchange proposes to set forth the new QCC Rebate in Section 6.B, and relocate the PIM and Facilitation Rebate currently in Section 6.B into Section 6.C, which is currently reserved. As proposed, Section 6.B will provide that Members that submit QCC orders when at least one side of the QCC transaction is a Non-Priority Customer will receive the below QCC Rebates. QCC Rebates will be paid to each agency contract side (''QCC Agency Side'') in all symbols traded on the Exchange. Specifically:

[3] A QCC Order is comprised of an originating order to buy or sell at least 1000 contracts that is identified as being part of a qualified contingent trade, as that term is defined in Supplementary Material .01 to Options 3, Section 7, coupled with a contra-side order or orders totaling an equal number of contracts. *See* Options 3, Section 7(j).

[4] The Solicitation or Solicited Order Mechanism is a process by which an Electronic Access Member (''EAM'') can attempt to execute orders of 500 or more contracts it represents as agent against contra orders that it solicited. *See* Options 3, Section 11(d). The Exchange will make a corrective change in Section 6.A to replace the reference to Solicitation Mechanism with Solicited Order Mechanism.

[5] The Facilitation Mechanism is a process by which an EAM can execute a transaction wherein the EAM seeks to facilitate a block-size order it represents as agent, and/or a transaction wherein the EAM solicited interest to execute against a block-size order it represents as agent. *See* Options 3, Section 11(b).

[6] All eligible volume from affiliated Members is aggregated in determining QCC and Solicitation volume totals, provided there is at least 75% common ownership between the Members as reflected on each Member's Form BD, Schedule A.

[7] A Priority Customer is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Nasdaq ISE Options 1, Section 1(a)(37).

[8] As set forth in Options 7, Section 4, Priority Customer Complex Tiers are based on Total Affiliated Member or Affiliated Entity complex order volume (excluding Crossing Orders and Responses to Crossing Orders) calculated as a percentage of Customer Total Consolidated Volume.

• When only one side of the QCC transaction is a Non-Priority Customer,[9] the Member will receive a $0.14 per contract rebate for each QCC Agency Side.

• When both sides of the QCC transaction are Non-Priority Customers, the Member will receive a $0.22 per contract rebate for each QCC Agency Side.

In addition, the Exchange proposes to provide an additional incentive of $0.03 per contract for each QCC Agency Side that qualifies for the QCC Rebate program if they achieve Priority Customer Complex Tier 2 or higher in a given month. The proposed incentive will be structured similarly to the existing note & incentive within Section 6.A in that Members will need to achieve the same Priority Customer Complex Tier 2 or higher to be eligible for the incentive. The proposed incentive will also be applied to each QCC Rebate and will be cumulative of the QCC Rebates so that qualifying Members could receive up to $0.17 per contract for each QCC Agency Side when only one side of the QCC transaction is a Non-Priority Customer, and up to $0.25 per contract for each QCC Agency Side when both sides of the QCC transaction are Non-Priority Customers.

Lastly, the Exchange proposes to define Non-Priority Customers in Section 1 because this term is currently used throughout Options 7,[10] and will also be used in proposed Section 6.B. Today, Non-Priority Customers include every market participant capacity in the Exchange's Pricing Schedule except for Priority Customers. This is also how the Exchange will use this term in proposed Section 6.B. As such, the Exchange proposes to define Non-Priority Customers in Section 1 as including Market Makers,[11] Non-Nasdaq ISE Market Makers (FarMMs),[12] Firm Proprietary [13]/Broker-Dealers,[14] and Professional Customers.[15]

Overall, Members will be eligible to receive higher rebates on qualifying QCC orders under Section 6.B compared to the rebates they receive today under Section 6.A. As such, Members may be incentivized to send more QCC and complex order flow to the Exchange.

Crossing Fee Cap

As set forth in Options 7, Section 6.H, the Exchange presently offers a Crossing Fee Cap of $90,000 per month, per Member, on all Firm Proprietary transactions that are part of the originating or contra-side of a Crossing Order.[16] Fees charged by the Exchange for Responses to Crossing Orders are not included in the calculation of the monthly fee cap. Surcharge fees charged by the Exchange for licensed products and the fees for index options as set forth in Section 5 are not included in the calculation of the monthly fee cap.[17] For purposes of the Crossing Fee Cap the Exchange attributes eligible volume to the ISE Member on whose behalf the Crossing Order was executed.

At this time, the Exchange proposes to increase the Crossing Fee Cap from $90,000 to $150,000. While the Crossing Fee Cap will increase under this proposal, the Exchange believes that Members will continue to be incentivized to bring Firm Proprietary Crossing Order flow to ISE.

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Act,[18] in general, and furthers the objectives of sections 6(b)(4) and 6(b)(5) of the Act,[19] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange's proposed changes to its Pricing Schedule are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for options securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has 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'. . . .'' [20]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, 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.'' [21]

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for options security transaction services. The Exchange is only one of sixteen options exchanges to which market participants may direct their order flow. Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules. As such, the proposal represents a reasonable attempt by the Exchange to increase its

[9] Non-Priority Customers include Market Makers, Non-Nasdaq ISE Market Makers (FarMMs), Firm Proprietary/Broker-Dealers, and Professional Customers.

[10] *See* Section 3, Section 4, and Section 5.C.

[11] The term ''Market Makers'' refers to Competitive Market Makers and Primary Market Makers, collectively. *See* Options 1, Section 1(a)(21).

[12] A Non-Nasdaq ISE Market Maker is a market maker as defined in section 3(a)(38) of the Securities Exchange Act of 1934, as amended, registered in the same options class on another options exchange.

[13] A Firm Proprietary order is an order submitted by a member for its own proprietary account.

[14] A Broker-Dealer order is an order submitted by a member for a broker-dealer account that is not its own proprietary account.

[15] A Professional Customer is a person or entity that is not a broker/dealer and is not a Priority Customer. *See also* Options 1, section 1(a)(40).

[16] Crossing Orders are contracts that are submitted as part of a Facilitation, Solicitation, PIM, Block or QCC order. All eligible volume from affiliated Members is aggregated for purposes of the Crossing Fee Cap, provided there is at least 75% common ownership between the Members as reflected on each Member's Form BD, Schedule A.

[17] In addition, a service fee of $0.00 per side applies to all order types that are eligible for the fee cap. The service fee would apply once a Member reaches the fee cap level and would apply to every contract side above the fee cap. A Member who does not reach the monthly fee cap is not charged the service fee. Once the fee cap is reached, the service fee shall apply to eligible Firm Proprietary orders in all Nasdaq ISE products. The service fee is not calculated in reaching the cap.

[18] 15 U.S.C. 78f(b).

[19] 15 U.S.C. 78f(b)(4) and (5).

[20] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[21] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

liquidity and market share relative to its competitors.

QCC Rebate

The Exchange believes that the proposed QCC Rebate program is reasonable, equitable, and not unfairly discriminatory. The proposed changes are designed to incentivize market participants to direct more QCC and complex order flow to ISE, which the Exchange believes would enhance market quality to the benefit of all market participants. The Exchange believes the proposed QCC Rebate structure is reasonable because the proposed changes provide opportunities for Members to receive higher rebates for each QCC Agency Side than they currently receive under the QCC and Solicitation Rebate program in Options 7, Section 6.A, which may incentivize more QCC order flow to the Exchange. As discussed above, qualifying Members presently receive up to $0.06 in the second QCC and Solicitation Rebate volume tier, $0.08 in the third tier, $0.10 in the fourth tier, $0.11 in the fifth tier, and $0.13 in the sixth and highest tier (*i.e.,* the $0.11 base rebate, the $0.01 note * incentive, and the $0.01 note & incentive). With the proposed changes, qualifying Members would receive $0.14 per contract (or $0.17 per contract if they also achieve Priority Customer Complex Tier 2 or higher in a given month) for each QCC Agency Side when only one side of the QCC transaction is a Non-Priority Customer, and $0.22 per contract (or $0.25 per contract if they also achieve Priority Customer Complex Tier 2 or higher in a given month) when both sides of the QCC transaction are Non-Priority Customers. The Exchange will continue to not provide any rebates under this proposal when both sides of the QCC transaction are Priority Customers, as is the case today. The Exchange believes that this is reasonable given that Priority Customers are already incentivized by having no transaction fees for Crossing Orders, including QCC orders.[22] The Exchange also notes that other competing exchanges offer alternative QCC rebates that depend on the capacity of the parties to the transaction.[23]

The Exchange also believes that the proposed additional $0.03 incentive that will be provided to Members that achieve Priority Customer Complex Tier 2 or higher in a given month (in addition to qualifying for the QCC Rebate program) is reasonable because this incentive is intended to encourage Members to send more QCC order and complex order flow to the Exchange. As discussed above, the proposed incentive is similar to the existing & incentive in Options 7, Section 6.A in that Members will need to achieve the same Priority Customer Complex Tier 2 or higher to be eligible for the incentive. Members, however, that qualify for the QCC Rebate Program will now receive a higher additional incentive under this proposal for each QCC Agency Side than they currently receive under the note & incentive in Section 6.A. As such, more Members may seek to qualify for the proposed incentive by sending additional QCC order and complex order flow to ISE. All market participants benefit from increased order interaction when more order flow is available on the Exchange.

The Exchange also believes that the proposed QCC Rebate program in Options 7, Section 6.B is equitable and not unfairly discriminatory because all Members will be eligible for the proposed rebates by sending QCC and complex order flow to the Exchange. Further, the Exchange believes that applying the proposed rebates where at least one party to the QCC transaction is a Non-Priority Customer is equitable and not unfairly discriminatory because Priority Customers do not receive any QCC incentives today under the QCC and Solicitation Rebate program in Options 7, Section 6.A when both sides of the QCC transaction are Priority Customers. As discussed above, Priority Customers are not assessed fees for QCC transactions today, and therefore do not need the added incentive of the proposed rebates. In addition, to the extent the proposed QCC Rebate program encourages Members to send more QCC and complex order flow to ISE, all market participants will benefit from the resulting additional liquidity and trading opportunities on ISE.

The Exchange believes that the proposed changes in Options 7, Section 6.A are reasonable, equitable, and not unfairly discriminatory because all of the changes are intended to make clear that the Exchange will continue to provide the Section 6.A rebates for solicited orders executed in the Solicited Order Mechanism or Facilitation Mechanism (*i.e.,* the Amended Solicited Orders) and that QCC orders will receive the proposed rebates in Section 6.B. In addition, the Exchange believes that it is reasonable, equitable, and not unfairly discriminatory to continue aggregating executed QCC volume with executed Amended Solicited Order volume towards the Section 6.A rebate tiers described above while only providing the Section 6.A rebates to the Amended Solicited Orders, as the Exchange will pay the new QCC Rebates in Section 6.B to QCC orders under this proposal. The Exchange also believes that this proposal will further encourage Members to bring additional QCC order flow to ISE in order to receive the Section 6.A rebates on their Amended Solicited Orders and Section 6.B rebates on their QCC orders, which, in turn, brings increased liquidity and additional opportunities for interaction with this order flow to the benefit of all market participants.

Lastly, the Exchange believes that its proposal to add the definition of ''Non-Priority Customers'' in Options 7, Section 1 is reasonable, equitable, and not unfairly discriminatory because it will bring greater transparency to the Exchange's Pricing Schedule by codifying how this term is used today throughout the Exchange's Pricing Schedule, and how it will be used in the proposed QCC Rebate program.

Crossing Fee Cap

The Exchange believes that its proposal to increase the Crossing Fee Cap from $90,000 to $150,000 is reasonable. The Crossing Fee Cap was established to reward Members for executing a higher volume of Firm Proprietary Crossing Orders on the Exchange by capping the associated fees. The Exchange believes that the increased fee cap will be set at a level that continues to appropriately reward Members for executing high volumes of such Crossing Orders. Despite the proposed increase, the Exchange believes that Members will continue to be incentivized to bring Firm Proprietary Crossing Order flow to ISE, as Members will still have the opportunity to pay no transaction fees for such orders beyond the $150,000 cap.

The Exchange also believes that the proposed increase to the Crossing Fee Cap is equitable and not unfairly discriminatory because it will apply uniformly to all Members engaged in

[22] *See* Options 7, Sections 3 and 4.

[23] *See* BOX Exchange (''BOX'') Fee Schedule, Section IV.D.1. BOX offers tiered QCC rebates to Participants that entered the order into the BOX System when at least one party to the QCC transaction is a Broker-Dealer or Market Maker. When only one side of the QCC transaction is a Broker-Dealer or Market Maker, Rebate 1 will apply. When both parties to the QCC transaction are a Broker Dealer or Market Maker, Rebate 2 will apply. *See also* Cboe EDGX Options Exchange (''EDGX'') Fee Schedule, QCC Initiator/Solicitation Rebate Tiers. Like BOX, EDGX offers tiered rebates for QCC transactions when at least one side of the transaction is of Non-Customer, Non-Professional capacity. When only one side of the transaction is of Non-Customer, Non-Professional capacity, Rebate 1 will apply. When both sides of the transaction are of Non-Customer, Non-Professional capacity, Rebate 2 will apply.

Firm Proprietary trading in options classes traded on the Exchange. The Exchange does not believe it is unfairly discriminatory to offer the Crossing Fee Cap to Firm Proprietary transactions as differentiated pricing already exists on the Exchange's Pricing Schedule to encourage different segments of order flow. For instance, the Exchange generally provides Priority Customer orders more favorable pricing through lower or no transaction fees, including Priority Customer Crossing Orders that are presently assessed no fees, and through rebate opportunities like the Priority Customer rebate currently provided for adding liquidity in Non-Select Symbols.[24] Professional Customer orders are presently charged a lower transaction fee for executed QCC orders and for orders executed in the Solicited Order Mechanism ($0.10 for Professional Customers versus $0.20 for all other Non-Priority Customers).[25] Broker-Dealer and Firm Proprietary orders are incentivized in the Exchange's PIM and Facilitation Rebate program.[26] Market Makers are offered rebates through the Exchange's Market Maker Plus program.[27] The Exchange further believes there is nothing impermissible about offering the Crossing Fee Cap solely to Firm Proprietary transactions given that this practice is consistent with firm fee caps in place on other options exchanges.[28] To the extent the amended Crossing Fee Cap continues to encourage additional Firm Proprietary Crossing Order flow to ISE, such order flow brings increased liquidity and additional opportunities for interaction with this order flow, which ultimately benefits all market participants.

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 not necessary or appropriate in furtherance of the purposes of the Act.

In terms of intra-market competition, the Exchange does not believe that this proposal will place any category of market participant at a competitive disadvantage. As discussed above, any Member may qualify for the proposed QCC Rebate program (which will be higher than the current rebates being provided under Section 6.A) by sending QCC and complex order flow to the Exchange. While the Exchange will apply the proposed rebates to QCC transactions where at least one party is a Non-Priority Customer, Priority Customers are not assessed fees for QCC transactions today, and therefore do not need the added incentive of the proposed rebates. Further, to the extent the Exchange's proposal incentivizes Members to bring additional QCC and complex order flow to ISE, the Exchange believes that the resulting additional volume and liquidity will benefit all market participants. The Exchange also does not believe that increasing the Crossing Fee Cap will impose an undue burden on intra-market competition because it will apply uniformly to all Members engaged in Firm Proprietary trading in options classes traded on the Exchange. To the extent the amended Crossing Fee Cap continues to provide an incentive for Members to bring additional Firm Proprietary Crossing Order flow to the Exchange, such order flow brings increased liquidity to the benefit of all market participants.

In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

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)(ii) of the Act.[29] 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: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) 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–ISE–2022–24 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–ISE–2022–24. 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,

[24] *See* Options 7, Sections 3 and 4. Non-Select Symbols are options overlying all symbols that are not included in the Penny Interval Program.

[25] *See* Options 7, Section 3 (note 16) and Section 4 (note 14).

[26] *See* Options 7, Section 6.B.

[27] *See* Options 7, Section 3 (note 5).

[28] *See, e.g.,* Nasdaq GEMX Options 7, Section 4.C and Nasdaq Phlx Options 7, Section 4.

[29] 15 U.S.C. 78s(b)(3)(A)(ii).

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–ISE–2022–24 and should be submitted on or before November 28, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

J. Matthew DeLesDernier,

Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96197; File No. SR–Phlx–2022–41]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Phlx's Pricing Schedule

November 1, 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 October 17, 2022, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') 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 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 amend Phlx's Pricing Schedule at Options 7.[3]

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* 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 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

1. Purpose

Phlx proposes to amend its Pricing Schedule at Options 7. Specifically, Phlx proposes to amend: (1) Options 7, Section 3, Rebates and Fees for Adding and Removing Liquidity in SPY, with respect to its pricing for Price Improvement XL (''PIXL'') executions in SPY; (2) Options 7, Section 4, Multiply Listed Options Fees (Includes options overlying equities, ETFs, ETNs and indexes which are Multiply Listed) (Excludes SPY and broad-based index options symbols listed within Options 7, Section 5.A), with respect to its Qualified Contingent Cross (''QCC'') Rebates and Monthly Firm Fee Cap; and (3) Options 7, Section 6, Other Transaction Fees, with respect to PIXL pricing other than options in SPY. Each change will be described below.

Options 7, Section 3

The Exchange proposes to amend Options 7, Section 3, Rebates and Fees for Adding and Removing Liquidity in SPY, with respect to its PIXL executions in SPY. Today, SPY PIXL Initiating Orders[4] are assessed a $0.05 per contract fee, however, members or member organizations that qualify for Options 7, Section 2, Customer[5] Rebate Tiers 2 through 6 or qualify for the Monthly Firm Fee Cap[6] are eligible for a rebate of $0.12 per contract for all SPY Complex PIXL Orders greater than 499 contracts, provided the member or member organization executes an average of 2,500 contracts per day of SPY Complex PIXL Orders in a month.[7] The Exchange separately assesses fees for PIXL Orders contra the Initiating Order[8] which are not being amended at this time.

At this time, the Exchange proposes to continue to assess SPY PIXL Initiating Orders a $0.05 per contract fee. Members or member organizations that qualify for Options 7, Section 2, Customer Rebate Tiers 2 through 6 or qualify for the Monthly Firm Fee Cap will continue to be eligible for a rebate of $0.12 per contract for all SPY Complex PIXL Orders greater than 499 contracts *when contra to an Initiating Order,* provided the member or member organization executes an average of 2,500 contracts per day of SPY Complex PIXL Orders in a month. The Exchange's proposal to further qualify that the SPY Complex PIXL Orders greater than 499 contracts must be contra to an Initiating Order, in addition to the member or member organization having executed an average of 2,500 contracts per day of SPY Complex PIXL Orders in a month. As is the case today, when the PIXL Order is contra to other than the Initiating Order, the PIXL Order is assessed $0.00 per contract, unless the PIXL Order is a Customer, in which case the Customer receives a rebate of $0.40 per contract.

Below is an example of the proposed change which presumes the market participant has met the qualifications for the rebate.

[30] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed pricing changes on October 3, 2022 as SR–Phlx–2022–40. The instant filing replaced SR–Phlx–2022–40 which was withdrawn on October 17, 2022.

[4] An order entered into a PIXL Auction mechanism shall be comprised of two orders, a PIXL agency order and a contra-side Initiating Order. *See* Options 3, Section 13.

[5] The term ''Customer'' applies to any transaction that is identified by a member or member organization for clearing in the Customer range at The Options Clearing Corporation (''OCC'') which is not for the account of a broker or dealer or for the account of a ''Professional'' (as that term is defined in Options 1, Section 1(b)(45)). *See* Options 7, Section 1(c).

[6] Today, Firms are subject to a Monthly Firm Fee Cap of $75,000. *See* Options 7, Section 4.

[7] A member may electronically submit for execution an order it represents as agent on behalf of a public customer, broker-dealer, or any other entity (''PIXL Order'') against principal interest or against any other order (except as provided in Options 3, Section 13(a)(6)) it represents as agent (''Initiating Order'') provided it submits the PIXL order for electronic execution into the PIXL Auction (''Auction'') pursuant to Options 3, Section 13.

[8] When the PIXL Order is contra to the Initiating Order, a Customer PIXL Order is assessed $0.00 per contract and all other Non-Customer market participants are assessed a $0.38 per contract fee when contra to an Initiating Order. Further, when the PIXL Order is contra to other than the Initiating Order, the PIXL Order is assessed $0.00 per contract, unless the PIXL Order is a Customer, in which case the Customer receives a rebate of $0.40 per contract. Finally, all other Non-Customer contra parties to the PIXL Order that are not the Initiating Order are assessed a Fee for Removing Liquidity of $0.50 per contract or are entitled to receive the Rebate for Adding Liquidity. When the PIXL Order is contra to a Lead Market Maker or Market Maker quote, which was established at the initiation of a PIXL auction, the Customer PIXL Order is not be eligible for a rebate. *See* Options 7, Section 3.

Assume:

NBBO and PHLX are both $1.00 × $1.50
Initiator sends PIXL Complex Order in SPY to buy 500 spreads (1000 contracts) for $1.45 (Market Maker not assigned in SPY is contra-side)

Instance 1

When no outside response to interact with the PIXL order—no change from Sep to Oct in pricing.

Oct 3 Pricing

Public Customer fee to execute PIXL Complex Order = $0.00 per contract
Initiating Order fee = $0.05 fee—$50.00
PIXL Order rebate = $0.12 per contract ($120.00)

The rebate is achieved because the PIXL Order trades against the Initiating Order in its entirety.

Instance 2

Assume:

Responders to the PIXL Complex Order indicate the following allocation process:
Initiating Order = 40% (400 contracts)
Auction Responders = 60% (600 contracts)

Sept Pricing

Public Customer fee to execute PIXL Complex Order = $0.00
(paired) = $0.05 fee—$20.00 ($0.05 × 400 contracts)
Responder fee = $0.50 per contract—$300.00
Break-Up rebate = ($0.40) per contract ($240.00)
PIXL Order rebate = $0.12 per contract ($120.00)

Oct 3 Pricing

Public Customer Charge to execute PIXL Complex Order = $0.00
Initiating Order (paired) = $0.05 fee—$20.00 ($0.05 × 400 contracts)
Responder fee = $0.50 per contract—$300.00
Break-Up rebate = ($0.40) per contract ($240.00)
Additional PIXL Order rebate = ($0.12) per contract ($48.00) ($0.12 × 400 contracts contra PIXL order)

With this change the rebate would be paid only to PIXL Complex Order contracts that were executed against the Initiating Order. The prior pricing rebate was for $120 (1000 contracts × $0.12) and the October pricing would be $48 (400 contracts × $0.12).

The Exchange desires to continue to incentivize members and member organizations to transact a greater number of SPY Complex PIXL Orders while also incentivizing members and member organizations to submit Customer order flow on Phlx. While the proposal no longer offers the $0.12 per contract rebate that is available today for the PIXL Agency Order when that PIXL Order is contra to other than the Initiating Order, the Exchange believes that market participants will continue to be incentivized to submit PIXL Agency Orders to Phlx because the Exchange continues to offer a rebate of $0.40 per contract when the PIXL Order is contra to other than the Initiating Order.

Options 7, Section 4

QCC

The Exchange proposes to amend Options 7, Section 4, Multiply Listed Options Fees (Includes options overlying equities, ETFs, ETNs and indexes which are Multiply Listed) (Excludes SPY and broad-based index options symbols listed within Options 7, Section 5.A) with respect to its QCC Rebates.

Today, the Exchange assesses a $0.20 per contract QCC Transaction Fees [9] to a Lead Market Maker,[10] Market Maker,[11] Firm [12] and Broker-Dealer.[13] Customers and Professionals [14] are not assessed a QCC Transaction Fee. QCC Transaction Fees apply to electronic QCC Orders [15] and Floor QCC Orders.[16] Rebates are paid on all qualifying executed electronic QCC Orders and Floor QCC Orders based on the following six tier rebate schedule:[17]

QCC REBATE SCHEDULE

Tier	Threshold	Rebate per contract
Tier 1	0 to 99,999 contracts in a month	$0.00
Tier 2	100,000 to 299,999 contracts in a month	0.05
Tier 3	300,000 to 499,999 contracts in a month	0.07
Tier 4	500,000 to 699,999 contracts in a month	0.08
Tier 5	700,000 to 999,999 contracts in a month	0.09
Tier 6	Over 1,000,000 contracts in a month	0.11

The Exchange does not pay a QCC Rebate where the transaction is either: (i) Customer-to-Customer; (ii) Customer-to-Professional; (iii) Professional-to-Professional; or (iv) a dividend, merger, short stock interest or reversal or conversion strategy execution (as defined in Options 7, Section 4).

[9] QCC Transaction Fees apply to electronic QCC Orders, as defined in Options 3, Section 12, and Floor QCC Orders, as defined in Options 8, Section 30(e).

[10] The term ''Lead Market Maker'' applies to transactions for the account of a Lead Market Maker (as defined in Options 2, Section 12(a)). A Lead Market Maker is an Exchange member who is registered as an options Lead Market Maker pursuant to Options 2, Section 12(a). An options Lead Market Maker includes a Remote Lead Market Maker which is defined as an options Lead Market Maker in one or more classes that does not have a physical presence on an Exchange floor and is approved by the Exchange pursuant to Options 2, Section 11. *See* Options 7, Section 1(c). The term ''Floor Lead Market Maker'' is a member who is registered as an options Lead Market Maker pursuant to Options 2, Section 12(a) and has a physical presence on the Exchange's trading floor. *See* Options 8, Section 2(a)(3).

[11] The term ''Market Maker'' is defined in Options 1, Section 1(b)(28) as a member of the Exchange who is registered as an options Market Maker pursuant to Options 2, Section 12(a). A Market Maker includes SQTs and RSQTs as well as Floor Market Makers. *See* Options 7, Section 1(c). The term ''Floor Market Maker'' is a Market Maker who is neither an SQT or an RSQT. A Floor Market Maker may provide a quote in open outcry. *See* Options 8, Section 2(a)(4).

[12] The term ''Firm'' applies to any transaction that is identified by a member or member organization for clearing in the Firm range at The Options Clearing Corporation. *See* Options 7, Section 1(c).

[13] The term ''Broker-Dealer'' applies to any transaction which is not subject to any of the other transaction fees applicable within a particular category. *See* Options 7, Section 1(c).

[14] The term ''Professional'' applies to transactions for the accounts of Professionals, as defined in Options 1, Section 1(b)(45) means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). *See* Options 7, Section 1(c).

[15] Electronic QCC Orders are described in Options 3, Section 12.

[16] Floor QCC Orders are described in Options 8, Section 30(e).

[17] Volume resulting from all executed electronic QCC Orders and Floor QCC Orders, including Customer-to-Customer, Customer-to-Professional, and Professional-to-Professional transactions and excluding dividend, merger, short stock interest or reversal or conversion strategy executions, is aggregated in determining the applicable volume tier.

At this time, the Exchange proposes to reduce the six tier rebate schedule to a two tier schedule as follows:

QCC REBATE SCHEDULE

Tier	Threshold	Rebate per contract
Tier 1	0 to 999,999 contracts in a month	$0.09
Tier 2	1,000,000 contracts or more in a month	0.17

The Exchange would pay a Tier 1 QCC Rebate of $0.09 per contract on all qualifying executed electronic QCC Orders and Floor QCC Orders up to 999,999 contracts in a month. The Exchange would pay a Tier 2 QCC Rebate of $0.17 per contract on all qualifying executed electronic QCC Orders and Floor QCC Orders of $1,000,000 contracts or more in a month. With this change, the Exchange would pay a $0.09 per contract QCC Rebate for each contract from the first execution up to 999,999 contracts in a month. Today, Members that execute 0 to 99,999 contracts in a month do not receive a QCC Tier 1 Rebate. Additionally, while today the Exchange pays a Tier 5 QCC Rebate of $0.09 per contract for 700,000 to 999,999 contracts in a month, with this proposal the proposed $0.09 per contract Tier 1 QCC Rebate may be up to 999,999 contracts in a month. Also, while today, the Exchange pays a Tier 6 QCC Rebate of $0.11 per contract for qualifying executed electronic QCC Orders and Floor QCC Orders over $1,000,000 contracts in a month, the proposed Tier 2 QCC Rebate would be increased to $0.17 per contract for $1,000,000 contracts or more in a month.

The Exchange believes that its proposal will incentivize members and member organizations to submit a greater amount of QCC Orders to Phlx in order to obtain a rebate.

Monthly Firm Fee Cap

The Exchange proposes to amend Options 7, Section 4, Multiply Listed Options Fees (Includes options overlying equities, ETFs, ETNs and indexes which are Multiply Listed) (Excludes SPY and broad-based index options symbols listed within Options 7, Section 5.A), with respect to its Monthly Firm Fee Cap. Today, Firms are subject to a maximum fee of $75,000 known as the ''Monthly Firm Fee Cap''. Firm Floor Option Transaction Charges and QCC Transaction Fees, as defined in Options 7, Section 4, in the aggregate, for one billing month may not exceed the Monthly Firm Fee Cap per member organization when such members are trading in their own proprietary account. The following pricing is excluded from the Monthly Firm Fee Cap: (1) all dividend, merger, and short stock interest strategy executions, as defined in Options 7, Section 4; (2) transactions in broad-based index options symbols listed within Options 7, Section 5.A.; and (3) reversal and conversion, jelly roll and box spread strategy executions as defined in this Options 7, Section 4. QCC Transaction Fees are included in the calculation of the Monthly Firm Fee Cap.[18]

At this time, the Exchange proposes to amend the Monthly Firm Fee Cap from $75,000 to $150,000. The Monthly Firm Fee Cap has remained at $75,000 since 2010.[19] The Exchange believes that while this cap is being increased, Firms will continue to be incentivized by the cap.

Options 7, Section 6

The Exchange proposes to amend Options 7, Section 6, Other Transaction Fees, at A. PIXL Pricing with respect to PIXL pricing other than options in SPY. Today, an Initiating Order in PIXL is assessed a $0.07 per contract fee, with the exception of SPY PIXL Orders which are assessed the pricing within Options 7, Section 4. Today, if the member or member organization qualifies for the Tier 3, 4 or 5 Customer Rebate in Options 7, Section 2 the member or member organization is assessed $0.05 per contract. If the member or member organization executes equal to or greater than 3.00% of National Customer Volume in Multiply-Listed equity and ETF Options Classes (excluding SPY Options) in a given month, the member or member organization is not assessed a fee for Complex PIXL Orders. Any member or member organization under Common Ownership with another member or member organization that qualifies for a Customer Rebate Tier 4 or 5 in Options 7, Section 2, or executes equal to or greater than 3.00% of National Customer Volume in Multiply-Listed equity and ETF Options Classes (excluding SPY Options) in a given month receives one of the PIXL Initiating Order discounts noted herein. Finally, members or member organizations that qualify for Customer Rebate Tiers 2 through 6 or qualify for the Monthly Firm Fee Cap are eligible for a rebate of $0.12 per contract for all Complex PIXL Orders (excluding SPY Options) greater than 499 contracts, provided the member or member organization executes an average of 2,500 contracts per day of Complex PIXL Orders in a month.

Similar to the change proposed for SPY PIXL within Options 7, Section 3, the Exchange proposes to amend Options 7, 6A. to provide that members or member organizations that qualify for Customer Rebate Tiers 2 through 6 or qualify for the Monthly Firm Fee Cap are eligible for a rebate of $0.12 per contract for all Complex PIXL Orders (excluding SPY Options) greater than 499 contracts *when contra to an Initiating Order,* provided the member executes an average of 2,500 contracts per day of Complex PIXL Orders in a month.

Below is an example of the proposed change which presumes the market participant has met the qualifications for the rebate.

Assume for Options 7, Section 6A:

NBBO and PHLX are both $1.00 × $1.50
Initiator sends PIXL Complex Order in AAPL to buy 500 spreads (1000 contracts) for $1.45 (Market Maker not assigned in AAPL is contra-side)
PIXL Agency Order qualifies for Customer Rebate Tier 5

Instance 1

When no outside response to interact with the PIXL order—no change from Sep to Oct in pricing.

Oct 3 Pricing

Public Customer fee to execute PIXL Complex Order = $0.00 per contract
Initiating Order fee = $0.07 fee—$70.00
PIXL Order rebate = $0.12 per contract ($120.00)

[18] Member organizations are required to notify the Exchange in writing of all accounts in which the member is not trading in its own proprietary account.

[19] The Monthly Firm Fee Cap was previously called the Firm Related Equity Option Cap. *See* Securities Exchange Act Release No. 65888 (December 5, 2011), 76 FR 77046 (December 9, 2011) (SR–Phlx–2011–160).

The rebate is achieved because the PIXL Complex Order trades against the Initiating Order in its entirety.

Instance 2

Assume:

Responders to the PIXL Complex Order indicate the following allocation process:

Initiating Order = 40% (400 contracts)
Auction Responders = 60% (600 contracts)
PIXL Agency Order qualifies for Customer Rebate Tier 5

Sept Pricing

Public Customer fee to execute PIXL Complex Order = $0.00
(paired) = $0.07 fee—$28.00 ($0.07 × 400 contracts)
Market Maker Responder Penny Symbol fee = $0.25 per contract ($0.25 × 600 contracts)—$150.00
PIXL Order rebate = $0.12 per contract ($0.12 × 1000 = $120.00)
PIXL Agency Order qualifies for $0.22 per contract rebate ($132.00) for Category C Customer Rebate which applies to PIXL Complex Orders ($0.22 × 600 contracts)

Oct 3 Pricing

Public Customer Charge to execute PIXL Complex Order = $0.00
Initiating Order (paired) = $0.07 fee—$28.00 ($0.07 × 400 contracts)
Market Maker Responder Penny Symbol fee = $0.25 per contract ($0.25 × 600 contracts)—$150.00
PIXL Order rebate = $0.12 per contract ($0.12 × 400 = $48.00)
PIXL Agency Order qualifies for $0.22 per contract rebate ($132.00) for Category C Customer Rebate which applies to PIXL Complex Orders ($0.22 × 600 contracts)

With this change the rebate would be paid only to PIXL Complex Order contracts that were executed against the Initiating Order. The prior pricing rebate was for $120 (1,000 contracts × $0.12) and the October pricing would be $48 (400 contracts × $0.12).

The Exchange desires to continue to incentivize members and member organizations to transact a greater number of Complex PIXL Orders while also incentivizing members and member organizations to submit Customer order flow on Phlx. While the proposal no longer offers the $0.12 per contract rebate that is available today for the PIXL Agency Order when that PIXL Order is contra to other than the Initiating Order, the Exchange believes that market participants will continue to be incentivized to submit PIXL Agency Orders to Phlx because the Exchange continues to offer Category C and D rebate for Complex Orders when the PIXL Order is contra to other than the Initiating Order.[20]

Technical Amendments

The Exchange proposes to add the terms ''member'' and member organization,'' where applicable, within the proposed rule text. Pursuant to General 1, Section 1(16), the term ''member'' means:

> a permit holder which has not been terminated in accordance with the By-Laws and these Rules of the Exchange. A member is a natural person and must be a person associated with a member organization. Any references in the rules of the Exchange to the rights or obligations of an associated person or person associated with a member organization also includes a member.

Pursuant to General 1, Section 1(17) the term ''member organization'' means:

> a corporation, partnership (general or limited), limited liability partnership, limited liability company, business trust or similar organization, transacting business as a broker or a dealer in securities and which has the status of a member organization by virtue of (i) admission to membership given to it by the Membership Department pursuant to the provisions of General 3, Sections 5 and 10 or the By-Laws or (ii) the transitional rules adopted by the Exchange pursuant to Section 6–4 of the By-Laws. References herein to officer or partner, when used in the context of a member organization, shall include any person holding a similar position in any organization other than a corporation or partnership that has the status of a member organization.

An entity may be either a member or member organization on Phlx and therefore both terms apply when describing transaction fees and caps applicable to entities that have been approved for membership on Phlx.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[21] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[22] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, 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.'' [23]

Likewise, in *NetCoalition* v. *Securities and Exchange Commission* [24] (''NetCoalition''), the D.C. Circuit upheld the Commission's use of a market-based approach in evaluating the fairness of market data fees against a challenge claiming that Congress mandated a cost-based approach.[25] As the court emphasized, the Commission ''intended in Regulation NMS that 'market forces, rather than regulatory requirements' play a role in determining the market data . . . to be made available to investors and at what cost.'' [26]

Further, ''[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'. . . .'' [27] Although the court and the SEC were discussing the cash equities markets, the Exchange believes

[20] When a PIXL Order is contra to a PIXL Auction Responder, a Customer PIXL Order will be assessed $0.00 per contract, other Non-Customer PIXL Orders will be assessed $0.30 per contract in Penny Symbols or $0.38 per contract in Non-Penny Symbols. A Responder that is a Lead Market Maker or a Market Maker will be assessed $0.25 per contract in Penny Symbols or $0.40 per contract in Non-Penny Symbols. Other Non-Customer Responders will be assessed $0.48 per contract in Penny Symbols or $0.70 per contract in Non-Penny Symbols when contra to a PIXL Order. A Responder that is a Customer will be assessed $0.00 per contract in Penny Symbols and Non-Penny Symbol. When a PIXL Order is contra to a resting order or quote a Customer PIXL Order will be assessed $0.00 per contract, other Non-Customer will be assessed $0.30 per contract and the resting order or quote will be assessed the appropriate Options Transaction Charge in Options 7, Section 4.

[21] 15 U.S.C. 78f(b).

[22] 15 U.S.C. 78f(b)(4) and (5).

[23] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[24] *NetCoalition* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010).

[25] *See NetCoalition,* at 534–535.

[26] *Id.* at 537.

[27] *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

that these views apply with equal force to the options markets.

Options 7, Section 3

The Exchange's proposal to amend Options 7, Section 3, with respect to its PIXL pricing for SPY options is reasonable because it will continue to incentivize members and member organizations to transact a greater number of SPY Complex PIXL Orders while also incentivizing members and member organizations to submit Customer order flow on Phlx. While the proposal no longer offers the $0.12 per contract rebate that is available today for the PIXL Agency Order when that PIXL Order is contra to other than the Initiating Order, the Exchange believes that market participants will continue to be incentivized to submit PIXL Agency Orders to Phlx because the Exchange continues to offer a rebate of $0.40 per contract when the PIXL Order is contra to other than the Initiating Order. Requiring SPY Complex PIXL Orders greater than 499 contracts to be contra to an Initiating Order to receive the rebate, provided the member or member organization executes an average of 2,500 contracts per day of SPY Complex PIXL Orders in a month, will continue to encourage members and member organizations to submit order flow to Phlx to obtain the rebate. As is the case today, when the PIXL Order is contra to other than the Initiating Order, the PIXL Order is assessed $0.00 per contract, unless the PIXL Order is a Customer, in which case the Customer receives a rebate of $0.40 per contract.

The Exchange's proposal to amend Options 7, Section 3, Rebates and Fees for Adding and Removing Liquidity in SPY, with respect to its PIXL pricing for SPY options is equitable and not unfairly discriminatory because all members and member organizations are eligible for the proposed rebate, provided they met the requisite qualifications. Any member or member organization may enter a qualifying order into the PIXL Auction. Members and member organizations would be uniformly paid the applicable rebate. Additionally, all market participants may interact with order flow which members and member organizations must transact in connection with this rebate.

Options 7, Section 4

QCC

The Exchange's proposal to amend Options 7, Section 4, with respect to its QCC Rebates, to reduce the current six tier rebate schedule to a proposed two tier schedule is reasonable because the proposal will incentivize members and member organizations to submit a greater amount of QCC Orders to Phlx. With this proposal, the Exchange would pay a Tier 1 QCC Rebate of $0.09 on all qualifying executed electronic QCC Orders and Floor QCC Orders up to 999,999 contracts in a month. The QCC Rebate would be paid for each contract from the first execution up to 999,999 contracts in a month. Today, a Member will not receive a Tier 1 QCC Rebate if they enter 99,999 contracts or fewer in a month, however once a Member enters 100,000 or more contracts, the Member would qualify for the current Tier 2 QCC Rebate for all 100,000 contracts. With this proposal all qualifying executed electronic QCC Orders and Floor QCC Orders up to 999,999 contracts in a month would be entitled to the proposed $0.09 per contract Tier 1 QCC Rebate. Additionally, while today the Exchange pays a Tier 5 QCC rebate of $0.09 per contract for qualifying executed electronic QCC Orders and Floor QCC Orders from 700,000 to 999,999 contracts in a month, with this proposal the $0.09 per contract Tier 1 QCC Rebate would be paid to Members who submit up to 999,999 contracts in a month. Also, the Exchange would pay a Tier 2 QCC Rebate of $0.17 per contract on all qualifying executed electronic QCC Orders and Floor QCC Orders of $1,000,000 contracts or more in a month. Today, the Exchange pays a Tier 6 QCC Rebate of $0.11 per contract for qualifying executed electronic QCC Orders and Floor QCC Orders over $1,000,000 contracts in a month. The proposed Tier 2 QCC Rebate would be increased to $0.17 per contract for $1,000,000 contracts or more in a month.

The Exchange's proposal to amend Options 7, Section 4, with respect to its QCC Rebates, to reduce the current six tier rebate schedule to a proposed two tier schedule is equitable and not unfairly discriminatory because all members and member organizations may qualify for a QCC Rebate provided the member or member organization executed qualifying electronic QCC Orders and Floor QCC Orders.

Monthly Firm Fee Cap

The Exchange's proposal to amend Options 7, Section 4, with respect to the Monthly Firm Fee Cap, to increase the Monthly Firm Fee Cap from $75,000 to $150,000 is reasonable because despite the increase, the Exchange believes Firms will continue to be incentivized by the opportunity to pay no fees beyond the $150,000 cap. The Monthly Firm Fee Cap has remained at $75,000 since 2010. Other members and member organizations may interact with the order flow submitted by Firms to Phlx to reach the cap.

The Exchange's proposal to amend Options 7, Section 4, with respect to the Monthly Firm Fee Cap, to increase the Monthly Firm Fee Cap from $75,000 to $150,000 is equitable and not unfairly discriminatory as other market participants benefit from an opportunity to pay reduced fees on Phlx as do Firms. Today, Customers are not assessed an Options Transaction Charge in multiply-listed Penny or non-Penny Symbols.[28] Customer liquidity benefits all market participants by providing more trading opportunities. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. Today, Lead Market Makers and Market Makers are subject to a Monthly Market Maker Cap of $500,000 for: (i) electronic Option Transaction Charges, excluding surcharges and excluding options overlying broad-based index options symbols listed within Options 7, Section 5.A; and (ii) QCC Transaction Fees (as defined in Exchange Options 3, Section 12 and Floor QCC Orders, as defined in Options 8, Section 30(e)).[29] With respect to Broker-Dealers, today, the Exchange waives the Floor Options Transaction Charge for Broker-Dealers executing facilitation orders pursuant to Options 8, Section 30 when such members would otherwise incur this charge for trading in their own proprietary account contra to a Customer (''BD-Customer Facilitation''), if the member's BD-Customer Facilitation average daily volume

[28] *See* Options 7, Section 4.

[29] *See* Options 7, Section 4. The trading activity of separate Lead Market Maker and Market Maker member organizations is aggregated in calculating the Monthly Market Maker Cap if there is Common Ownership between the member organizations. All dividend, merger, short stock interest, reversal and conversion, jelly roll and box spread strategy executions (as defined in Options 7, Section 4) are excluded from the Monthly Market Maker Cap. Lead Market Makers or Market Makers that (i) are on the contra-side of an electronically-delivered and executed Customer order, excluding responses to a PIXL auction; and (ii) have reached the Monthly Market Maker Cap will be assessed fees as follows: $0.05 per contract Fee for Adding Liquidity in Penny Symbols; $0.18 per contract Fee for Removing Liquidity in Penny Symbols; $0.18 per contract in Non-Penny Symbols; and $0.18 per contract in a non-Complex electronic auction, including the Quote Exhaust auction and, for purposes of this fee, the opening process. A Complex electronic auction includes, but is not limited to, the Complex Order Live Auction (''COLA''). Transactions which execute against an order for which the Exchange broadcast an order exposure alert in an electronic auction will be subject to this fee.

(including both FLEX and non-FLEX transactions) exceeds 10,000 contracts per day in a given month.[30] Finally, today, Professional Floor Options Transaction Charges are less favorable than Customers but more favorable than Firms as Broker-Dealers are assessed a lower Options Transaction Charge as compared to Floor Lead Market Makers, Floor Market Makers. Additionally, the Exchange believes that the proposal is equitable and not unfairly discriminatory because members and member organizations that are JBOs [31] could be subject to the Firm Related Equity Option Cap, as are other members, as long as the JBO trades for their own proprietary account. Additionally, the proposed change would encourage JBOs that are not members or member organizations to seek to become members or member organizations to further reduce their transaction fees.

Options 7, Section 6

The Exchange's proposal to amend Options 7, Section 6, with respect to its PIXL pricing [32] is reasonable because it will continue to incentivize members and member organizations to transact a greater number of Complex PIXL Orders while also incentivizing members and member organizations to submit Customer order flow on Phlx. While the proposal no longer offers the $0.12 per contract rebate that is available today for the PIXL Agency Order when that PIXL Order is contra to other than the Initiating Order, the Exchange believes that market participants will continue to be incentivized to submit PIXL Agency Orders to Phlx because the Exchange continues to offer Category C and D rebates for Complex Orders when the PIXL Order is contra to other than the Initiating Order.[33] Requiring Complex PIXL Orders greater than 499 contracts to be contra to an Initiating Order to receive the rebate, provided the member or member organization executes an average of 2,500 contracts per day of Complex PIXL Orders in a month, will continue to encourage members and member organizations to submit order flow to Phlx to obtain the rebate.

The Exchange's proposal to amend Options 7, Section 6, with respect to its PIXL pricing is equitable and not unfairly discriminatory because all members and member organizations are eligible for the proposed rebate, provided they met the requisite qualifications. Any member or member organization may enter a qualifying order into the PIXL Auction. Members and member organizations would be uniformly paid the applicable rebate. Additionally, all market participants may interact with order flow which members or member organizations must transact in connection with this rebate.

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 not necessary or appropriate in furtherance of the purposes of the Act.

Intermarket Competition

The proposal does not impose an undue burden on intermarket competition. The Exchange believes its proposal remains competitive with other options markets and will offer market participants with another choice of where to transact options. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

Intramarket Competition

The proposed amendments do not impose an undue burden on intramarket competition.

Options 7, Section 3

The Exchange's proposal to amend Options 7, Section 3, Rebates and Fees for Adding and Removing Liquidity in SPY, with respect to its PIXL pricing for SPY options does not impose an undue burden on competition because all members and member organizations are eligible for the proposed rebate, provided they met the requisite qualifications. Any member or member organization may enter a qualifying order into the PIXL Auction. Members and member organizations would be uniformly paid the applicable rebate. Additionally, all market participants may interact with order flow which members and member organizations must transact in connection with this rebate.

Options 7, Section 4

QCC

The Exchange's proposal to amend Options 7, Section 4, with respect to its QCC Rebates, to reduce the current six tier rebate schedule to a proposed two tier schedule does not impose an undue burden on competition because all members and member organizations may qualify for a QCC Rebate provided the member or member organization executed qualifying electronic QCC Orders and Floor QCC Orders.

Monthly Firm Fee Cap

The Exchange's proposal to amend Options 7, Section 4, with respect to the Monthly Firm Fee Cap, to increase the Monthly Firm Fee Cap from $75,000 to $150,000 does not impose an undue burden on competition as other market participants benefit from an opportunity to pay reduced fees on Phlx as do Firms. Today, Customers are not assessed an Options Transaction Charge in multiply-listed Penny or non-Penny Symbols.[34] Customer liquidity benefits all market participants by providing more trading opportunities. An increase in the

[30] *See* Options 7, Section 4, which states, ''. . . In addition, the Broker-Dealer Floor Options Transaction Charge (including Cabinet Options Transaction Charges) will be waived for members executing facilitation orders pursuant to Options 8, Section 30 when such members would otherwise incur this charge for trading in their own proprietary account contra to a Customer ('BD-Customer Facilitation'), if the member's BD-Customer Facilitation average daily volume (including both FLEX and non-FLEX transactions) exceeds 10,000 contracts per day in a given month. NDX, NDXP, and XND Options Transactions will be excluded from each of the waivers set forth in the above paragraph.''

[31] The term ''Joint Back Office'' or ''JBO'' applies to any transaction that is identified by a member or member organization for clearing in the Firm range at OCC and is identified with an origin code as a JBO. A JBO will be priced the same as a Broker-Dealer. A JBO participant is a member, member organization or non-member organization that maintains a JBO arrangement with a clearing broker-dealer (''JBO Broker'') subject to the requirements of Regulation T Section 220.7 of the Federal Reserve System as further discussed at Options 6D, Section 1. *See* Options 7, Section 1(c).

[32] The PIXL pricing in Options 7, Section excludes SPY options.

[33] When a PIXL Order is contra to a PIXL Auction Responder, a Customer PIXL Order will be assessed $0.00 per contract, other Non-Customer PIXL Orders will be assessed $0.30 per contract in Penny Symbols or $0.38 per contract in Non-Penny Symbols. A Responder that is a Lead Market Maker or a Market Maker will be assessed $0.25 per contract in Penny Symbols or $0.40 per contract in Non-Penny Symbols. Other Non-Customer Responders will be assessed $0.48 per contract in Penny Symbols or $0.70 per contract in Non-Penny Symbols when contra to a PIXL Order. A Responder that is a Customer will be assessed $0.00 per contract in Penny Symbols and Non-Penny Symbol. When a PIXL Order is contra to a resting order or quote a Customer PIXL Order will be assessed $0.00 per contract, other Non-Customer will be assessed $0.30 per contract and the resting order or quote will be assessed the appropriate Options Transaction Charge in Options 7, Section 4.

[34] *See* Options 7, Section 4.

activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. Today, Lead Market Makers and Market Makers are subject to a Monthly Market Maker Cap of $500,000 for: (i) electronic Option Transaction Charges, excluding surcharges and excluding options overlying broad-based index options symbols listed within Options 7, Section 5.A; and (ii) QCC Transaction Fees (as defined in Exchange Options 3, Section 12 and Floor QCC Orders, as defined in Options 8, Section 30(e)).[35] With respect to Broker-Dealers, today, the Exchange waives the Floor Options Transaction Charge for Broker-Dealers executing facilitation orders pursuant to Options 8, Section 30 when such members would otherwise incur this charge for trading in their own proprietary account contra to a Customer (''BD-Customer Facilitation''), if the member's BD-Customer Facilitation average daily volume (including both FLEX and non-FLEX transactions) exceeds 10,000 contracts per day in a given month.[36] Finally, today, Professional Floor Options Transaction Charges are less favorable than Customers but more favorable than Firms as Broker-Dealers are assessed a lower Options Transaction Charge as compared to Floor Lead Market Makers, Floor Market Makers. Additionally, the Exchange believes that the proposal is equitable and not unfairly discriminatory because members and member organizations that are JBOs[37] could be subject to the Firm Related Equity Option Cap, as are other members, as long as the JBO trades for their own proprietary account. Additionally, the proposed change would encourage JBOs that are not members or member organizations to seek to become members or member organizations to further reduce their transaction fees.

Options 7, Section 6

The Exchange's proposal to amend Options 7, Section 6, with respect to its PIXL pricing does not impose an undue burden on competition because all members and member organizations are eligible for the proposed rebate, provided they met the requisite qualifications. Any member or member organization may enter a qualifying order into the PIXL Auction. Members and member organizations would be uniformly paid the applicable rebate. Additionally, all market participants may interact with order flow which members and member organizations must transact in connection with this rebate.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

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)(ii) of the Act.[38]

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: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) 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–Phlx–2022–41 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–Phlx–2022–41. 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–Phlx–2022–41 and should

[35] *See* Options 7, Section 4. The trading activity of separate Lead Market Maker and Market Maker member organizations is aggregated in calculating the Monthly Market Maker Cap if there is Common Ownership between the member organizations. All dividend, merger, short stock interest, reversal and conversion, jelly roll and box spread strategy executions (as defined in Options 7, Section 4) are excluded from the Monthly Market Maker Cap. Lead Market Makers or Market Makers that (i) are on the contra-side of an electronically-delivered and executed Customer order, excluding responses to a PIXL auction; and (ii) have reached the Monthly Market Maker Cap will be assessed fees as follows: $0.05 per contract Fee for Adding Liquidity in Penny Symbols; $0.18 per contract Fee for Removing Liquidity in Penny Symbols; $0.18 per contract in Non-Penny Symbols; and $0.18 per contract in a non-Complex electronic auction, including the Quote Exhaust auction and, for purposes of this fee, the opening process. A Complex electronic auction includes, but is not limited to, the Complex Order Live Auction (''COLA''). Transactions which execute against an order for which the Exchange broadcast an order exposure alert in an electronic auction will be subject to this fee.

[36] *See* Options 7, Section 4, which states, ''. . . In addition, the Broker-Dealer Floor Options Transaction Charge (including Cabinet Options Transaction Charges) will be waived for members executing facilitation orders pursuant to Options 8, Section 30 when such members would otherwise incur this charge for trading in their own proprietary account contra to a Customer ('BD-Customer Facilitation'), if the member's BD-Customer Facilitation average daily volume (including both FLEX and non-FLEX transactions) exceeds 10,000 contracts per day in a given month. NDX, NDXP, and XND Options Transactions will be excluded from each of the waivers set forth in the above paragraph.''

[37] The term ''Joint Back Office'' or ''JBO'' applies to any transaction that is identified by a member or member organization for clearing in the Firm range at OCC and is identified with an origin code as a JBO. A JBO will be priced the same as a Broker-Dealer. A JBO participant is a member, member organization or non-member organization that maintains a JBO arrangement with a clearing broker-dealer (''JBO Broker'') subject to the requirements of Regulation T Section 220.7 of the Federal Reserve System as further discussed at Options 6D, Section 1. *See* Options 7, Section 1(c).

[38] 15 U.S.C. 78s(b)(3)(A)(ii).

be submitted on or before November 28, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[39]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–24142 Filed 11–4–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96201; File No. SR–MIAX–2022–40]

Self-Regulatory Organizations: Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by Miami International Securities Exchange, LLC To Remove the Fill-Or-Kill (''FOK'') Order Type and Fill Or Kill (''FOK'') eQuotes From the Exchange

November 1, 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 October 27, 2022, Miami International Securities Exchange, LLC (''MIAX Options'' 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 is filing a proposal to remove the fill-or-kill (''FOK'')[3] order type and fill or kill (''FOK'') eQuotes[4] from the Exchange.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/* at MIAX Options' 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 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 offers a number of different order types for use on the Exchange.[5] One of the order types the Exchange offers to Members[6] is a fill-or-kill (''FOK'') order. A fill-or-kill order is a limit order that is to be executed in its entirety at a single price as soon as it is received and, if not so executed is cancelled. A fill-or-kill order is not valid during the opening rotation process described in Rule 503.[7] Similarly, the Exchange offers a fill or kill (''FOK'') eQuote which is an eQuote submitted by a Market Maker[8] that must be matched with another quote or order for an execution in its entirety at a single price upon receipt into the System or will be immediately cancelled. An FOK eQuote does not automatically cancel or replace the Market Maker's previous Standard quote or eQuote. An FOK eQuote is not valid during the opening rotation process described in Rule 503.[9]

In Rule 516, Order Types Defined, the Exchange states it will issue a Regulatory Circular listing which order types, among the order types set forth in the Rule, are available.[10] Additionally, the rule provides that Regulatory Circulars will also be issued when an order type that had been in usage on the Exchange will no longer be available for use. Similarly, in Rule 517, Quote Types Defined, the Exchange states it will issue a Regulatory Circular listing which quote types, among those quote types set forth in the Rule, are available.[11] Additionally, the rule provides that Regulatory Circulars will also be issued when a quote type that had been in usage on the Exchange will no longer be available for use. The Exchange determined that FOK orders and FOK eQuotes were not order types or eQuote types that were being regularly used by Members on the Exchange. In April of 2021, the Exchange issued Regulatory Circulars to announce that FOK orders[12] and FOK eQuotes[13] would no longer be available for use on the Exchange. Prior to undertaking the effort to remove FOK orders and FOK eQuotes completely from the System,[14] the Exchange wanted to ensure that there were no unforeseen consequences from disabling FOK orders and FOK eQuotes, hence the delay between disabling usage via Regulatory Circular and formally removing the order type from use on the Exchange.

The Exchange now proposes to permanently remove the functionality from the Exchange's System and to also remove references to FOK orders and FOK eQuotes from the Exchange's Rulebook. Specifically, the Exchange proposes to eliminate references to FOK orders and FOK eQuotes in the following Exchange Rules: Exchange Rule 308, Exemptions from Position Limits; Rule 515, Execution of Orders and Quotes; Rule 516, Order Types Defined; Rule 517, Quote Types Defined; Rule 529, Order Routing to Other Exchanges; Rule 605, Market Maker Orders; and Rule 612, Aggregate Risk Manager (ARM). In connection with the proposed change to remove references to FOK orders and FOK eQuotes from the Rulebook, the Exchange also proposes to amend cross-references to other rules that need to be updated for accuracy as a result of the removal of FOK orders and FOK eQuotes. These proposed changes are non-substantive edits that are intended to harmonize the Rulebook with the System functionality and provide consistency and clarity throughout the Rulebook.

First, the Exchange proposes to amend Exchange Rule 308(c)(vi)(A), to remove paragraph (A) which contains a reference to a fill-or-kill instruction. The Exchange then proposes to amend subparagraph (c)(vi)(B) to be

[39] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Rule 516(b)(2).

[4] *See* Exchange Rule 517(a)(2)(v).

[5] *See* Exchange Rule 516.

[6] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[7] *See* Exchange Rule 516(b)(2).

[8] The term ''Market-Makers'' refers to ''Lead Market Makers'', ''Primary Lead Market-Makers'' and ''Registered Market Makers'' collectively. *See* Exchange Rule 100.

[9] *See supra* note 4.

[10] *See* Exchange Rule 516.

[11] *See* Exchange Rule 517.

[12] *See* MIAX Regulatory Circular 2021–20, Fill-or-Kill Orders Will No Longer Be Supported on the MIAX Options Exchange (April 8, 2021), *available at https://www.miaxoptions.com/sites/default/files/circular-files/MIAX_Options_RC_2021_20.pdf.*

[13] *See* MIAX Regulatory Circular 2021–21, Fill-or-Kill eQuotes Will No Longer Be Supported on the MIAX Options Exchange (April 9, 2021), *available at https://www.miaxoptions.com/sites/default/files/circular-files/MIAX_Options_RC_2021_21.pdf.*

[14] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

renumbered to proposed paragraph (c)(vi)(A).

Next, the Exchange proposes to amend Exchange Rule 515, Execution of Orders and Quotes, to remove references to FOK orders in subparagraph (c)(1) and subparagraph (c)(3)(i)(E). Additionally, the Exchange proposes to remove the contents of paragraph (f) in its entirety and mark the paragraph as reserved for future use. Also, within current subparagraph 515(g) the Exchange proposes to amend the cross-reference to Exchange Rule 517(a)(2)(vi) to Rule 517(a)(2)(v). This proposed change reflects the proposed renumbering of Exchange Rule 517, discussed below, after the paragraph pertaining to fill or kill eQuotes is removed.

Next, the Exchange proposes to amend Exchange Rule 516, Order Types Defined, to eliminate subparagraph (b)(2) in its entirety. The Exchange also proposes to adjust the hierarchical numbering order to reflect the removal of current subparagraph (b)(2) by renumbering current subparagraphs (b)(3) and (b)(4) to paragraphs (b)(2) and (b)(3), respectively. The Exchange also proposes to amend Exchange Rule 510, Minimum Price Variations and Minimum Trading Increments, to amend the cross-reference contained in paragraph 510(b) from ''Rule 516(b)(3)'' to ''Rule 516(b)(2)'' to reflect the proposed renumbering of Exchange Rule 516, discussed above.

The Exchange also proposes to amend Exchange Rule 517, Quote Types Defined, to remove subparagraph (a)(2)(v) in its entirety. Also, as a result of the removal of this paragraph, the Exchange proposes to renumber current subparagraph (a)(2)(vi) to proposed subparagraph (a)(2)(v). Further, the Exchange proposes to eliminate subparagraph (d)(4) in its entirety. The Exchange then proposes to amend current subparagraphs (d)(5) and (d)(6) to renumber as proposed paragraphs (d)(4) and (d)(5), respectively.

The Exchange proposes to amend Exchange Rule 529, Order Routing to Other Exchanges, to remove the references to FOK orders and FOK eQuotes contained within subparagraph 529(b)(2)(iii).

The Exchange proposes to amend Exchange Rule 604(b)(1) by amending a cross-reference to current Rule 516(b)(3), non-displayed penny orders, to proposed Rule 516(b)(2). This amendment reflects the proposed re-numbering changes to the Rulebook resulting from removal of FOK orders as described above.

The Exchange also proposes to amend Exchange Rule 605, Market Maker Orders, by deleting the reference to fill-or-kill orders within Rule 605(a).

Lastly, the Exchange proposes to amend Exchange Rule 612, Aggregate Risk Manager (ARM), by removing references to FOK eQuotes within Interpretations and Policies .02(c).

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act [15] in general, and furthers the objectives of Section 6(b)(5) of the Act [16] 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 mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes the proposed change promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system as the proposal removes an order type and a quote type infrequently used by the Exchange's Members. Removal of infrequently used functionality simplifies the operation of the Exchange's System, as the Exchange does not need to support and maintain order types and quote types that are not regularly used. Additionally, removing the reference to FOK orders and FOK eQuotes in the Exchange's Rulebook provides consistency and clarity throughout the Rulebook. Clarity and precision in the Exchange's Rulebook protects investors and the public by clearly enumerating the order types and eQuote types available for use on the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes the proposed change will not impose any burden on intra-market competition as the Exchange originally disabled FOK orders and FOK eQuotes via a Regulatory Circular.[17] The Exchange now proposes to remove the functionality completely from the Exchange's System and to update the Exchange's Rulebook accordingly. The Exchange does not believe its proposal will impose any burden on intra-market competition as all Members are equally affected as these order types and quote types were infrequently used and have been unavailable for use on the Exchange since being disabled via Regulatory Circular.

The Exchange does not believe the proposal will impose any burden on inter-market competition as not every option exchange offers FOK orders.[18] However, for those Members that wish to use the FOK order type there are exchanges that will accept and process this order type.[19]

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 [20] and Rule 19b–4(f)(6) [21] 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.

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] *See supra* notes 12 and 13.

[18] BOX Options Exchange offers a Fill and Kill (FAK) order instruction but not fill-or-kill. *See* Box Options Exchange Rule 7110(e)(ii).

[19] *See* Cboe Exchange Rule 5.6, and NYSE Arca Exchange Rule 6.91–O.

[20] 15 U.S.C. 78s(b)(3)(A).

[21] 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.

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–MIAX–2022–40 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–MIAX–2022–40. 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–MIAX–2022–40, and should be submitted on or before November 28, 2022.

[22] 17 CFR 200.30–3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–24145 Filed 11–4–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96198; File No. SR–MIAX–2022–38]

Self-Regulatory Organizations: Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by Miami International Securities Exchange LLC To Amend Its Fee Schedule

November 1, 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 October 12, 2022, Miami International Securities Exchange LLC (''MIAX'' or ''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 is filing a proposal to amend the MIAX Options Fee Schedule (the ''Fee Schedule'').

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings,* at MIAX'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 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to amend footnote ''*'' of the MIAX Price Improvement Mechanism (''PRIME'') Fees table[3] to increase the enhanced PRIME Break-up credit of $0.69 to $0.73 for EEMs that submit a Priority Customer PRIME Order in Non-Penny Classes that is submitted to the PRIME Auction that trades with PRIME AOC Reponses and/or PRIME Participating Quotes or Orders, if the PRIME Order experiences a break-up of greater than forty percent (40%). The Exchange initially filed this proposal on September 30, 2022 (SR–MIAX–2022–34). On October 12, 2022, the Exchange withdrew SR–MIAX–2022–34 and resubmitted the proposal (SR–MIAX–2022–36). On October 19, 2022, the Exchange withdrew SR–MIAX–2022–36 and resubmitted this proposal (SR–MIAX–2022–38).

The proposed changes are immediately effective.

Background

The MIAX Price Improvement Mechanism (''PRIME'') is a process by which a Member[4] may electronically submit for execution an order it represents as agent (an ''Agency Order'') against principal interest and/or solicited interest. The Member that submits the Agency Order (''Initiating Member'') agrees to guarantee the execution of the Agency Order by submitting a contra-side order representing principal interest or solicited interest (''Contra-Side Order'').[5] When the Exchange receives a properly designated Agency Order for Auction processing, a request for response (''RFR'') detailing the option, side, size and initiating price is broadcasted to MIAX participants up to an optional designated limit price.[6] Members may submit responses to the RFR, which can be either an Auction or Cancel (''AOC'') order[7] or an AOC

[3] *See* Section 1)a)v) of the Exchange's Fee Schedule on its public website (available at *www.miaxoptions.com/fees*).

[4] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[5] *See* Exchange Rule 515A(a).

[6] *See* Exchange Rule 515A(a)(2)(B).

[7] An Auction-or-Cancel or ''AOC'' order is a limit order used to provide liquidity during a specific Exchange process (such as the Opening Imbalance process described in Rule 503) with a time in force that corresponds with that event. AOC orders are

eQuote.[8] The PRIME mechanism is used for orders on the Exchange's Simple Order Book.[9]

The Exchange provides a PRIME Break-up credit of $0.60 per contract for Non-Penny Classes in a PRIME Auction.[10] The Exchange subsequently adopted an enhanced PRIME Break-up credit of $0.69 per contract for Priority Customer PRIME Orders in Non-Penny Classes when the order break-up percentage was greater than 40%.[11] The enhanced PRIME Break-up credit of $0.69 per contract is applied to the EEM that submitted a PRIME Order in Non-Penny classes that is submitted to a PRIME Auction that trades with PRIME AOC Responses and/or PRIME Participating Quotes or Orders, if the PRIME Order experiences a break-up of greater than forty percent (40%). The Exchange now proposes to increase the per contract credit from $0.69 to $0.73. The decision to increase the enhanced Priority Customer Break-up credit is based on an analysis of current revenue and volume levels and is designed to continue to encourage Priority Customer order flow to PRIME Auctions.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act[12] in general, and furthers the objectives of Section 6(b)(4) of the Act[13] in particular, in that it is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act[14] in that it is designed to promote just and equitable principles of trade, 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 and dealers.

The Exchange believes its proposal provides for the equitable allocation of reasonable dues and fees and is not unfairly discriminatory for the following reasons. The decision to increase the enhanced Priority Customer Break-up credit is based on an analysis of current revenue and volume levels and is designed to continue to encourage Priority Customer order flow to PRIME Auctions. The Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is one of 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than approximately 11% of the market share of executed volume of multiply-listed equity and exchange-traded fund (''ETF'') options trades as of September 26, 2022, for the month of September 2022.[15] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, as of September 26, 2022, the Exchange has a total market share of 5.23% of all equity options volume, for the month of September 2022.[16]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue use of certain categories of products, in response to fee changes. For example, on March 1, 2019, the Exchange filed with the Commission an immediately effective filing to decrease certain credits assessable to Members pursuant to the PCRP.[17] The Exchange experienced a decrease in total market share between the months of February and March of 2019. Accordingly, the Exchange believes that the March 1, 2019, fee change may have contributed to the decrease in the Exchange's market share and, as such, the Exchange believes competitive forces constrain options exchange transaction and non-transaction fees.

Accordingly, competitive forces constrain the Exchange's transaction fees, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. In response to the competitive environment, the Exchange offers specific rates and credits in its Fee Schedule, like those of other options exchanges' fees schedules, which the Exchange believes provides incentives to Members to increase order flow of certain qualifying orders.

The Exchange believes its proposal to increase the enhanced PRIME Break-up Credit for Non-Penny Classes for Priority Customers is reasonable, equitably allocated and not unfairly discriminatory because this change is for business and competitive reasons. In order to attract order flow the Exchange initially set its rebates and fees for its PRIME Auctions so that they were meaningfully higher/lower than other options exchanges that provide comparable price improvement mechanisms.[18] The Exchange now believes that it is appropriate to further adjust these fees so that they are competitive with other Exchanges that offer similar price improvement functionality and maintain a similar credit methodology. Specifically, the Cboe Exchange provides a Break-up Credit of $0.60 in Non-Penny Classes[19] and the BOX Exchange provides a Break-up Credit of $0.81 in Non-Penny Classes,[20] therefore the Exchange's proposed enhanced Break-up credit of $0.73 in Non-Penny Classes is in line with Break-up credits in Non-Penny Classes currently available on other exchanges. The Exchange believes its proposed enhanced Break-up credit in Non-Penny Classes will allow the Exchange to remain competitive and should enable the Exchange to continue to attract order flow to PRIME Auctions and to also maintain market share.

The Exchange believes that its proposal will continue to encourage Priority Customer order flow to PRIME

not displayed to any market participant, are not included in the MBBO and therefore are not eligible for trading outside of the event, may not be routed, and may not trade at a price inferior to the away markets. *See* Exchange Rule 516(b)(4).

[8] AOC eQuote An Auction or Cancel or ''AOC'' eQuote is a quote submitted by a Market Maker to provide liquidity in a specific Exchange process (such as the Opening Imbalance Process described in Rule 503) with a time in force that corresponds with the duration of that event and will automatically expire at the end of that event. AOC eQuotes are not displayed to any market participant, are not included in the MBBO and therefore are not eligible for trading outside of the event. An AOC eQuote does not automatically cancel or replace the Market Maker's previous Standard quote or eQuote. *See* Exchange Rule 517(a)(2)(ii).

[9] The ''Simple Order Book'' is the Exchange's regular electronic book of orders and quotes. *See* Exchange Rule 518(a)(15).

[10] *See* Section 1)a)v) of the Exchange's Fee Schedule on its public website (available at *www.miaxoptions.com/fees*).

[11] *See* Securities Exchange Act Release No. 93306 (October 13, 2021), 86 FR 57869 (October 19, 2021) (SR–MIAX–2021–42).

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(4).

[14] 15 U.S.C. 78f(b)(5).

[15] *See* MIAX's ''The market at a glance/MTD AVERAGE'', available at *https://www.miaxoptions.com/* (Data as of 9/1/2022–9/26/2022).

[16] *See id.*

[17] *See* Securities Exchange Act Release No. 85301 (March 13, 2019), 84 FR 10166 (March 19, 2019) (SR–MIAX–2019–09).

[18] *See* Cboe Exchange Rule 5.73 and 5.74; *See also* BOX Exchange Rule 7150 and 7245.

[19] *See* Cboe Exchange Fee Schedule, ''Break-Up Credits,'' on its public website (available at *https://cdn.cboe.com/resources/membership/Cboe_FeeSchedule.pdf*).

[20] *See* Section IV. Electronic Transaction Fees, B. PIP and COPIP Transactions, of the BOX Options Exchange Fee Schedule on its public website (available at *https://boxoptions.com/fee-schedule/*).

Auctions. Increased Priority Customer order flow benefits all market participants because it continues to attract liquidity to the Exchange by providing more trading opportunities. This attracts Market Makers and other liquidity providers, thus, facilitating price improvement in the auction process, signaling additional corresponding increase in order flow from other market participants, and, as a result, increasing liquidity on the Exchange.

As noted above, the Exchange operates in a highly competitive market. The Exchange is only one of several options venues to which market participants may direct their order flow, and it represents a small percentage of the overall market. The Exchange believes that the proposed fees are reasonable, equitable, and not unfairly discriminatory in that at least one competing options exchange offers similar fees and credits in connection with similar price improvement auctions.[21]

The Exchange also believes that this proposal is consistent with Section 6(b)(5) of the Act [22] because it perfects the mechanisms of a free and open market and a national market system and protects investors and the public interest because it provides an additional incentive for Members to increase Priority Customer order flow to the Exchange in order to obtain the highest volume threshold, which benefits all market participants by providing more trading opportunities and tighter spreads.

In addition, The Exchange believes that its proposal is consistent with Section 6(b)(5) of the Act [23] because it perfects the mechanisms of a free and open market and a national market system and protects investors and the public interest because Priority Customer order flow will bring greater volume and liquidity to the Exchange, which benefits all market participants by providing more trading opportunities and tighter spreads. To the extent Priority Customer order flow is increased by this proposal, market participants will increasingly compete for the opportunity to trade on the Exchange including sending more orders and provided narrower and larger-sized quotations in the effort to trade with such Priority Customer order flow.

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and self-regulatory organization (''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.'' [24]

The Exchange believes that the ever-shifting market shares among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue or reduce use of certain categories of products, in response to transaction and non-transaction fee changes. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. The Exchange believes the proposal reflects a reasonable and competitive pricing structure which will continue to incentivize market participants to direct liquidity adding orders to the Exchange, which the Exchange believes would enhance liquidity and market quality on the exchange to the benefit of all Members.

For the reasons discussed above, the Exchange submits that the proposal satisfies the requirements of Sections 6(b)(4) and 6(b)(5) of the Act [25] in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to unfairly discriminate between customers, issuers, brokers, or dealers.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[26] the Exchange does not believe that the proposed rule change will impose any burden on intra-market or intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes its proposal to increase its enhanced PRIME Break-up Credit for Non-Penny Classes for Priority Customers is reasonable, equitably allocated and not unfairly discriminatory as the credit will be applied equally to all Members eligible to receive the credit. The Exchange believes that its proposal will continue to encourage Priority Customer order flow to PRIME Auctions. Increased Priority Customer order flow benefits all market participants because it continues to attract liquidity to the Exchange by providing more trading opportunities and tighter spreads.

The Exchange does not believe that its proposal will impose any burden on inter-market competition that is not necessary or appropriate in furtherance of the purposes of the Act because, as noted above, at least one other competing options exchange currently has similar rebates in place in connection with similar price improvement auctions.[27] Additionally, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. In such an environment, the Exchange must continually adjust its fees and incentives to remain competitive with other exchanges and to attract order flow to the Exchange. The Exchange is one of 16 options exchanges competing for order flow. Based on publicly available information, and excluding index-based options, no single options exchange has more than approximately 11% of the market share of executed multiply-listed equity and ETF options as of September 26, 2022, for the month of September 2022.[28] Market participants can readily choose to send their orders to other exchanges if they deem fee levels or incentives at those other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and incentives to remain competitive with other exchanges and to attract order flow. The Exchange believes that the proposed rule change reflects this competitive environment.

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.'' [29] The

[21] *See* supra note 20.

[22] 15 U.S.C. 78f(b)(1) and (b)(5).

[23] 15 U.S.C. 78f(b)(4).

[24] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

[25] 15 U.S.C. 78f(b)(4) and (5).

[26] 15 U.S.C. 78f(b)(8).

[27] *See supra* note 20.

[28] *See supra* note 15.

[29] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 47396, 37499 (June 29, 2005).

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'. . . .''.[30] Accordingly, the Exchange does not believe its proposed fee change imposes 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

Written comments were neither solicited nor received.

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)(ii) of the Act,[31] and Rule 19b–4(f)(2)[32] 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–MIAX–2022–38 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–MIAX–2022–38. 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–MIAX–2022–38, and should be submitted on or before November 28, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–24143 Filed 11–4–22; 8:45 am]

BILLING CODE 8011–01–P

[30] *NetCoalition* v. *SEC*, 615 F.3d 525, 539 (D.C. Cir 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[31] 15 U.S.C. 78s(b)(3)(A)(ii).

[32] 17 CFR 24.19b–4(f)(2).

[33] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96194; File No. SR–Phlx–2022–42]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Standard Monthly Expirations for XND

November 1, 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 October 19, 2022, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. 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 permit Phlx to list up to 12 standard monthly expirations for Nasdaq 100 Micro Index Options (''XND'').

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* 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 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Phlx proposes to amend its index listing rules at Options 4A, Section 12(a)(4) to allow it to list up to12 standard monthly expirations for Nasdaq 100 Micro Index Options (''XND'').

Currently, Options 4A, Section 12(a)(4) provides that the Exchange may list: (i) up to six (6) standard monthly expirations at any one time in a class, but will not list index options that expire more than twelve (12) months out; (ii) up to 12 standard monthly expirations at any one time for any class that the Exchange (as the Reporting Authority) uses to calculate a volatility index; and (iii) up to 12 standard (monthly) expirations in NDX options.[4] Today, the maximum number of monthly expirations permitted by Options 4A, Section 12(a)(4) for XND options is six (6) standard monthly expirations.

At this time, like Nasdaq-100 Index® options (''NDX''), the Exchange proposes to permit up to 12 standard (monthly) expirations in XND options. This would permit the Exchange to list the same number of monthly expirations (up to 12) for XND options as currently permitted for options on the corresponding full-value index, Nasdaq-100 Index.

Today, XND options trade independently of and in addition to NDX options, and the XND options are subject to the same rules that presently govern the trading of NDX options, including sales practice rules, margin requirements, trading rules, and position and exercise limits. Like NDX, XND options are European-style and cash-settled, and have a contract multiplier of 100. The contract specifications for XND options mirror in all respects those of the NDX options contract already listed on the Exchange, except that XND options are based on 1/100th of the value of the Nasdaq-100 Index, and are P.M.-settled pursuant to Options 4A, Section 12(a)(5).[5]

Market participants may use XND options as a hedging vehicle to meet their investment needs in connection with the Nasdaq-100 Index. Since both products are used to hedge exposure to the Nasdaq-100 Index, the Exchange believes it is appropriate to permit the Exchange to be able to list the same number of monthly expirations for XND options as it does today for NDX options.

The Exchange notes that Cboe Exchange, Inc.'s (''Cboe'') rules permit it to list up to 12 standard monthly expirations for Mini-Russell 2000 Index (''Mini-RUT'' or ''MRUT'') and Mini S&P 500 Index (''Mini-SPX'' or ''XSP'').[6] Mini-SPX is p.m.-settled and subject to a pilot program similar to XND.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, in that it is designed to promote just and equitable principles of trade, 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.

Allowing Phlx to list up to 12 standard monthly expirations for XND options will remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors, because it will allow the Exchange to be able to list the same number of expirations for options on a micro index (XND) as it currently lists for NDX options, which are options on the corresponding full-value index, Nasdaq-100 Index. The Exchange notes that because the same components comprise XND as the Nasdaq-100 Index, market participants may use XND options as a hedging vehicle to meet their investment needs in connection with the corresponding full-value index-related product. Therefore, by allowing the Exchange to be able to list a consistent number of expirations between options on the full-value and micro index, the proposed rule change will benefit investors by assisting them in more effectively using options that track the same index to meet their investment needs.

The Exchange notes that today, Cboe rules permit it to list up to 12 standard monthly expirations for Mini-Russell 2000 Index (''Mini-RUT'' or ''MRUT'') and Mini S&P 500 Index (''Mini-SPX'' or ''XSP'').[9]

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 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 intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act as all monthly expirations listed for XND options will be equally available, or continue to be equally available, to all market participants who trade such options. Also, the proposed number of expirations will apply, or continue to apply, in the same manner to all XND options. The proposed rule change makes it possible for the same expirations to be listed for options on the micro index (XND) that are currently available for XND [sic] options, which are options on the full-value index, Nasdaq-100 Index.

The Exchange does not believe that the proposed rule change regarding the number of standard monthly expirations permissible for XND options will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because XND is a proprietary Exchange product. To the extent that allowing up to 12 standard monthly expirations for XND options trading on the Exchange may make the Exchange a more attractive marketplace to market participants at other exchanges, such market participants are free to elect to become market participants on Phlx. As noted above, the Exchange believes that being able to list a consistent number of monthly expirations of options on both the full-value and micro index may permit investors to more effectively use options that track the same index to meet their investment needs.

This proposal enhances intermarket competition because it permits Phlx's proprietary product, XND, the same flexibility to trade, and hedge, with 12 standard monthly expirations as certain Cboe proprietary products.

[4] Options 4A, Section 12(a)(4) states, ''Expiration Months and Weeks. Index options contracts may expire at three (3)-month intervals or in consecutive weeks or months. The Exchange may list: (i) up to six (6) standard monthly expirations at any one time in a class, but will not list index options that expire more than twelve (12) months out; (ii) up to 12 standard monthly expirations at any one time for any class that the Exchange (as the Reporting Authority) uses to calculate a volatility index; and (iii) up to 12 standard (monthly) expirations in NDX options.''

[5] The Exchange notes that NDX options are both a.m.-settled and p.m.-settled while XND options are only p.m.-settled.

[6] *See* Cboe Rule 4.13(a)(2).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] *See* Cboe Rule 4.13(a)(2).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or 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 if consistent with the protection of investors and the public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act [10] and Rule 19b–4(f)(6) [11] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [12] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Exchange states that waiver of the operative delay will protect investors because it will allow the Exchange to be able to list expirations for XND options that are consistent with the expirations for related NDX options, and assist market participants in more effectively utilizing both the full-value index and reduced-value option as hedging vehicles to meet their investment needs in connection with the Nasdaq-100 Index product as soon as feasible. Further, the Exchange states that there is investor demand to be able to transact in the same number of expirations for XND options as the Exchange currently lists for NDX options (that is, 12 standard monthly expirations). For these reasons, and because the proposed rule change does not raise any novel regulatory issues, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[14]

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–Phlx–2022–42 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–Phlx–2022–42. 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 a.m. and 3 p.m. Copies of such 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–Phlx–2022–42 and should be submitted on or before November 28, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–24141 Filed 11–4–22; 8:45 am]

BILLING CODE 8011–01–P

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 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, along with a brief description and text of 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.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[15] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[License No. 02/02–0703]

RF Investment Partners SBIC II, L.P.; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that RF Investment Partners SBIC II, L.P. 501 Madison Avenue, 14th Floor, New York, NY 10022, a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection with the financing of a small concern, has sought an exemption under section 312 of the Act and 13 CFR 107.730, Financings which constitute conflicts of interest of the Small Business Administration (''SBA'') regulations. RF Investment Partners SBIC II, L.P., is seeking a written exemption from SBA for a proposed financing to SPATCO Energy Solutions, LLC, 8303 University Executive Park Dr. Suite 400, Charlotte, NC 28262.

The financing is brought within the purview of 13 CFR 107.730(a)(1) of the regulations because RF Investment Partners SBIC II, L.P. will provide financing to its Associate under Common Control in the company, SPATCO Energy Solutions, LLC therefore this transaction is considered *Provide financing to any of your Associates* requiring SBA's prior written exemption. RF Investment Partners SBIC II, L.P. has not made its investment in SPATCO Energy

Solutions, LLC, and is seeking pre-financing SBA approval.

Notice is hereby given that any interested person may submit written comments on this transaction within fifteen days of the date of this publication to the Associate Administrator, Office of Investment and Innovation, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416.

Bailey DeVries,

Associate Administrator, Office of Investment and Innovation, U.S. Small Business Administration.

[FR Doc. 2022–24154 Filed 11–4–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[License No. 04/04–0345]

Plexus Fund V–A, L.P.; Conflicts of Interest Exemption

Notice is hereby given that Plexus Fund V–A, L.P., 4242 Six Forks Road, Suite 950, Raleigh, NC 27609, a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection with the financing of a small business concern, has sought an exemption under section 312 of the Act and 13 CFR 107.730—*Financings which constitute conflicts of interest* of the Small Business Administration (''SBA'') regulations. Plexus Fund V–C, L.P. is seeking a written exemption from SBA for a proposed financing to Medicus IT Holdings, LLC, 100 North Point Center East, Suite 150, Alpharetta, GA 30022.

The financing is brought within the purview of 13 CFR 107.730(a) of the regulations because Medicus IT Holdings, LLC is an Associate of Plexus Fund V–A, L.P. because Associates Plexus Fund III, L.P., Plexus Fund QP III, L.P., Plexus Fund IV–A, L.P., Plexus Fund IV–B, L.P., and Plexus Fund IV–C, L.P. own a greater than ten percent interest in Medicus IT Holdings, LLC, therefore this transaction is considered *Financing which constitute conflicts of interest* requiring SBA's prior written exemption.

Notice is hereby given that any interested person may submit written comments on this transaction within fifteen days of the date of this publication to the Associate Administrator, Office of Investment and Innovation, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416.

Bailey DeVries,

Associate Administrator, Office of Investment and Innovation, United States Small Business Administration.

[FR Doc. 2022–24150 Filed 11–4–22; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

[License No. 04/04–0346]

Plexus Fund V–B, L.P.; Conflicts of Interest Exemption

Notice is hereby given that Plexus Fund V–B, L.P., 4242 Six Forks Road, Suite 950, Raleigh, NC 27609, a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection with the financing of a small business concern, has sought an exemption under Section 312 of the Act and 13 CFR 107.730—*Financings which constitute conflicts of interest* of the Small Business Administration (''SBA'') regulations. Plexus Fund V–C, L.P. is seeking a written exemption from SBA for a proposed financing to Medicus IT Holdings, LLC, 100 North Point Center East, Suite 150, Alpharetta, GA 30022.

The financing is brought within the purview of 13 CFR 107.730(a) of the regulations because Medicus IT Holdings, LLC is an Associate of Plexus Fund V–B, L.P. because Associates Plexus Fund III, L.P., Plexus Fund QP III, L.P., Plexus Fund IV–A, L.P., Plexus Fund IV–B, L.P., and Plexus Fund IV–C, L.P. own a greater than ten percent interest in Medicus IT Holdings, LLC, therefore this transaction is considered *Financing which constitute conflicts of interest* requiring SBA's prior written exemption.

Notice is hereby given that any interested person may submit written comments on this transaction within fifteen days of the date of this publication to the Associate Administrator, Office of Investment and Innovation, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416.

Bailey DeVries,

Associate Administrator, Office of Investment and Innovation, United States Small Business Administration.

[FR Doc. 2022–24158 Filed 11–4–22; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

[License No. 04/04–0347]

Plexus Fund V–C, L.P.; Conflicts of Interest Exemption

Notice is hereby given that Plexus Fund V–C, L.P., 4242 Six Forks Road, Suite 950, Raleigh, NC 27609, a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection with the financing of a small business concern, has sought an exemption under section 312 of the Act and 13 CFR 107.730—*Financings which constitute conflicts of interest* of the Small Business Administration (''SBA'') regulations. Plexus Fund V–C, L.P. is seeking a written exemption from SBA for a proposed financing to Medicus IT Holdings, LLC, 100 North Point Center East, Suite 150, Alpharetta, GA 30022.

The financing is brought within the purview of 13 CFR 107.730(a) of the regulations because Medicus IT Holdings, LLC is an Associate of Plexus Fund V–C, L.P. because Associates Plexus Fund III, L.P., Plexus Fund QP III, L.P., Plexus Fund IV–A, L.P., Plexus Fund IV–B, L.P., and Plexus Fund IV–C, L.P. own a greater than ten percent interest in Medicus IT Holdings, LLC, therefore this transaction is considered *Financing which constitute conflicts of interest* requiring SBA's prior written exemption.

Notice is hereby given that any interested person may submit written comments on this transaction within fifteen days of the date of this publication to the Associate Administrator, Office of Investment and Innovation, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416.

Bailey DeVries,

Associate Administrator, Office of Investment and Innovation, United States Small Business Administration.

[FR Doc. 2022–24149 Filed 11–4–22; 8:45 am]

BILLING CODE P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2022–0031]

Privacy Act of 1974; System of Records

AGENCY: Social Security Administration (SSA).

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, we are issuing public notice of our intent to modify an

existing system of records entitled, Visitor Intake Process—Customer Service Record System (60–0350), last published on December 17, 2007. This notice publishes details of the modified system as set forth below under the caption, **SUPPLEMENTARY INFORMATION**.

DATES: The system of records notice (SORN) is applicable upon its publication in today's **Federal Register**, with the exception of the new routine uses, which are effective December 7, 2022. We invite public comment on the routine uses or other aspects of this SORN. In accordance with the Privacy Act of 1974, we are providing the public a 30-day period in which to submit comments. Therefore, please submit any comments by December 7, 2022.

ADDRESSES: The public, Office of Management and Budget (OMB), and Congress may comment on this publication by writing to the Executive Director, Office of Privacy and Disclosure, Office of the General Counsel, SSA, Room G–401 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, or through the Federal e-Rulemaking Portal at *http://www.regulations.gov.* Please reference docket number SSA–2022–0031. All comments we receive will be available for public inspection at the above address and we will post them to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Tristin Dorsey, Government Information Specialist, Privacy Implementation Division, Office of Privacy and Disclosure, Office of the General Counsel, SSA, Room G–401 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, telephone: (410) 966–5855, email: *tristin.dorsey@ssa.gov* and Elisa Vasta, Government Information Specialist, Privacy Implementation Division, Office of Privacy and Disclosure, Office of the General Counsel, SSA, Room G–401 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, telephone: (410) 966–5855, email: *elisa.vasta@ssa.gov.*

SUPPLEMENTARY INFORMATION: We are modifying the system of records name from ''Visitor Intake Process—Customer Service Record System'' to ''Appointments, Visitor Information, and Customer Service Record System'' to accurately reflect the system. We are clarifying the system location to recognize that we may also maintain records in a cloud-based environment. We are also modifying the authority for maintenance of the system to include section 205(a) of the Social Security Act. We are expanding the purposes for which SSA may use the information in the system to include establishing, rescheduling, and cancelling appointments and tracking opt-in and opt-out of electronic messaging selections.

In addition, we are clarifying the categories of individuals covered by the system and the categories of records maintained in the system for easier reading. We are expanding the record source categories to include individuals who schedule, reschedule, or cancel appointments and additional existing SSA systems of records. We are revising routine uses No. 3 and 8 to incorporate gender-inclusive language, in support of E.O. 13988, Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation. We are also adding three new routine uses to permit disclosures to appropriate agencies, entities, and persons to assist us in addressing a suspected or confirmed breach; to third parties when an individual involved with a request needs assistance to communicate because of a hearing impairment or a language barrier (*e.g.,* to interpreters, telecommunications relay system operators); and to contractors, cooperative agreement awardees, Federal and State agencies, and Federal congressional support agencies for research and statistical activities. In the past, we disclosed information from this system of records to the entities listed above under our efficient administration routine use. We are establishing this new routine use to distinguish disclosures that we make specifically for research purposes.

Lastly, we are clarifying in the policies and practices for the storage of records that SSA will maintain records in electronic form only. We are modifying the policies and practices for the retrieval of records to clarify that we will also retrieve records by date of birth and internal agency processing reference numbers. We are modifying record access procedures to remove references to telephone, for consistency with agency access regulations. We are also modifying the notice throughout to correct miscellaneous stylistic formatting and typographical errors of the previously published notice, and to ensure the language reads consistently across multiple systems. We are republishing the entire notice for ease of reference.

In accordance with 5 U.S.C. 552a(r), we have provided a report to OMB and Congress on this modified system of records.

Matthew Ramsey,

Executive Director, Office of Privacy and Disclosure, Office of the General Counsel.

SYSTEM NAME AND NUMBER:

Appointments, Visitor Information, and Customer Service Record System, 60–0350

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Social Security Administration, Office of Systems, Robert M. Ball Building, 6401 Security Boulevard, Baltimore, MD 21235–6401.

Information is also located in additional locations in connection with cloud-based services and kept at an additional location as backup for business continuity purposes.

SYSTEM MANAGER(S):

Social Security Administration, Deputy Commissioner for Systems, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 966–5855.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sections 205(a), 222, 223, 225, 1611, 1615, 1631, and 1633 of the Social Security Act, as amended; and the Federal Records Act of 1950, as amended.

PURPOSE(S) OF THE SYSTEM:

We use the information in this system of records to:

- Provide management information on interviews;
- Provide a source for customer service record data collection for interviews and capture discrete data about the volume and nature of inquiries to support management decisions in the areas of process improvement and resource allocation;
- Assist with filing claims for benefits under titles II and/or XVI; transacting post-entitlement actions, if currently entitled to benefits under titles II and/or XVI; and transacting applications for a Social Security number (SSN) and other actions related to an SSN;
- Establish, reschedule, or cancel appointments; or other actions or queries that may require an interview at SSA;
- Track opt-in and opt-out of electronic messaging selections; and
- Provide a means of collecting information, and generating ''High Risk'' alerts, when applicable, concerning individuals we reasonably believe will attempt to contact one of our facilities and may pose a security risk, including

individuals who attempt, threaten, or commit an act of violence or a violent crime, or have an outstanding arrest warrant. We will use information collected from the ''High Risk'' alert to advise the intake employees at any SSA office that the potential security risk may require them to use extra caution when dealing with the individual who is before them and/or who has scheduled an appointment. This information allows us to create a standard approach to ensure the safety of SSA employees, visitors, security personnel, and facilities.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system maintains information about individuals who visit an SSA office, including those conducting business with SSA and individuals that may accompany such visitor; individuals who establish, reschedule, or cancel an appointment with SSA (*e.g.,* applicants, claimants, beneficiaries, recipients, third-party assistors, attorneys, non-attorney representatives, and representative payees); and individuals we reasonably believe will attempt to contact one of our facilities to conduct business and may pose a security risk, including those who attempt, threaten, or commit an act of violence or a violent crime or have an outstanding arrest warrant.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system maintains records on visitors including, but not limited to:

- Visitor information, such as SSN; name; date of birth; relationship to the applicant or beneficiary; mailing address; email address; telephone number; the time the visitor entered and left the office; an assigned group number; and the number of interviews and any remarks associated with the visit;
- Appointment information, such as date, time, type, and source of appointment; appointment unit number (unit establishing appointment); length of the appointment; internal agency processing reference numbers (*e.g.,* transaction number or unique identifier); opt-in and opt-out of electronic messaging selections; and name of office facilitating the appointment;
- Notice information, such as close-out notice type (*e.g.,* title II 6-month closeout letter, title XVI SSA–L991) and date/time sent;
- Confirmations of scheduled, rescheduled, and cancelled appointments;
- Interview information, such as each occurrence; subject of interview; waiting time; preferred language; type of translator; the number of the interviews pending in the queue; interview disposition (*e.g.,* completed, deleted, left without service); interview priority; start and end time; and name of interviewer;
- ''High Risk'' alert information about individuals we reasonably believe will attempt to contact one of our facilities and may pose a security risk, including individuals who attempt, threaten, or commit an act of violence or a violent crime or have an outstanding arrest warrant (*e.g.,* name, SSN, date of birth, specific nature of the threat or act of violence, and the date, time, and location of the threat or act of violence); and
- Source of the report from the Automated Incident Reporting System.

RECORD SOURCE CATEGORIES:

We obtain information in this system from individuals who schedule, reschedule, or cancel appointments, visit, or participate in interviews at SSA, which may include applicants, claimants, beneficiaries, appointed representatives, representative payees, and third parties; local, State, and Federal agencies; SSA-generated information, such as computer date/time stamps at various points in the interview process; and additional existing SSA systems of records such as the Master Files of SSN Holders and SSN Applications, 60–0058; Claims Folders System, 60–0089; Master Beneficiary Record, 60–0090; Supplemental Security Income Record and Special Veterans Benefits, 60–0103; Pay, Leave, and Attendance Records, 60–0238; Personnel Records in Operating Offices, 60–0239; Electronic Disability Claim File, 60–0320; Requests for Accommodations from Members of the Public (RAMP), 60–0378; and Social Security Administration Violence Evaluation and Reporting System, 60–0379.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

We will disclose records pursuant to the following routine uses; however, we will not disclose any information defined as ''return or return information'' under 26 U.S.C. 6103 of the Internal Revenue Code (IRC), unless authorized by a statute, the Internal Revenue Service (IRS), or IRS regulations.

1. To the Office of the President, in response to an inquiry from that office made on behalf of, and at the request of, the subject of the record or a third party acting on the subject's behalf.

2. To a congressional office in response to an inquiry from that office made on behalf of, and at the request of, the subject of the record or third party acting on the subject's behalf.

3. To the Department of Justice (DOJ), a court or other tribunal, or another party before such court or tribunal, when:

(a) SSA, or any component thereof; or

(b) any SSA employee in their official capacity; or:

(c) any SSA employee in their individual capacity where DOJ (or SSA, where it is authorized to do so) has agreed to represent the employee; or

(d) the United States or any agency thereof where we determine the litigation is likely to affect SSA or any of its components, SSA is a party to the litigation or has an interest in such litigation, and SSA determines that the use of such records by DOJ, a court or other tribunal, or another party before the tribunal is relevant and necessary to the litigation, provided, however, that in each case, we determine that such disclosure is compatible with the purpose for which the records were collected.

4. To contractors and other Federal agencies, as necessary, for assisting SSA in the efficient administration of its programs. We will disclose information under this routine use only in situations in which SSA may enter into a contractual or similar agreement with a third party to assist in accomplishing an agency function relating to this system of records.

5. To student volunteers, individuals working under a personal services contract, and other workers who technically do not have the status of Federal employees, when they are performing work for us, as authorized by law, and they need access to personally identifiable information (PII) in our records in order to perform their assigned agency functions.

6. To the National Archives and Records Administration (NARA) under 44 U.S.C. 2904 and 2906.

7. To Federal, State, and local law enforcement agencies and private security contractors, as appropriate, information necessary:

(a) to enable them to ensure the safety of our employees and customers, the security of our workplace, and the operation of our facilities; or

(b) to assist investigations or prosecutions with respect to activities that affect such safety and security or activities that disrupt the operation of our facilities.

8. To the appropriate law enforcement official, SSA may disclose information regarding a Social Security beneficiary,

claimant, attorney, non-attorney representative, or representative payee who is the subject of an outstanding arrest warrant for having committed, or having attempted to commit, a violent crime for the purposes of determining whether SSA should include an individual's information in this system or remove an individual's information from the system because they no longer meet the criteria (*e.g.,* the individual is in custody of law enforcement, is no longer a suspect, has been exonerated, or is deceased).

9. To another Federal agency or Federal entity, when we determine that information from this system of records is reasonably necessary to assist the recipient agency or entity in:

(a) responding to a suspected or confirmed breach; or

(b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

10. To appropriate agencies, entities, and persons when:

(a) SSA suspects or has confirmed that there has been a breach of the system of records;

(b) SSA has determined that, as a result of the suspected or confirmed breach, there is a risk of harm to individuals, SSA (including its information systems, programs, and operations), the Federal Government, or national security; and

(c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with SSA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

11. To third parties when an individual involved with a request needs assistance to communicate because of a hearing impairment or a language barrier (*e.g.,* to interpreters, telecommunications relay system operators).

12. To contractors, cooperative agreement awardees, State agencies, Federal agencies, and Federal congressional support agencies for research and statistical activities that are designed to increase knowledge about present or alternative Social Security programs; are of importance to the Social Security program or beneficiaries; or are for an epidemiological project that relates to the Social Security program or beneficiaries. We will disclose information under this routine use pursuant only to a written agreement between the organization or agency and SSA.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

We maintain records in this system in electronic form.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

We will retrieve records by SSN, name, date of birth, and internal agency processing reference numbers.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

In accordance with NARA rules codified at 36 CFR 1225.16, we maintain records in accordance with approved NARA General Records Schedule (GRS) 3.1, item 011 and GRS 6.5, item 010.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

We retain electronic files containing personal identifiers in secure storage areas accessible only by our authorized employees and contractors who have a need for the information when performing their official duties. Security measures include, but are not limited to, the use of codes and profiles, personal identification numbers and passwords, and personal identification verification cards. We restrict access to specific correspondence within the system based on assigned roles and authorized users. We use audit mechanisms to record sensitive transactions as an additional measure to protect information from unauthorized disclosure or modification.

We annually provide our employees and contractors with appropriate security awareness training that includes reminders about the need to protect PII and the criminal penalties that apply to unauthorized access to, or disclosure of, PII (5 U.S.C. 552a(i)(1)). Furthermore, employees and contractors with access to databases maintaining PII must annually sign a sanctions document that acknowledges their accountability for inappropriately accessing or disclosing such information.

RECORD ACCESS PROCEDURES:

Individuals may submit requests for information about whether this system contains a record about them by submitting a written request to the system manager at the above address, which includes their name, SSN, or other information that may be in this system of records that will identify them. Individuals requesting notification of, or access to, a record by mail must include: (1) a notarized statement to us to verify their identity; or (2) must certify in the request that they are the individual they claim to be and that they understand that the knowing and willful request for, or acquisition of, a record pertaining to another individual under false pretenses is a criminal offense.

Individuals requesting notification of, or access to, records in person must provide their name, SSN, or other information that may be in this system of records that will identify them, as well as provide an identity document, preferably with a photograph, such as a driver's license. Individuals lacking identification documents sufficient to establish their identity must certify in writing that they are the individual they claim to be and that they understand that the knowing and willful request for, or acquisition of, a record pertaining to another individual under false pretenses is a criminal offense.

These procedures are in accordance with our regulations at 20 CFR 401.40 and 401.45.

CONTESTING RECORD PROCEDURES:

Same as record access procedures. Individuals should also reasonably identify the record, specify the information they are contesting, and state the corrective action sought and the reasons for the correction with supporting justification showing how the record is incomplete, untimely, inaccurate, or irrelevant. These procedures are in accordance with our regulations at 20 CFR 401.65(a).

NOTIFICATION PROCEDURES:

Same as records access procedures. These procedures are in accordance with our regulations at 20 CFR 401.40 and 401.45.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

72 FR 71470, Visitor Intake Process—Customer Service Record System.

83 FR 54969, Visitor Intake Process—Customer Service Record System.

[FR Doc. 2022–24174 Filed 11–4–22; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice 11916]

60-Day Notice of Proposed Information Collection: Medical Clearance Update

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and

Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to *January 6, 2023.*

ADDRESSES: You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2022–0044'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: Yellandmj@state.gov.*
- *Regular Mail:* Send written comments to: Medical Director, Office of Medical Clearances, Bureau of Medical Services, 2401 E Street NW, SA–1, Room H–242, Washington, DC 20522–0101.
- *Fax:* 202–647–0292, *Attention:* Medical Clearance Director.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Medical Clearance Update.
- *OMB Control Number:* 1405–0131.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Bureau of Medical Services: MED/CP/CL.
- *Form Number:* DS–3057.
- *Respondents:* Contractors and eligible family members.
- *Estimated Number of Respondents:* 7,205.
- *Estimated Number of Responses:* 7,205.
- *Average Time Per Response:* 30 minutes.
- *Total Estimated Burden Time:* 3,603 hours.
- *Frequency:* As needed.
- *Obligation to Respond:* Mandatory.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

Form DS–3057 is designed to collect medical information to provide medical providers with current and adequate information to base decisions on whether contractors and eligible family members will have sufficient medical resources at a diplomatic mission abroad to maintain the health and fitness of the individual and family members.

Methodology

The respondent will obtain the DS–3057 form from their human resources representative or download the form from a department website. The respondent will complete and submit the form offline.

Michelle Yelland,

Director of Medical Clearances, Bureau of Medical Clearances, Department of State.

[FR Doc. 2022–24222 Filed 11–4–22; 8:45 am]

BILLING CODE 4710–36–P

DEPARTMENT OF STATE

[Public Notice: 11836]

30-Day Notice of Proposed Information Collection: Request for Department of State Personal Identification Card

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to December 7, 2022.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.
- *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument, and supporting documents, to John Ferguson, who may be reached on 202–647–0511 or at *fergusonjm3@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Request for Department of State Personal Identification Card.
- *OMB Control Number:* 1405–0232.
- *Type of Request:* Extension of a currently approved collection.
- *Originating Office:* Office of Domestic Facilities Protection (DS/DO/DFP).
- *Form Number:* DS–1838 and DS–7783.
- *Respondents:* Department employees and contractors.
- *Estimated Number of Respondents:* 30,000.
- *Estimated Number of Responses:* 30,000.
- *Average Time per Response:* 5 minutes.
- *Total Estimated Burden Time:* 2,500 hours per year.
- *Frequency:* On occasion (when new badge is required or badge expires).
- *Obligation to Respond:* Mandatory.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed

personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The collection of the information requested on the DS–1838 and DS–7783 is necessary to comply with:

• Homeland Security Presidential Directive 12 (HSPD–12) was issued August 27, 2004 to set policy for a common, reliable, and secure identification standard for federal employees and contractors for accessing federally-controlled facilities and federal information systems. In order to keep Federal and other facilities where there is potential for terrorist attacks secure, wide variations in the quality and security of forms of identification need to be eliminated.

• Federal Information Processing Standard Publication 201 (FIPS 201) is a United States Federal Government standard that specifies Personal Identity Verification (PIV) requirements for Federal employees and contractors. The NIST (National Institute of Standards and Technology) Computer Security Division initiated a new program for improving the identification and authentication of Federal employees and contractors for access to Federal facilities and information systems.

All Department employees and contractors are required to submit application for a Personal Identification Card (DS–1838 domestically or DS–7783 overseas) at the time of hire.

Methodology

Information is collected by use of the DS–1838 (available through the Automated Badge Request) or DS–7783. Neither form is publicly available but must be downloaded from within the Department.

K. Andrew Wroblewski,

Deputy Assistant Secretary, Assist. Director, Diplomatic Security Service, Bureau of Diplomatic Security, Department of State.

[FR Doc. 2022–24176 Filed 11–4–22; 8:45 am]

BILLING CODE 4710–43–P

DEPARTMENT OF STATE

[Public Notice 11913]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Chryssa & New York'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition ''Chryssa & New York'' at the Dia Center for the Arts at Dia Chelsea, New York, New York; the Menil Collection, Houston, Texas; Wrightwood 659, Chicago, Illinois, by Alphawood Foundation, through its subsidiary Alphawood Exhibitions LLC; and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Elliot Chiu, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Stacy E. White,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2022–24208 Filed 11–4–22; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 11915]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''A World Within Reach: Greek and Roman Art From the Loeb Collection'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to an agreement with their foreign owner or custodian for temporary display in the exhibition ''A World Within Reach: Greek and Roman Art from the Loeb Collection'' at the Harvard Art Museums, Cambridge, Massachusetts, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Elliot Chiu, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Stacy E. White,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2022–24209 Filed 11–4–22; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 11914]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Comparative Hell: Arts of Asian Underworlds'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition ''Comparative Hell: Arts of Asian Underworlds'' at the Asia Society Museum, New York, New York; the Asian Art Museum, San Francisco, California; and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Elliot Chiu, Attorney-Adviser, Office of

the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State L/PD, 2200 C Street, NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Stacy E. White,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2022–24207 Filed 11–4–22; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 11897]

60-Day Notice of Proposed Information Collection: JADE Act Questionnaire

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to January 6, 2023.

ADDRESSES: You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2022–0040'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: PRA_BurdenComments@state.gov.*

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Tonya Whigham who may be reached at *PRA_BurdenComments@state.gov* or at 202–485–7586.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* JADE Act Questionnaire.
- *OMB Control Number:* 1405–0236.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* CA/VO.
- *Form Number:* DS–5537.
- *Respondents:* Burmese Applicants for U.S. Visas.
- *Estimated Number of Respondents:* 20,500.
- *Estimated Number of Responses:* 20,500.
- *Average Time per Response:* 30 minutes.
- *Total Estimated Burden Time:* 10,250 hours.
- *Frequency:* Once per application.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The Tom Lantos Block Burmese Jade Junta's Anti-Democratic Efforts (JADE) Act of 2008, Public Law 110–286, renders certain individuals involved in specified Burmese organizations or activities ineligible for U.S. visas, including: leaders of the State Peace and Development Council (SPDC), the Burmese military, or the Union Solidarity Development Association (USDA); officials of the SPDC, the Burmese military, or the USDA involved in human rights violations and impeding democracy in Burma; and Burmese persons who provided substantial economic or political support to the SPDC, Burmese military, or USDA. Immediate family members of these individuals are also ineligible for United States visas. Department of State consular officers will use the information provided to evaluate and adjudicate the individual applicant's eligibility for a visa consistent with these requirements.

Methodology

Visa applicants from Burma will fill out and submit the supplemental form and provide it to consular officers. Consular officers will use the form to screen for potential visa ineligibility under the JADE Act.

Julie M. Stufft,

Deputy Assistant Secretary, Bureau of Consular Affairs, Department of State.

[FR Doc. 2022–24215 Filed 11–4–22; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Research, Engineering, and Development Advisory Committee (REDAC); Notice of Public Meeting

AGENCY: Federal Aviation Administration, Department of Transportation.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a meeting of the Research, Engineering, and Development Advisory Committee (REDAC).

DATES: The meeting will be held on November 18, 2022, from 10 a.m.–12 Noon, EST. The meeting will be open to the public, except from 10 a.m. to 11:15 a.m. when a partially closed session will occur in order to conduct a review and discussion of the technical content contained within the FAA's Unmanned Aircraft System-Advanced Air Mobility Integration Research Plan. Requests for accommodations to a disability must be received by November 10, 2022. Individuals requesting to speak during the meeting must submit a written copy of their remarks to DOT by November 10, 2022. Requests to submit written materials to be reviewed during the meeting must be received no later than November 10, 2022.

ADDRESSES: The meeting will be held in a virtual setting. Virtual attendance information will be provided upon registration. A detailed agenda will be

available on the REDAC internet website at *http://www.faa.gov/go/redac* at least one week before the meeting, along with copies of the meeting minutes after the meeting.

FOR FURTHER INFORMATION CONTACT: Chinita Roundtree-Coleman, REDAC PM/Lead, FAA/U.S. Department of Transportation, at *chinita.roundtree-coleman@faa.gov* or (609) 485–7149. Any committee-related request should be sent to the person listed in this section.

SUPPLEMENTARY INFORMATION:

I. Background

The Research, Engineering, and Development Advisory Committee was created under the Federal Advisory Committee Act (FACA), in accordance with Public Law 100–591 (1988) and Public Law 101–508 (1990) to provide advice and recommendations to the FAA Administrator in support of the Agency's Research and Development (R&D) portfolio.

II. Agenda

At the meeting, the agenda will cover the following topics:

- FAA's Unmanned Aircraft System-Advanced Air Mobility Integration Research Plan
- FAA Research and Development Strategies, Initiatives and Planning,
- Impacts of emerging technologies, new entrant vehicles, and dynamic operations within the National Airspace System.

III. Public Participation

The meeting will be open to the public, except from 10 a.m. to 11:15 a.m., when a partially closed session will occur in order to conduct a review and discussion of the technical content contained within the FAA's Unmanned Aircraft System-Advanced Air Mobility Integration Research Plan. The meeting will be partially closed to the public consistent with Exemption 4 of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(4), which allows FAA to close a meeting if an open meeting would disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential.

The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

There will be 45 minutes allotted for oral comments from members of the public joining the meeting. To accommodate as many speakers as possible, the time for each commenter may be limited. Individuals wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name, address, and organizational affiliation of the proposed speaker. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the FAA may conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks for inclusion in the meeting records and circulation to REDAC members before the deadline listed in the **DATES** section. All prepared remarks submitted on time will be accepted and considered as part of the meeting's record. Any member of the public may present a written statement to the committee at any time.

Issued in Washington, DC.

Chinita Roundtree-Coleman,

REDAC PM/Lead, Federal Aviation Administration.

[FR Doc. 2022–24156 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Transportation Project in Florida

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitation on claims for judicial review of actions by Florida Department of Transportation (FDOT) and other Federal agencies.

SUMMARY: The FHWA, on behalf of the FDOT, is issuing this notice to announce actions taken by FDOT and other Federal Agencies that are final agency actions. These actions relate to the proposed State Road (S.R.) 85 Project Development and Environment (PD&E) Study (Financial Management Number 220171–2–22–01). The proposed S.R. 85 project will add capacity to S.R. 85 from S.R. 123 (Roger J. Clary Highway) to Mirage Avenue, a distance of approximately 12.2 miles. Improvements consist of roadway widening from four to six lanes, bridge replacements, improvements at signalized intersections, reconstruction of the interchange at I–10 as a Diverging Diamond Interchange (DDI), and the construction of stormwater management facilities. These actions grant licenses, permits, or approvals for the project.

DATES: By this notice, the FHWA, on behalf of FDOT, is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal Agency actions on the listed highway project will be barred unless the claim is filed on or before April 6, 2023. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For FDOT: Jennifer Marshall, P.E., Director, Office of Environmental Management, FDOT, 605 Suwannee Street, MS 37, Tallahassee, Florida 32399; telephone (850) 414–4447; email: *Jennifer.Marshall@dot.state.fl.us.* The FDOT Office of Environmental Management's normal business hours are 8 a.m. to 5 p.m. (eastern standard time), Monday through Friday, except State holidays.

SUPPLEMENTARY INFORMATION: Effective May 26, 2022, the FHWA assigned, and the FDOT assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that FDOT and other Federal Agencies have taken final agency actions subject to 23 U.S.C. 139 (l)(1) by issuing licenses, permits, or approvals for the proposed improvement highway project. The actions by FDOT and other Federal Agencies on the project, and the laws under which such actions were taken are described in the Finding of No Significant Impacts issued on November 1, 2022 and in other project records for the listed project. The Finding of No Significant Impacts and other documents for the listed project are available by contacting FDOT at the address provided above. The Finding of No Significant Impacts and additional project documents can be viewed and downloaded from the project website at: *https://nwflroads.com/projects/220171-2.* The project subject to this notice is:

Project Location: Okaloosa County, Florida, S.R. 85 PD&E Study in the City of Crestview and unincorporated Okaloosa County within Eglin Air Force Base. The project adds capacity to S.R. 85 from S.R. 123 (Roger J. Clary Highway) to Mirage Avenue, a distance of approximately 12.2 miles.

Project Actions: This notice applies to the Finding of No Significant Impacts and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321 *et seq.*]; Federal–Aid Highway Act (FAHA)

[23 U.S.C. 109 and 23 U.S.C. 128]; 23 CFR part 771.

2. *Air:* Clean Air Act (CAA) [42 U.S.C. 7401–7671(q)], with the exception of project level conformity determinations [42 U.S.C. 7506].

3. *Noise:* Noise Control Act of 1972 [42 U.S.C. 4901–4918]; 23 CFR 772.

4. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [23 U.S.C. 138 and 49 U.S.C. 303]; 23 CFR part 774; Land and Water Conservation Fund (LWCF) [54 U.S.C. 200302–200310].

5. *Wildlife:* Endangered Species Act (ESA) [16 U.S.C. 1531–1544 and 1536]; Marine Mammal Protection Act [16 U.S.C. 1361–1423h], Anadromous Fish Conservation Act [16 U.S.C. 757(a)–757(f)]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Migratory Bird Treaty Act (MBTA) [16 U.S.C. 703–712]; Magnuson-Stevenson Fishery Conservation and Management Act of 1976, as amended [16 U.S.C. 1801–1891d], with Essential Fish Habitat requirements [16 U.S.C. 1855(b)(2)].

6. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 3006101 *et seq.*]; Archaeological Resources Protection Act of 1979 (ARPA) [16 U.S.C. 470(aa)–470(II)]; Preservation of Historical and Archaeological Data [54 U.S.C. 312501–312508]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013; 18 U.S.C. 1170].

7. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000 d–2000d–1]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

8. *Wetlands and Water Resources:* Clean Water Act (section 319, section 401, section 404) [33 U.S.C. 1251–1387]; Coastal Barriers Resources Act (CBRA) [16 U.S.C. 3501–3510]; Coastal Zone Management Act (CZMA) [16 U.S.C. 1451–1466]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300f–300j–26]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Emergency Wetlands Resources Act [16 U.S.C. 3921, 3931]; Wetlands Mitigation, [23 U.S.C. 119(g) and 133(b)(3)]; Flood Disaster Protection Act [42 U.S.C. 4001–4130].

9. *Hazardous Materials:* Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) [42 U.S.C. 9601–9675]; Superfund Amendments and Reauthorization Act of 1986 (SARA); Resource Conservation and Recovery Act (RCRA) [42 U.S.C. 6901–6992(k)].

10. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Issued on: November 1, 2022.

Karen M. Brunelle,

Director, Office of Project Development, Federal Highway Administration, Tallahassee, Florida.

[FR Doc. 2022–24168 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2010–0031]

Long Island Rail Road's Request To Amend Its Positive Train Control Safety Plan and 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 October 21, 2022, Long Island Rail Road (LIRR) submitted a request for amendment (RFA) to its FRA-approved Positive Train Control Safety Plan (PTCSP). As this RFA may involve a request for FRA's approval of proposed material modifications to an FRA-certified positive train control (PTC) system, FRA is publishing this notice and inviting public comment on the railroad's RFA to its PTCSP.

DATES: FRA will consider comments received by November 28, 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–2010–0031. 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: In general, title 49 United States Code (U.S.C.) section 20157(h) requires FRA to certify that a host railroad's PTC system complies with title 49 Code of Federal Regulations (CFR) part 236, subpart I, before the technology may be operated in revenue service. Before making certain changes to an FRA-certified PTC system or the associated FRA-approved PTCSP, a host railroad must submit, and obtain FRA's approval of, an RFA to its PTCSP under 49 CFR 236.1021.

Under 49 CFR 236.1021(e), FRA's regulations provide that FRA will publish a notice in the **Federal Register** and invite public comment in accordance with 49 CFR part 211, if an RFA includes a request for approval of a material modification of a signal and train control system. Accordingly, this notice informs the public that, on October 21, 2022, LIRR submitted an RFA to its PTCSP for its Advanced Civil Speed Enforcement System II (ACSES II), and that RFA is available in Docket No. FRA–2010–0031. LIRR's RFA describes LIRR's proposed Onboard PTC Software Version 7_02_0024, including its Tunnel Protection Package for its East Side Access passenger service.

Interested parties are invited to comment on LIRR's RFA to its PTCSP by submitting written comments or data. During FRA's review of this railroad's RFA, 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. *See* 49 CFR 236.1021; *see also* 49 CFR 236.1011(e). Under 49 CFR 236.1021, FRA maintains the authority to approve, approve with conditions, or deny a railroad's RFA to its PTCSP 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. 2022–24123 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2022–0225]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: ALYI'S BLUE DIAMOND (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 7, 2022.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2022–0225 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2022–0225 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2022–0225, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel ALYI'S BLUE DIAMOND is:

—*Intended Commercial Use of Vessel:* ''Pleasure cruising, diving excursions, sport fishing.''

—*Geographic Region Including Base of Operations:* ''Maine, Massachusetts, New Hampshire, Rhode Island, Connecticut, New York, New Jersey, Delaware, Virginia, North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, Texas.'' (Base of Operations: Miami, FL)

—*Vessel Length and Type:* 52′ Motor

The complete application is available for review identified in the DOT docket as MARAD 2022–0225 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2022–0225 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be

followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can 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.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2022–24196 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2022–0220]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: GIDDY-UP (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 7, 2022.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2022–0220 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2022–0220 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2022–0220, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel GIDDY-UP is:

—*Intended Commercial Use of Vessel:* ''Recreational and local charter services.''

—*Geographic Region Including Base of Operations:* ''Florida.'' (Base of Operations: Miami, FL)

—*Vessel Length and Type:* 28.9′ Motor

The complete application is available for review identified in the DOT docket as MARAD 2022–0220 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2022–0220 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can 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.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2022–24190 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2022–0218]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: FEISTY LADY (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 7, 2022.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2022–0218 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2022–0218 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2022–0218, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel FEISTY LADY is:

—*Intended Commercial Use of Vessel:* ''Occasional small group captained charter through local cruising grounds.''

—*Geographic Region Including Base of Operations:* ''Washington, Oregon, California.'' (Base of Operations: Bellingham, WA.)

—*Vessel Length and Type:* 49′ Motor.

The complete application is available for review identified in the DOT docket as MARAD 2022–0218 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2022–0218 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can 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.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.

Secretary, Maritime Administration.

[FR Doc. 2022–24188 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2022–0224]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: VENTAJERO 4 (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 7, 2022.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2022–0224 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2022–0224 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2022–0224, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel VENTAJERO 4 is:

—*Intended Commercial Use of Vessel:* ''Private charters for groups of up to six guests around the Puerto Rico coast line.''

—*Geographic Region Including Base of Operations:* ''Puerto Rico.'' (Base of Operations: Fajardo, PR)

—*Vessel Length and Type:* 51′ Sail

The complete application is available for review identified in the DOT docket as MARAD 2022–0224 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

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Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2022–0224 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.

Secretary, Maritime Administration.

[FR Doc. 2022–24192 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

Renewal of the Voluntary Tanker Agreement Program; Revised Form of the Voluntary Agreement

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice of publication of the voluntary tanker agreement.

SUMMARY: The Maritime Administration (MARAD) announces the renewal of the Voluntary Tanker Agreement Program and the publication of its revised Voluntary Tanker Agreement (VTA). The revised VTA replaces a prior version that was last published in Volume 73 of the **Federal Register** at page 51692 (September 4, 2008). After publishing the proposed text in the **Federal Register** in 2019 and hosting a public hearing in August 2020, MARAD has incorporated public input into the revised VTA.

FOR FURTHER INFORMATION CONTACT: David Hatcher, Director, Office of Sealift Support, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W25–310, Washington, DC 20590. Telephone (202) 366–0688; Fax (202) 366–5904, or *David.Hatcher1@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 708 of the Defense Production Act of 1950, as amended (50 U.S.C. 4558) (DPA section 708), entitled ''Voluntary agreements and plans of action for preparedness programs and expansion of production capacity and supply,'' authorizes the President, upon a finding that conditions exist which may pose a direct threat to the national defense or its preparedness programs, ''to consult with representatives of industry, business, financing, agriculture, labor and other interests'' in order to provide the making of such voluntary agreements. It further authorizes the President to delegate that authority to individuals who are appointed by and with the advice and consent of the Senate, upon the condition that such individuals obtain the prior approval of the Attorney General after the Attorney General's consultation with the Federal Trade Commission. Section 401 of Executive Order 13603 delegated this authority of the President to the Secretary of Transportation (Secretary), among others. By 49 CFR 1.93(l), the Secretary delegated to the Maritime Administrator the authority, in consultation and coordination with the Department of Transportation's Office of Intelligence, Security and Emergency Response, to develop and enter into maritime-related voluntary agreements such as the VTA.

Through its Tanker Security Fleet authority at 46 U.S.C. 53407, MARAD is authorized to establish emergency preparedness programs. Section 53407 provides that participants to a Tanker Security Fleet operating agreement must enter into an emergency preparedness agreement to make commercial transportation resources (including services) available, upon request by the Secretary of Defense during a time of war or national emergency, or whenever the Secretary of Defense determines that it is necessary for national security or contingency operation. Accordingly, MARAD is establishing the Voluntary Tanker Agreement Program (VTA Program) as an emergency preparedness program and the VTA as its corresponding emergency preparedness agreement.

Through advance arrangements in joint planning, including the development of VTAs, VTA Program participants will provide product tanker capacity to support a significant portion of surge and sustainment requirements in the deployment of U.S. military forces during armed conflicts or other national emergencies.

Regulations governing voluntary agreements appear at 44 CFR part 332. The revised form of agreement below will replace the VTA that was published in Volume 73 of the **Federal Register** at page 51692 (September 4, 2008). A draft revised agreement was published in Volume 84 of the **Federal Register** on pages 58824–29 (November 1, 2019). A public hearing on the proposed revised agreement was held on August 18, 2020, by teleconference (85 FR 45297 (July 27, 2020)). MARAD received comments proposing changes and clarifications (detailed below) to the draft revised agreement and made changes to the text reflecting the comments and harmonizing the text with the Voluntary Intermodal Sealift Agreement (VISA), an active emergency preparedness agreement for dry cargo contingency sealift capacity also created under 46 U.S.C. subtitle V authority and DPA Section 708 authorities and administered by MARAD.

The Department of Justice, in consultation with the Federal Trade Commission, has issued a finding that the revised VTA, as published below, satisfies the statutory criteria of the DPA section 708 required to implement the voluntary agreement (50 U.S.C. 4558(f)(1)(B)). In 2009, Congress amended the DPA to note that each voluntary agreement expires five years after the date it becomes effective. Accordingly, the terms of the VTA published herein will remain effective for a period of five years from the date of this publication.

Because the revised agreement below contains changes from the VTA published on September 4, 2008, both former and new participants must submit a new application. VTA Program applications are available from MARAD upon request.

Comments on the Proposed Voluntary Tanker Agreement

In response to the agency's **Federal Register** document published on November 1, 2019 (84 FR 58824) seeking public comment on the proposed VTA, MARAD received six separate comment submissions from, or on behalf of, the following individuals or entities: American Waterway Operators; Crowley Maritime Corporation; Jonathan Kaskin, Navy League of the United States; Maersk Line, Limited; Schuyler Line Navigation Company; and Timothy Boemecke, United States Transportation Command. MARAD responds below to all substantive comments.

Four commenters suggested that the VTA include incentives for program participants to carry Government cargoes in peacetime, as with the VISA and Civil Reserve Air Fleet (CRAF) programs, to ensure the viability of the VTA Program fleet. As with VISA and CRAF, a pledge of tanker capacity to the Government for national defense transportation demonstrates a commitment on the part of the U.S.-Flag carrier to the security and welfare of the Nation. Like the VISA and CRAF programs, and in accordance with Department of Defense Instruction 4500.57, secs. 6.3 and 6.4, VTA participants will receive contracting priorities for peacetime cargo.

One commenter suggested that one of the enumerated responsibilities of the Tanker Requirements Committee (TRC) in Sec. IV.A. should be to identify those National Defense Features that should be installed on VTA Program vessels, subject to the availability of funds, to meet the agency's statutory mission of supporting a United States merchant marine capable of serving as a naval and military auxiliary in time of war or national emergency (46 U.S.C. 50101(a)(2)). We agree and have reflected this in the updated VTA at Sec. IV.A.5.

One commenter suggested that the TRC include a designated representative from the United States Navy, in addition to other enumerated Department of

Defense (DoD) components, to represent the requirements of those naval vessels that would be supplied by tankers enrolled in the VTA Program. MARAD notes that the Military Sealift Command (MSC), the Department of the Navy's logistics command with responsibility for supplying fuel to naval vessels, is already a member of the TRC, and concludes that MSC would represent the above interests on the Committee. However, the TRC Co-Chairs may also, at their discretion under the TRC's rules at Sec. IV.C., designate other representatives from the Navy to sit on TRC to represent fleet fueling requirements.

One commenter suggested that the Preface be amended to state that program participants will be afforded the first opportunity to meet DoD peacetime and contingency tanker requirements, and that if they are unable to meet these requirements, the balance of DoD tanker requirements may be fulfilled by non-participant tankers. Such language, which is also found in VISA, offers additional incentive for tanker carriers to commit capacity under the VTA to receive the express contracting priority. This addition also reserves DoD's right to charter tankers, after exhausting the capacities committed under the agreement, to meet its needs in armed conflicts and emergencies. The Preface language has been amended to reflect the suggestion, together with the above comment on contracting incentives for program participants.

One commenter suggested that the VTA Program should be limited to product tankers operating exclusively in international commerce, rather than also including vessels operating in domestic or mixed domestic and international trades, to incentivize the expansion of an internationally-sailing U.S.-Flag tanker fleet and to ensure that DoD would have access to deep- sea tanker capacity with global operations. We disagree. First, the purpose of the VTA Program is to provide DoD with the greatest possible volume of U.S.-Flag product tanker tonnage for use by the armed forces in the event of an armed conflict or national emergency. Any limitation on enrolling qualified tonnage beyond a vessel's registry and technical characteristics would frustrate that purpose and fail to provide DoD with sufficient tanker capacity to meet its emergency requirements. As part of its statutory mission, MARAD supports and promotes the growth of the internationally-trading U.S.-Flag tanker fleet. The intent of the VTA Program, with the aforementioned peacetime contracting priority, and in conjunction with other agency programs, is to incentivize carriers to register more deep-sea tankers in the United States. Second, the VTA's terms and the responsibilities of the TRC in Sec. IV.A. will ensure that program participants would only enroll those vessels whose technical characteristics are best suited to satisfying DoD's tanker sealift needs, allowing the VTA Program to dynamically support evolving mission requirements.

One commenter suggested that the VTA Program should grant additional priority for the carriage of peacetime Government cargoes to coastwise-qualified U.S.-Flag tankers (those tankers holding coastwise endorsements under 46 U.S.C. 12112 and eligible to carry merchandise between points of the United States under 46 U.S.C. 55102) over those vessels only holding registry endorsements (as defined in 46 U.S.C. 12111), to strengthen the coastwise tanker fleet. MARAD disagrees. As stated above, the purpose of the VTA Program is to maximize U.S.-Flag worldwide tonnage availability, and the agency's mission is to support and maintain a United States-based merchant marine capable of supporting the Nation's domestic and international trade in peacetime and supplying the Nation's forces in armed conflicts, regardless of which endorsements the vessel holds. Further, MARAD does not typically contract for the transportation of cargoes by sea but is able to certify that a given vessel is enrolled under a VTA and thus can be granted general contracting priority. Other agencies of the Government contracting for ocean transportation of cargo may elect to grant additional priority on the basis of which endorsements a vessel holds at the time of contracting, but such decisions are beyond the scope of this effort to develop a voluntary agreement.

One commenter suggested that the determination of a prevailing market rate for an enrolled vessel's charter hire under Sec. V.B. of the VTA, if activated, should be determined by either MSC or MARAD, rather than only MSC. We believe such an arrangement would confuse the lines of authority under the agreement, which grants MARAD the responsibility of securing tonnage commitments from participating tanker carriers and United States Transportation Command (USTRANSCOM), the DoD joint command overseeing MSC, the power to charter participants' enrolled vessels if their VTA is activated. As USTRANSCOM holds the chartering authority under the VTA and would likely have access to the same market information as MARAD, the responsibility of determining a prevailing market rate on which to base charter hire rates belongs with USTRANSCOM. If implemented, the suggestion would likely lead to duplicative analyses between USTRANSCOM and MARAD. Should any participating tanker carrier have concerns about the methodology used by USTRANSCOM in any vessel market analysis, it may raise those concerns with USTRANSCOM directly or through the TRC.

One commenter inquired as to whether the agency would require a minimum number of tanker carriers to enroll vessels under their VTAs for the TRC to convene and carry out its defined responsibilities due to the inclusion of participating tanker carriers on the TRC in accordance with Sec. VI.C. of the agreement. The agency contemplates that the TRC will convene as soon as is practicable and will notify all VTA Program participants in advance of its convening.

The Voluntary Tanker Agreement Program

The Voluntary Tanker Agreement

Abbreviations

''CFR''—Code of Federal Regulations
''Commander''—Commander, United States Transportation Command
''CONOPS''—Concept of Operations
''DLA''—Defense Logistics Agency
''DoD''—United States Department of Defense
''DOJ''—United States Department of Justice
''DOT''—United States Department of Transportation
''DPA''—Defense Production Act of 1950, as amended (50 U.S.C. Chapter 55)
''FAR''—Federal Acquisition Regulations (as codified at Title 48, CFR)
''FTC''—Federal Trade Commission
''JCS''—Joint Chiefs of Staff
''MARAD''—Maritime Administration, DOT
''NCA''—National Command Authorities
''POL''—Petroleum, Oil, and Lubricants
''SecDef''—United States Secretary of Defense
''Secretary''—United States Secretary of Transportation
''TRC''—Tanker Requirements Committee
''TSP''—Tanker Security Program
''U.S.C.''—United States Code
''USTRANSCOM''—United States Transportation Command (including its component units Air Mobility Command, Military Sealift Command, Military Surface Deployment and Distribution Command, Joint Operational Support Airlift Center, and Joint Enabling Capabilities Command)
''VTA''—Voluntary Tanker Agreement

Definitions

For purposes of this agreement, the following definitions apply:

Administrator—Maritime Administrator.

Attorney General—Attorney General of the United States.

Broker—A person who arranges for transportation of cargo for a fee.

Chair–FTC—Chairperson of the Federal Trade Commission (FTC).

Charter—Any agreement or commitment by which the possession or services of a vessel are secured for a period of time, or for one or more voyages, whether or not a demise of the vessel.

Clean Tankers or Clean Tonnage—Product tankers that are inspected and approved by DLA Energy Quality Assurance Representatives (QAR), capable of meeting DoD quality standards, and able to carry refined petroleum products.

Commercial—Transportation service provided for profit by privately owned (not government owned) vessels to a private or government shipper. The type of service may be either common carrier or contract carriage.

Contingency—Includes, but is not limited to a ''contingency operation'' as defined at 10 U.S.C. section 101(a)(13), and a JCS-directed, NCA-approved action undertaken with military forces in response to: (i) natural disasters; (ii) terrorists or subversive activities; or (iii) required military operations, whether or not there is a declaration of war or national emergency.

Contingency contracts—DoD contracts in which Participants implement advance commitments of capacity and services to be provided in the event of a Contingency.

Controlling interest—More than a 50-percent interest by stock ownership.

Foreign-flag vessel—A vessel registered or documented under the law of a country other than the United States of America.

Non-participant—An operator, as defined under this section, that is not subject to a VTA.

Operator—A person that either owns and controls an eligible vessel or that charters and operates an eligible vessel through a demise charter that transfers virtually all the rights and obligations of the vessel owner to the demise charterer, such as that of crewing, supplying, maintaining, insuring, and navigating the vessel.

Program participant—An operator, as defined under this section, and signatory party to a current VTA or an operator that voluntarily remains subject to the terms of their expired VTA as provided for in 46 U.S.C. 53407(c), and otherwise as defined within Section VII of this document.

Person—Includes individuals and corporations, partnerships, and associations existing under or authorized by the laws of the United States or any state, territory, district, or possession thereof, or of a foreign country.

Product Tanker—A double-hulled self-propelled tank vessel, within the meaning of 46 U.S.C. sections 2101(32), (48), and (49), that is capable of simultaneously carrying two or more separated grades of refined petroleum products, including POL.

U.S.-Flag Vessel—A vessel registered or documented under the laws of the United States of America.

Voluntary Tanker Agreement (VTA)—The MARAD emergency preparedness agreement establishing the terms and conditions for VTA Program participants.

Volunteers—Any vessel owner/operator who is an ocean carrier and who offers to make capacity, resources, or systems available to support contingency requirements.

Preface

The Maritime Administrator (Administrator), through delegated authority at 49 CFR 1.93(a), has established the Voluntary Tanker Agreement Program as an emergency preparedness program pursuant to 46 U.S.C. 53407. In accordance with section 53407, MARAD is requiring all contractors for vessels covered by operating agreements to enter into emergency preparedness agreements to make commercial transportation resources (including services) available, upon request by the Secretary of Defense (SecDef) during a time of war or national emergency, or whenever the SecDef determines that it is necessary for national security or contingency operation.

Pursuant to the authority contained in Section 708 of the Defense Production Act of 1950, as amended (DPA) (50 U.S.C. 4558), the Maritime Administrator (Administrator), through delegated authority at 49 CFR 1.93(l) and after consultation and coordination with the Department of Transportation's Office of Intelligence, Security and Emergency Response, consultation with the Department of Defense (DoD) and representatives of the tanker industry, has developed this Voluntary Tanker Agreement (VTA) as the emergency preparedness agreement under the VTA Program to provide DoD with the commercial product tanker capacity necessary to meet national defense contingency requirements. USTRANSCOM procures commercial tanker capacity to meet requirements for DoD operations worldwide through arrangements with common carriers and by charter. DoD, (through USTRANSCOM), and DOT (through MARAD) maintains and operates a fleet of ships owned by, or under charter to, the Federal Government to meet the petroleum, oil, and lubricant (POL) needs of the military services which cannot be met by existing commercial services.

The VTA Program is designed to provide DoD a coordinated, seamless transition from peacetime to wartime for

the acquisition of commercial tanker capacity to augment DoD's organic tanker capacity. The VTA establishes the terms, conditions, and procedures under which persons or entities may become VTA Program participants and agree voluntarily to make tankers available to DoD. The emergency preparedness program is designed to create a close working relationship among MARAD, USTRANSCOM (the DoD-designated representative for purposes of the VTA), and the program participants through which DoD requirements and the needs of the civil economy can be met through cooperative action. The VTA affords program participants flexibility to respond to defense requirements and adjust their commercial operations to minimize disruption whenever possible. The VTA further affords program participants defenses to civil and criminal actions for violations of antitrust laws when carrying out their obligations under the agreement.

Program participants will be afforded the first opportunity to meet DoD peacetime and contingency sealift requirements within applicable law and regulations, to the extent that operational requirements are met. In the event program participants are unable to fully meet the contingency requirements, the shipping capacity made available under VTA may be supplemented by ships and capacity from charter tankers not subject to a VTA in accordance with applicable law and by ships requisitioned in accordance with the emergency vessel acquisition authority under 46 U.S.C. 56301.

The Administrator, by delegation from the Secretary of Transportation (Secretary), has established this emergency preparedness program pursuant to 46 U.S.C. 53407 with the approval of the Secretary of Defense (SecDef). The Administrator, in conjunction with the SecDef, must ensure that all contractors with operating agreements enter into a VTA as an emergency preparedness agreement.

The VTA below replaces the VTA that was published in Volume 73 of the **Federal Register** at page 51692 (Sept. 4, 2008) and expired in 2013 (the ''2008'' VTA''). Previous participants under the 2008 VTA who wish to participate in the VTA Program must submit new applications to participate in the VTA below, which contains different substantive provisions from the 2008 VTA.

The Voluntary Tanker Agreement

I. Purpose and Finding

The purpose of the VTA Program is to provide a responsive transition from peace to contingency operations through procedures agreed upon in advance to provide tanker capacity to support DoD contingency requirements. The VTA establishes terms for the commitment of tanker capacity to satisfy DoD contingency requirements. The VTA Program is intended to promote and facilitate DoD's use of existing commercial tanker resources in a manner which minimizes disruption to commercial operations whenever possible. The VTA will change from standby to active status upon activation by appropriate authority as described in Section VI.

The Administrator has determined, in consultation and coordination with the Department of Transportation's Office of Intelligence, Security and Emergency Response, and pursuant to 50 U.S.C. 4558(c)(1), that conditions exist which may pose a direct threat to the national defense of the United States or its preparedness programs and has certified to the Attorney General that a standby agreement for the utilization of tanker capacity is necessary for the national defense. The Attorney General, in consultation with the FTC Chair, by notice in the **Federal Register** on October 6, 2022 (87 FR 60706)issued its finding that tanker capacity to meet national defense requirements cannot be provided by the industry through a voluntary agreement having fewer anticompetitive effects or without a voluntary agreement.

II. Authorities

A. Maritime Administration

DPA Section 708 (50 U.S.C. 4558), 46 U.S.C. 53407, E.O. 13603, E.O. 12656, 49 CFR 1.93, 49 CFR 1.81(a)(10).

B. U.S. Transportation Command (USTRANSCOM)

1. 10 U.S.C. 113, 161–69.

2. DoD Directive 5158.4 designating Commander to provide air, land, and sea transportation for the DoD.

III. General

A. Scope, Activation, and Prioritization

1. The VTA Program provides for the time-phased availability of Program Participants' tanker capacities to meet NCA-directed DoD Contingency requirements in the most demanding defense-oriented armed conflicts and national emergencies, and for less demanding defense- oriented situations through pre-negotiated contingency contracts between the government and program participants utilizing an emergency planning agreement—the VTA. Such arrangements will be jointly planned with MARAD, USTRANSCOM, and program participants in peacetime to allow effective, and efficient and best valued use of commercial tanker capacity, provide DoD assured Contingency access, and minimize commercial disruption, whenever possible.

2. Activation of the VTA will occur in accordance with the terms in Section VI.

3. The following schedule establishes the prioritized order for utilization of commercial tanker capacity to meet DoD peacetime and contingency requirements:

a. U.S.-Flag vessel capacity operated by a program participant;

b. U.S.-Flag vessel capacity operated by a non-participant;

c. Combination U.S./foreign flag vessel capacity operated by a program participant;

d. Combination U.S./foreign flag vessel capacity operated by a non-participant;

e. U.S. owned or operated foreign flag vessel capacity of a non-participant; and

f. Foreign-owned or operated foreign flag vessel capacity of a non-participant.

B. Participation

1. Operators of tanker vessels greater than 20,000 deadweight tons (DWT) may become program participants by submitting an executed copy of the form specified in Section VII and subject to subsequent MARAD approval.

2. Operators of Integrated Tug-Barges (ITBs) and Articulated Tug-Barges (ATBs) greater than 20,000 DWT may become program participants by submitting an executed copy of the form specified in Section VII and subject to subsequent MARAD approval.

3. Operators of tankers or ITB and ATB vessels of less than 20,000 deadweight tons may also submit an application and become program participants if such vessels are deemed to meet U.S. national security requirements or the needs of MARAD and USTRANSCOM, and MARAD accepts the application.

4. For the purposes of the VTA, program participation includes the corporate entity entering this VTA and all United States subsidiaries and affiliates of that entity which own or operate ships in the course of their regular business and in which that entity has more than fifty percent control either by stock ownership or otherwise.

5. A list of program participants will be published annually in the **Federal Register**.

C. Effective Date and Duration of Participation

This VTA is effective upon execution of the application form in Section VII by the Participant and the Administrator or their authorized designees and will remain in effect until terminated in accordance with 44 CFR 332.4 and 50 U.S.C. 4558(h)(9) or expires in accordance with 50 U.S.C. 4558(f)(2).

D. Withdrawal From the Agreement

Program participants may withdraw from this VTA, subject to the fulfillment of obligations incurred under the agreement prior to the date such withdrawal becomes effective, by giving written notice to the Administrator. Withdrawal should be communicated in writing to the Administrator, including a specific date, after which the withdrawing participant must cease all activities under the VTA. Withdrawal from this VTA will not deprive a program participant of an antitrust defense otherwise available to it in accordance with DPA Section 708 for the fulfillment of obligations incurred prior to withdrawal.

E. Rules and Regulations

Program participants acknowledge and agree to abide by all provisions of DPA Section 708 and regulations related thereto which are promulgated by the Secretary, the Attorney General, the FTC, and the Federal Emergency Management Agency. Standards and procedures pertaining to voluntary agreements have been promulgated in 44 CFR part 332. The Administrator will inform program participants of new rules and regulations as they are issued.

F. Responsibilities and Roles

1. The SecDef, through USTRANSCOM, will:

a. Define requirements for contingency tanker capacity to augment DoD tanker capacities.

b. Keep MARAD and program participants apprised of contingency tanker capacity required and capacity committed by program participants.

c. Obtain contingency tanker capacity through the implementation of specific pre- negotiated DoD contingency contracts with program participants.

d. Notify the Administrator upon activation of the VTA.

e. Co-chair (with MARAD) the Tanker Requirements Committee (TRC).

f. Establish procedures, in accordance with applicable law and regulation, providing program participants with necessary determinations for use of foreign-flag vessels to replace an equivalent U.S.-Flag capacity to transport a participant's normal peacetime DoD cargo, when the participant's U.S.-Flag assets are removed from regular service to meet VTA Contingency requirements.

g. Provide a reasonable time to permit an orderly return of a program participant's vessel(s) to its regular schedule and termination of its foreign flag capacity arrangements as determined through coordination between DoD and the participants. Review and endorse the program participants' requests to MARAD for use of foreign-flag replacement capacity for non-DoD government cargo, when U.S.-Flag capacity is required to meet Contingency requirements.

2. The Secretary, through MARAD, will:

a. Review the volume of product tanker resources committed in DoD contracts and notify USTRANSCOM if the level of VTA commitment will have serious adverse impact on the commercial tanker industry's ability to provide essential services. MARAD's analysis will be based on the consideration that all VTA capacity committed will be activated. This notification will occur on an as required basis upon the Commander's acceptance of VTA commitments from the program participants. USTRANSCOM and MARAD will coordinate to ensure that the volume of product tanker assets committed under the VTA will not have an adverse, national economic impact.

b. Upon request by the Commander and approval by SecDef to activate this VTA, identify product tanker capacity to meet DoD Contingency requirements, in support of DoD priorities.

c. Establish procedures, pursuant to 46 U.S.C. 53407(f), for determinations regarding the equivalency and duration of the use of foreign-flag vessels to replace U.S.-Flag vessel capacity to transport the cargo of a program participant which has entered into an operating agreement under 46 U.S.C. 53403 whose U.S.-Flag vessel capacity has been removed from regular service to meet VTA contingency requirements. Such foreign flag vessels will be eligible to transport cargo that is subject to the Military Transportation Act of 1904 (10 U.S.C. 2631), government-financed exports under Public Resolution 17 (46 U.S.C. 55304), and the Cargo Preference Act of 1954 (46 U.S.C. 55305). However, the use of such foreign-flag vessels to transport cargo subject to 10 U.S.C. 2631 must have the concurrence of USTRANSCOM before it becomes effective.

d. Co-chair (with USTRANSCOM) the Tanker Requirements Committee (TRC).

e. Ensure that all requirements of 44 CFR 332.3 are met, including that the Attorney General, or suitable delegate(s) from DOJ, and the FTC Chair, or suitable delegate(s) from the FTC, have awareness of activities under the VTA, including activation, deactivations, and scheduling of meetings of the TRC or any subcommittee established under this Agreement.

f. Seek necessary waivers of the coastwise trading statutes as required, in accordance with 46 U.S.C. 501. To the extent feasible, program participants with coastwise-qualified vessels or vessel capacity (as defined in 46 U.S.C. 12112) will secure arrangements to protect their ability to maintain services for their domestic commercial customers and to fulfill their commercial peacetime commitments with coastwise-qualified U.S.-Flag vessels. In situations where the activation of this VTA deprives a program participant of all or a portion of its coastwise-qualified vessels or vessel capacity and, at the same time, creates a general shortage of coastwise-qualified vessel(s) or vessel capacity on the market, the Administrator may request that the Secretary of Homeland Security grant a temporary waiver of the coastwise trading statutes, in accordance with 46 U.S.C. 501, to permit a participant to charter or otherwise utilize non-coastwise-qualified vessel(s) or vessel capacity, with priority consideration recommended for U.S.-crewed vessel(s) or vessel capacity. The vessel(s) or vessel capacity for which such waivers are requested will be approximately equal to the coastwise-qualified vessel(s) or vessel capacity chartered or under contract to DoD.

3. The Attorney General and the FTC Chair, or suitable delegate(s) thereof:

a. Will fulfill all roles assigned to them under Section 708 of the DPA, 50 U.S.C. 4558.

b. May attend TRC meetings and request to be apprised on any activities taken in accordance with activities under this Agreement.

c. May request and review any proposed action undertaken pursuant to this Agreement.

d. If any DOJ or FTC Representative believes any actions proposed or taken are not consistent with relevant antitrust protections provided by the DPA, he or she will provide warning and guidance to the Committee as soon as the potential issue is identified.

e. If questions arise about the antitrust protections applicable to any particular action, the TRC Co-Chairs may request

the Attorney General or the Attorney General's designee, in consultation with the FTC, to provide an opinion on the legality of the action under relevant DPA antitrust protections.

G. Amendment of the Agreement

1. The Attorney General may modify this VTA, in writing, after consultation with the FTC Chair, Secretary, through his or her representative MARAD, and SecDef, through his or her representative, Commander. The Administrator, Commander, and program participants may modify this VTA at any time by mutual agreement, but only in writing with the approval of the Attorney General and the FTC Chair.

2. A program participant may propose amendments to the VTA at any time.

H. Administrative Expenses

Administrative and out-of-pocket expenses incurred by a program participant will be borne solely by the program participant.

I. Record Keeping

1. MARAD and the DoD have primary responsibility for maintaining records in accordance with 44 CFR part 332.

2. The Director, Office of Sealift Support, MARAD, will be the official custodian of records related to the carrying out of this VTA, except records of direct dealings between the DoD and program participants.

3. For direct dealings between the DoD and program participants, the designee of the SecDef will be the official custodian of records, but the Director, Office of Sealift Support, MARAD will have complete access thereto.

4. In accordance with 44 CFR 332.3(d), each program participant must maintain for five years all minutes of meetings, transcripts, records, documents, and other data, including any communications with other program participants or with any other member of the industry, related to the carrying out of this VTA. Each program participant agrees to make available to the Administrator, the Commander, the Attorney General, and the FTC Chair for inspection and copying at reasonable times and upon reasonable notice any item that this section requires the program participant to maintain. Any record maintained under this section must be available for public inspection and copying, unless exempted on the grounds specified in 5 U.S.C. 552(b)(1), (3) or (4) or identified as privileged and confidential information in accordance with 50 U.S.C. 4555(d), and 44 CFR 332.5.

J. Requisition of Ships of Non-Participants

The Administrator, upon Presidential authorization, may requisition ships of non-participants to supplement capacity made available for defense operations under this VTA and to balance the economic burden of defense support among companies operating in U.S. trade. Non- participant owners of requisitioned tankers may not participate in the TRC and will not enjoy the immunities provided by this VTA.

K. Temporary Replacement Vessel

Notwithstanding 10 U.S.C. 2631, 46 U.S.C. 55304, 55305, 55312, or any other statute governing the oceanic shipments of cargo and supplies procured for or financed by the United States Government—

1. A program participant that is also a contractor under the Tanker Security Program (TSP) (46 U.S.C. 53401–11) may operate or employ in foreign commerce a foreign-flag vessel or foreign-flag vessel capacity as a temporary replacement for a United States-documented vessel or United States-documented vessel capacity that is activated by the SecDef under this VTA.

2. Such replacement vessel or vessel capacity will be eligible during the replacement period to transport preference cargoes subject to 10 U.S.C. 2631, and 46 U.S.C. 55304, 55305, or 55312, to the same extent as the eligibility of the vessel or vessel capacity replaced.

IV. Tanker Requirements Committee

A. Establishment and Scope of Authority

There is established a Tanker Requirements Committee (TRC) to provide USTRANSCOM, MARAD, and program participants a forum to:

1. Analyze DoD contingency tanker requirements;

2. Identify commercial tanker capacity that may be used to meet DoD requirements related to contingencies and, as requested by USTRANSCOM, exercises and special movements;

3. Develop and recommend Concepts of Operations (CONOPS) to meet DoD-approved contingency requirements and, as requested by USTRANSCOM, exercises and special movements;

4. Advise the Administrator on the tanker capacity that each program participant controls which is capable of meeting contingency requirements; and

5. Identify National Defense Features appropriate for installation on commercial tankers to enhance their service capabilities for operation upon activation under this Agreement.

B. TRC Leadership

The TRC will be co-chaired by MARAD and USTRANSCOM and will convene as jointly determined by the co-chairs.

C. TRC Membership and Meetings

1. TRC regular membership will consist of designated representatives from MARAD, USTRANSCOM, Military Sealift Command, Defense Logistics Agency-Energy, each program participant, and maritime labor. Other attendees may be invited at the discretion of the co-chairs. Representatives will provide technical advice and support to ensure maximum coordination, efficiency, and effectiveness in the use of program participants' resources.

2. All program participants will be invited to open committee meetings. For selected committee meetings, attendance may be limited to designated program participants to meet specific operational requirements.

3. The co-chairs may establish working groups within TRC. Program participants may be assigned to working groups as necessary to develop specific CONOPS. Each working group will be co-chaired by representatives designated by MARAD and USTRANSCOM.

4. In general, program participants will not be asked to share competitively sensitive information directly with other program participants. Direct sharing of information among program participants will be requested only when necessary and will be closely supervised by the TRC Co-Chairs, including requiring appropriate safeguards regarding program participant use and dissemination of other program participants' data.

D. Prohibition on Contract Negotiations

TRC participation will not be used for contract negotiations and/or contract discussions between carriers and DoD; such negotiations and/or discussions will be in accordance with applicable DoD contracting policies and procedures.

E. TRC Co-Chairs' Responsibilities

TRC co-chairs will:

1. Notify the Attorney General, the FTC Chair, and the program participants of the time, place, and nature of each meeting and of the proposed agenda of each meeting to be held to carry out this VTA;

2. Provide for publication in the **Federal Register** of a notice of the time, place, and nature of each meeting. If a

meeting is open, a **Federal Register** notice will be published reasonably in advance of the meeting. If a meeting is closed, a **Federal Register** notice will be published within ten days of the meeting and will include the reasons why the meeting is closed;

3. Establish the agenda for each meeting and be responsible for adherence to the agenda;

4. Provide for a written summary or other record of each meeting and provide copies of transcripts or other records to the Attorney General, the FTC Chair, and all program participants; and

5. Take necessary actions to protect from public disclosure any data discussed with or obtained from program participants which a participant has identified as privileged and confidential in accordance with DPA Sections 708(h)(3) and 705(e) (50 U.S.C. 4558(h)(3) and 4555(d)), or which qualifies for withholding under 44 CFR 332.5.

V. Activation of the VTA

A. Determination of Necessity

This VTA may be activated in whole or in part at the request of the Commander, with the approval of SecDef, to support contingency operations when there is a tanker capacity emergency. A tanker capacity emergency will be deemed to exist when the Commander finds that tanker capacity required to support operations of U.S. forces outside the continental United States cannot be supplied through the commercial tanker charter market in accordance with applicable laws and regulations or other voluntary arrangements. The Commander will immediately notify the Administrator when such a finding has been made and upon activation of this VTA. The Administrator will then notify the Attorney General and the FTC Chair when such a finding is made.

B. Tanker Charters

USTRANSCOM will work directly with tanker operators in the making of charter parties and other arrangements to meet the defense requirement, keeping the Administrator informed. To reduce risk to owners and to control cost to the government, all government charters will be time charters, unless specifically designated as voyage charters by the contracting officer. If vessels are chartered between program participants, participants will keep the Administrator informed.

The Administrator will keep the Attorney General and the FTC Chair informed of the actions taken under this VTA.

C. Termination of Charters

USTRANSCOM, as the contracting officer, will notify the Administrator as far as possible in advance of the prospective termination of the need for tanker capacity under this VTA.

D. Determination of Tanker Capacity Need

Upon activation of this VTA, USTRANSCOM will consult with the TRC to determine which enrolled tankers best meet the requirements of the declared tanker capacity emergency, based on the tankers' characteristics. This may result in activation of only a portion of the committed tanker fleet.

VI. Terms and Conditions

A. Program Participants

1. Each program participant agrees to contribute tanker capacity as requested by the Administrator in accordance with Section VI. B. below at such times and in such amounts as the Administrator, as requested by DoD, will determine to be necessary to meet the essential needs of the DoD for the transportation of DoD petroleum and petroleum products in bulk by sea.

2. Each program participant further agrees to make tankers and tanker capacity available to other program participants when requested by the Administrator, on the advice of TRC, in order to ensure that contributions to meet DoD requirements are made on a proportionate basis whenever possible or to ensure that no participating tanker operator is disproportionately hampered in meeting the needs of the civil economy.

B. Proportionate Contribution of Capacity

1. Any entity receiving payments under TSP must become a program participant with respect to all tankers enrolled in TSP at all times until the date the TSP operating agreement would have terminated according to 46 U.S.C. 53404(a). Such participation will satisfy the requirement for a TSP participant to be enrolled in an emergency preparedness program approved by SecDef as provided in 46 U.S.C. 53407.

2. Program participants hereto not receiving TSP payments under TSP, agree to contribute tanker capacity under this VTA in the proportion that its controlled tonnage bears to the total controlled tonnage of all program participants. Because exact proportions may not be feasible, each program participant agrees that variances are permissible at the discretion of the Administrator.

3. Controlled tonnage will include tankers, ITBs, and ATBs of over 20,000 DWT capacity, which are:

a. Militarily useful in the transportation of refined DoD cargoes pursuant to the requirements of associated war plans;

b. Vessels in which, as of the effective date of the activation of this VTA, the program participant or any of its U.S. subsidiaries or affiliates has a controlling interest and which are registered in the United States or any non-U.S. registry approved by TRC, and will include:

i. Vessels on charter or under contract to such program participant for a period of six months or more from the effective date of activation of this VTA, regardless of flag of registry, exclusive of tonnage available to the program participant under contracts of affreightment and consecutive voyage charter; provided that, in the event an owner of a vessel terminates a time charter in accordance with a war clause, the affected tonnage will be excluded from the chartering participant's controlled tonnage; and

ii. Any other non-U.S.-Flag tonnage which a program participant may offer to designate as controlled tonnage and which TRC accepts;

c. And may not include:

i. Tankers described in subparagraph b. which are chartered out or under contract to others for a remaining period of six months or more from the effective date of activation of this VTA; or

ii. Certain vessels which are fitted with special gear and are on permanent station for the storage of crude oil from a production platform and vessels which may have a dual role of production storage and transportation use to a limited location.

4. Chemical tankers and tankers in dirty trade may contribute Clean Tanker capacity only after being certified as being able to meet DoD quality standards to carry refined petroleum products to meet DoD requirements.

5. This VTA will not be deemed to commit any vessel with respect to which the law of the country of registration requires the approval of the government before entering into this VTA or furnishing such vessel under the terms of this VTA until such time as the required approval has been obtained.

6. The obligations of program participants to contribute clean tanker capacity under this VTA will be calculated on a proportionate basis wherever possible among the program participants by TRC.

7. A vessel on charter to a program participant will not be subject to a relet to the DoD in the case where the period

of the relet would be longer than the term of the program participant's charter or in the case where the relet would otherwise breach the terms of the charter, but such tonnage will be included in the calculation of the program participant's controlled tonnage.

8. The Administrator retains the right under law to requisition ships of program participants. A program participant's ships which are directly requisitioned by the U.S. Government or which are called up pursuant to other U.S. Government voluntary arrangements will be credited against the participant's proportionate contribution under this VTA. Ships on charter to the DoD when this VTA is activated will not be so credited.

C. Reports of Controlled Tonnage

Twice annually, or upon request of the Administrator and in such form as may be requested, each program participant must submit information as to controlled tonnage necessary for the carrying out of this VTA. Information which a program participant identifies as privileged and confidential will be withheld from public disclosure in accordance with DPA Sections 708(h)(3) and 705(e) (50 U.S.C. 4558(h)(3) and 4555(d)), and 44 CFR 332.5.

D. Freight Rates Under the VTA

1. The rate of charter hire applicable to each charter under this VTA will be the prevailing market rate effective at the time of the proposed loading of the vessel. The USTRANSCOM Contracting Officer will determine the prevailing market rate utilizing the price analysis techniques set forth in FAR Subpart 15.4 to determine that the negotiated rates are fair and reasonable, utilizing market or previous contract prices. Time charter hire rates, for either U.S. or foreign-flag tankers, will be expressed in terms of a per diem rate(s).

2. The rate of charter hire fixed with respect to each charter will apply for the entire period of the charter, except that:

a. For a consecutive voyage charter, the rate of charter will be increased or decreased to reflect increases or decreases in the price of bunker fuel applicable in the area of the vessel's trade; and

b. Reimbursement for increased war risk insurance premiums will be made in accordance with Section VI.E.

E. War Risk Insurance

1. Increased war risk insurance premiums for time-chartered vessels will be paid by DoD, or MARAD war risk insurance policies will be implemented.

2. For voyage and consecutive voyage charters, the program participant will be reimbursed for increases in war risk insurance premiums that are applicable to the actual voyage but are announced after the charter rate is established by the broker panel.

3. For any ship chartered under this VTA, the SecDef may procure from the Secretary war risk insurance on hull and machinery, war risk protection and indemnity insurance, and Second Seaman's War Risk Insurance, subject to 46 U.S.C. 53905.

F. Antitrust Defense

Under the provisions of DPA Subsection 708(j) (50 U.S.C. 4558(j)), each program participant in the VTA will have available as a defense to any civil or criminal action brought for violation of the antitrust laws with respect to any act or omission to act to develop or carry out the VTA, that such act or omission to act was taken by the program participant in the course of developing or carrying out this VTA, that the program participant fully complied with the provisions of the DPA and the rules promulgated thereunder, and that the program participant acted in accordance with the terms of this VTA. This defense will not be available to the program participant for any act or omission occurring after the termination of the VTA, nor will it be available, upon the modification of the VTA, with respect to any subsequent act or omission that is beyond the scope of the modified VTA, except that no such termination or modification will be accomplished in a way that will deprive program participants of this antitrust defense for the fulfillment of obligations incurred. This defense will be available only if and to the extent that the program participants asserting it demonstrate that the action, which includes a discussion or agreement, was within the scope of this VTA, and taken at the direction of the USTRANSCOM and/or MARAD, and with appropriate oversight and approval of USTRANSCOM and/or MARAD. The person asserting the defense bears the burden of proof. The defense will not be available if the person against whom it is asserted shows that the action was taken for the purpose of violating the antitrust laws of the United States.

VII. Application and Agreement

The Administrator has adopted and makes available a form on which tanker operators may apply for and become program participants in this VTA (''Application and Agreement to Participate in the Voluntary Tanker Agreement''). The form will incorporate by reference the terms of this VTA.

Application and Agreement To Participate in the Voluntary Tanker Agreement

The applicant identified below hereby applies to participate in the Maritime Administration's agreement entitled ''Voluntary Tanker Agreement'' (VTA). The text of this VTA was published in__**Federal Register**__,__, 2022 (*citation placeholder*).

This VTA is authorized pursuant to 46 U.S.C. 53407 and under Section 708 of the Defense Production Act of 1950, as amended (50 U.S.C. 4558). Regulations governing this VTA appear at 44 CFR part 332.

The applicant, if approved, hereby acknowledges and agrees to the incorporation by reference into this application and agreement of the entire text of the Voluntary Tanker Agreement published in__**Federal Register**_,_, 2022 (*citation placeholder*), as though said text were physically recited herein.

The applicant, as program participant, agrees to comply with the provisions of Section 708 of the Defense Production Act of 1950, as amended (50 U.S.C. 4558), the regulations of 44 CFR part 332 and 46 U.S.C. 53407, and the terms of the Voluntary Tanker Agreement.

Further, the applicant, if approved as a program participant, hereby agrees to contractually commit to make vessels or capacity available for use by the Department of Defense and to other program participants for the purpose of meeting national defense requirements.

(Corporate Secretary)

(Applicant-Corporate Name)

(Name of authorized official)
(CORPORATE SEAL or Notary)

(Position Title)

(Signature of authorized official)
UNITED STATES OF AMERICA
DEPARTMENT OF TRANSPORTATION
MARITIME ADMINISTRATION
Effective Date:
By order of the Maritime Administrator.

Secretary, Maritime Administration.

(Authority: 50 U.S.C. 4558, 46 U.S.C. 53407, E.O. 13603, E.O. 12656, 49 CFR 1.93, 49 CFR 1.81(a)(10), 44 CFR part 332)

By order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2022–24184 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2022–0223]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: MIDNIGHT (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 7, 2022.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2022–0223 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2022–0223 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2022–0223, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel MIDNIGHT is:

—*Intended Commercial Use of Vessel:* ''Uninspected vessel for sailing excursions and teaching on Lake Erie.''

—*Geographic Region Including Base of Operations:* ''Ohio, Pennsylvania, New York and Michigan.'' (Base of Operations: Lorain, OH)

—*Vessel Length and Type:* 44′ Sail

The complete application is available for review identified in the DOT docket as MARAD 2022–0223 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2022–0223 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can 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.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2022–24194 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2022–0221]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: SILVER MAMA (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 7, 2022.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2022–0221 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2022–0221 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2022–0221, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel SILVER MAMA is:

—*Intended Commercial Use of Vessel:* ''Coastwise trade.''

—*Geographic Region Including Base of Operations:* ''Florida. Vessel already possesses a MARAD endorsement for operating in New York waters under docket MARAD–2017–0149.'' (Base of Operations: Miami, FL)

—*Vessel Length and Type:* 78.7′ Motor

The complete application is available for review identified in the DOT docket as MARAD 2022–0221 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2022–0221 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can 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.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2022–24189 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2022–0219]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: CAVIAR (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 7, 2022.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2022–0219 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2022–0219 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2022–0219, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel CAVIAR is:

—*Intended Commercial Use of Vessel:* ''Owner intends to use the vessel for high end day charter, including, bay cruises, sunset cruises, special events.''

—*Geographic Region Including Base of Operations:* ''California.'' (Base of Operations: San Diego, CA)

—*Vessel Length and Type:* 70.3′ Motor

The complete application is available for review identified in the DOT docket as MARAD 2022–0219 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES.** Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2022–0219 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

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(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2022–24193 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2022–0222]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: TREMONDO (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 7, 2022.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2022–0222 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2022–0222 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2022–0222, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel TREMONDO is:

—*Intended Commercial Use of Vessel:* ''Day Charter.''
—*Geographic Region Including Base of Operations:* ''Puerto Rico.'' (Base of Operations: San Juan, PR)
—*Vessel Length and Type:* 29′ Sail

The complete application is available for review identified in the DOT docket as MARAD 2022–0222 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2022–0222 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can 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.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2022–24197 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2022–0226]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: THE AQUAHOLIC (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 7, 2022.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2022–0226 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2022–0226 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2022–0226, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel THE AQUAHOLIC is:

—*Intended Commercial Use of Vessel:* ''We plan to use this vessel for cruising charters and add it to an established legal charter company's (sic) fleet here in the marina.''

—*Geographic Region Including Base of Operations:* ''California.'' (Base of Operations: Marina Del Rey, CA)

—*Vessel Length And Type:* 42′ Motor

The complete application is available for review identified in the DOT docket as MARAD 2022–0226 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES.** Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2022–0226 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can 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.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2022–24191 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Bureau of Transportation Statistics

[Docket Number DOT–OST–2022–15247]

Agency Information Collection Activity; New Information Collection: Freight Logistics Optimization Works (FLOW) Initiative

AGENCY: Office of the Assistant Secretary for Research and Technology (OST–R), Bureau of Transportation Statistics (BTS), U.S. Department of Transportation.

ACTION: 30-Day notice of new information collection.

SUMMARY: On July 18, 2022, the Bureau of Transportation Statistics (BTS) announced its intention in a **Federal Register** Notice (87 FR 42796) to request

that the Office of Management and Budget (OMB) approve the following information collection: The Freight Logistics Optimization Works (FLOW) Project. Over the past several years, the U.S. supply chain has struggled with unprecedented congestion under COVID-induced surges of containerized cargo through our ports and intermodal networks. In March of this year, the White House announced the launch of the Freight Logistics Optimization Works (FLOW) initiative with the Department of Transportation and the freight industry to facilitate a collaboration and sharing of intermodal trade data. This collaboration would help improve supply chain efficiencies and reduce overall costs to U.S. consumers. The FLOW initiative builds on previous work by the Administration's Supply Chain Disruptions Task Force to ensure the expeditious movement of cargo from ship to shelf. In accordance with the Paperwork Reduction Act of 1995, BTS announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval. BTS encouraged interested parties to submit comments to docket number 2022–15247, during the 60-day comment period. No comments were received.

DATES: Written comments should be submitted by December 7, 2022.

ADDRESSES: BTS seeks public comments on its proposed information collection. Comments should address whether the information will have practical utility; the accuracy of the estimated burden hours of the proposed information collection' 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 respondents, including the use of automated collection techniques or other forms of information technology. Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street NW, Washington, DC 20503, Attention: BTS Desk Officer.

FOR FURTHER INFORMATION CONTACT: Demetra V. Collia, Bureau of Transportation Statistics, Office of the Assistant Secretary for Research and Technology, USDOT, Office of Safety Data and Analysis, RTS–34, E36–302, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, Phone No. (202) 366–1610; Fax No. (202) 366–3383; email: *demetra.collia@dot.gov.* Office hours are from 8:30 a.m. to 5 p.m., EST, Monday through Friday, except Federal holidays.

Data Confidentiality Provisions: The confidentiality of the Freight Logistics Optimization Works (FLOW) initiative with the Department of Transportation and the freight industry to facilitate a collaboration and sharing of intermodal trade data submitted to BTS is protected under the BTS Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2018 (Pub. L. 115–435 Foundations for Evidence-Based Policymaking Act of 2018, Title III). In accordance with these confidentiality statutes, only statistical (aggregated) and non-identifying data will be made publicly available by BTS through its reports. BTS will not release data to any public or private entity, nor any information that might reveal the identity of individuals, organizations or businesses without explicit consent of the data providers.

SUPPLEMENTARY INFORMATION:

I. The Data Collection

The Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35; as amended) and 5 CFR part 1320 require each Federal agency to obtain OMB approval to initiate an information collection activity. BTS is seeking OMB approval for the following BTS information collection activity:

Title: Freight Logistics Optimization Works (FLOW) Project.

OMB Control Number: 2138–0049.

Type of Review: New collection.

Respondents: Businesses in the Freight Industry.

Number of Potential Responses: No more than 200 companies.

Estimated Time per Response: 26.5 hours.

Frequency: Annual.

Total Annual Burden Hours: Estimated Total Annual Burden is 5,300.

Privacy Act

You may review DOT's complete Privacy Act Statement in the **Federal Register** published on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

Demetra V. Collia,

Director, Office of Safety Data and Analysis, Office of the Assistant Secretary for Research and Technology, U.S. Department of Transportation.

[FR Doc. 2022–24125 Filed 11–4–22; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form Project

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 excise taxes on excess inclusions of REMIC residual interests.

DATES: Written comments should be received on or before January 6, 2023 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 *pra.comments@irs.gov*. Include OMB Control No. 1545–1379 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Sara Covington, at (202) 317–5744 or Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *sara.l.covington@irs.gov*.

SUPPLEMENTARY INFORMATION: *Title:* Excise Taxes on Excess Inclusions of REMIC Residual Interests.

OMB Number: 1545–1379.

Form Number: 8831.

Abstract: Taxpayers use Form 8831 to report and pay excise tax on any transfer of a residual interest in a REMIC to a disqualified organization, the amount due if the tax is waived, and the excise tax due on pass-through entities with interests held by disqualified organizations.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 31.

Estimated Time per Respondent: 7 hours, 39 minutes.

Estimated Total Annual Burden Hours: 237 hours.

The following paragraph applies to all of 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 as long as 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: November 1, 2022.

Sara L. Covington,

IRS Tax Analyst.

[FR Doc. 2022–24132 Filed 11–4–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

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 proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Settlement Funds.

DATES: Written comments should be received on or before January 6, 2023 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 *pra.comments@irs.gov*. Include OMB Control No. 1545–1299 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Sara Covington, at (202)317–5744, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *sara.l.covington@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Settlement Funds.

OMB Number: 1545–1299.

Form Number: TD 8459.

Abstract: This final regulation prescribes reporting requirements for settlement funds, which are funds established or approved by a governmental authority to resolve or satisfy certain liabilities, such as those involving tort or breach of contract. The final regulation relates to the tax treatment of transfers to these funds, the taxation of income earned by the funds, and the tax treatment of distributions made by the funds.

Current Actions: There is no change in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals, business or other for-profit organizations, not for-profit institutions, farms and Federal, state, local or tribal governments.

Estimated Number of Respondents: 2,750.

Estimated Time per Respondent: 1.288 hrs.

Estimated Total Annual Burden Hours: 3,542.

The following paragraph applies to all of 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 as long as 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: November 1, 2022.

Sara L. Covington,

IRS Tax Analyst.

[FR Doc. 2022–24130 Filed 11–4–22; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

Vol. 87 Monday,

No. 214 November 7, 2022

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 413 and 512

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

[CMS–1768–F]

RIN 0938–AU79

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule updates and revises the End-Stage Renal Disease (ESRD) Prospective Payment System for calendar year 2023. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. In addition, this rule updates requirements for the ESRD Quality Incentive Program and finalizes changes to the ESRD Treatment Choices Model.

DATES: This final rule is effective on January 1, 2023, except for the amendment to 42 CFR 413.234 in instruction number 4, which is effective January 1, 2025.

FOR FURTHER INFORMATION CONTACT: *ESRDPayment@cms.hhs.gov*, for issues related to the ESRD PPS and coverage and payment for renal dialysis services furnished to individuals with acute kidney injury (AKI).

ESRDApplications@cms.hhs.gov, for issues related to applications for the Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) or the Transitional Drug Add-on Payment Adjustment (TDAPA).

Delia Houseal, (410) 786–2724, for issues related to the ESRD Quality Incentive Program (QIP).

ETC-CMMI@cms.hhs.gov, for issues related to the ESRD Treatment Choices (ETC) Model.

SUPPLEMENTARY INFORMATION:

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Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents.

I. Executive Summary

A. Purpose

This rule finalizes changes related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), the ESRD Quality Incentive Program (QIP), and the ESRD Treatment Choices (ETC) Model.

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule updates the ESRD PPS for CY 2023.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA

amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This rule updates the AKI payment rate for CY 2023.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act. The Program fosters improved patient outcomes by establishing incentives for facilities to meet or exceed performance standards established by the Centers for Medicare & Medicaid Services (CMS). This final rule finalizes several updates for Payment Year (PY) 2023, including the suppression of individual ESRD QIP measures for PY 2023 under the measure suppression policy previously finalized for the duration of the COVID–19 public health emergency (PHE), as well as updates for PY 2024, PY 2025, and PY 2026.

4. End-Stage Renal Disease Treatment Choices (ETC) Model

The ETC Model is a mandatory Medicare payment model tested under section 1115A of the Act. The ETC Model is operated by the Center for Medicare and Medicaid Innovation (Innovation Center), and tests the use of payment adjustments to encourage greater utilization of home dialysis and kidney transplants, to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures.

The ETC Model was finalized as part of a final rule published in the **Federal Register** on September 29, 2020, titled, ''Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' (85 FR 61114), referred to herein as the ''Specialty Care Models final rule.'' In this rule, we finalize certain changes to the ETC Model, including adding a parameter to the Performance Payment Adjustment (PPA) achievement scoring methodology and adding an additional protection related to flexibilities for furnishing and billing kidney disease patient education services by ETC Participants. This final rule also discusses our intent to disseminate participant-level model performance information to the public.

B. Summary of the Major Provisions

1. ESRD PPS

- *Rebasing and revision of the End-Stage Renal Disease Bundled (ESRDB) market basket for CY 2023:* We are updating the ESRDB market basket to a 2020 base year, reflecting the most recent and complete set of Medicare Cost Report (MCR) data as well as other publicly available data. In addition, we are updating the labor-related share of the ESRD PPS base rate to reflect the 2020 labor-related cost share weights designated in the ESRDB market basket.
- *Update to the ESRD PPS base rate for CY 2023:* The final CY 2023 ESRD PPS base rate is $265.57. This amount reflects the application of the wage index budget-neutrality adjustment factor (0.999730) and a productivity-adjusted market basket increase of 3.0 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $265.57 (($257.90 × 0.999730) × 1.030 = $265.57).
- *Annual update to the wage index:* We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2023, we are updating the wage index values based on the latest available data.
- *Permanent cap on wage index decreases:* For CY 2023 and subsequent years, we are establishing a permanent policy to apply a 5-percent cap on any ESRD facility's wage index decrease from its wage index in the prior year, regardless of the circumstances causing the decline.
- *Wage index floor:* We are raising the wage index floor, for areas with wage index values below the floor, from 0.5000 to 0.6000.
- *Outlier policy refinement:* The ESRD PPS has an outlier policy that targets 1.0 percent of total Medicare ESRD PPS expenditures in outlier payments for ESRD beneficiaries who require a high level of renal dialysis services. We are modifying the methodology for calculating the fixed-dollar loss (FDL) amounts for adult patients.
- *Annual update to the outlier policy:* We are updating the outlier policy based on the most current data and our refinement to the outlier policy. Accordingly, we are updating the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2023 using the latest available CY 2021 claims data. We are updating the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2021 claims data, and calculating the FDL amount for adult patients using the latest available claims data from CY 2019, CY 2020, and CY 2021, in accordance with the methodology discussed in section II.B.1.c.(4) of this final rule. For pediatric beneficiaries, the final FDL amount will decrease from $26.02 to $23.29, and the final MAP amount will decrease from $27.15 to $25.59, as compared to CY 2022 values. For adult beneficiaries, the final FDL amount will decrease from $75.39 to $73.19, and the final MAP amount will decrease from $42.75 to $39.62. The 1.0 percent target for outlier payments was not achieved in CY 2021. Outlier payments represented approximately 0.5 percent of total payments rather than 1.0 percent.
- *Definition of an oral-only drug:* Beginning January 1, 2025, we will include the word functional in the definition of oral-only drug at 42 CFR 413.234(a). Specifically, under the final definition, an oral-only drug will be a drug or biological product with no injectable *functional* equivalent or other form of administration other than an oral form.
- *Update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2023:* The final CY 2023 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is $9.79. This offset amount reflects the application of the productivity-adjusted market basket increase of 3.0 percent ($9.50 × 1.030 = $9.79).
- *TPNIES applications received for CY 2023:* In this final rule, we announce our determinations on the three TPNIES applications under consideration for the TPNIES for CY 2023 payment.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

We are updating the AKI payment rate for CY 2023. The final CY 2023 payment rate is $265.57, which is the same as the base rate finalized under the ESRD PPS for CY 2023.

3. ESRD QIP

We are finalizing our proposals to suppress the Standardized Hospitalization Ratio (SHR) clinical measure, Standardized Readmission Ratio (SRR) clinical measure, In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) clinical measure, Long-Term Catheter Rate clinical measure, Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure, and

Kt/V Dialysis Adequacy Comprehensive clinical measure for PY 2023 under our previously finalized measure suppression policy because we have determined that circumstances caused by the public health emergency (PHE) due to COVID–19 have significantly affected the measures and resulting performance scores. We are also suppressing the Standardized Fistula Rate clinical measure for PY 2023 under our previously finalized measure suppression policy because we have determined that the circumstances caused by the COVID–19 PHE have also significantly affected the Standardized Fistula Rate clinical measure and resulting performance score. Additionally, we are finalizing that we will calculate the minimum Total Performance Score (mTPS) for PY 2023 based on the seven measures that are not suppressed. We are also finalizing our proposal to use CY 2019 data to calculate performance standards for the PY 2023 ESRD QIP. We are also updating the technical specifications of the SHR clinical measure and SRR clinical measure so that the measure results are expressed as rates instead of ratios beginning with the PY 2024 ESRD QIP. We are finalizing our proposal to add the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure to the ESRD QIP measure set beginning with the PY 2025 ESRD QIP. We are also finalizing our proposal to convert the Standardized Transfusion Ratio (STrR) reporting measure to a clinical measure beginning with PY 2025, and are further finalizing our proposal to express this measure as a rate to align with the technical updates to also express the SHR and SRR clinical measure results as rates. In addition, we are finalizing our proposal to convert the Hypercalcemia clinical measure to a reporting measure, beginning with PY 2025. Furthermore, we are finalizing our proposal to create a new Reporting Measure domain and to re-weight remaining measure domains beginning with PY 2025.

This final rule also includes a summary of public comments received in response to requests for information that appeared in the CY 2023 ESRD PPS proposed rule. In those requests for information, we solicited feedback on several important topics, including potential quality measures for home dialysis, the expansion of our quality reporting programs to allow us to provide more actionable and comprehensive information on health care disparities across multiple variables and new care settings, and on the possible future inclusion of two potential social drivers of health screening measures in the ESRD QIP.

4. ETC Model

In this final rule, we are updating the PPA achievement scoring methodology beginning in the fifth Measurement Year (MY5) of the ETC Model, which begins January 1, 2023. We are also clarifying the requirements for qualified staff to furnish and bill kidney disease patient education services under the ETC Model's Medicare program waivers. In addition, we discuss our intent to disseminate participant-level model performance information to the public.

C. Summary of Costs and Benefits

In section VII.D.5 of this final rule, we set forth a detailed analysis of the impacts that the finalized changes will have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact table in section VII.D.5.a of this final rule displays the estimated change in payments to ESRD facilities in CY 2023 compared to estimated payments in CY 2022. The overall impact of the CY 2023 changes is projected to be a 3.1 percent increase in payments. Hospital-based ESRD facilities have an estimated 3.1 percent increase in payments compared with freestanding facilities with an estimated 3.0 percent increase. We estimate that the aggregate ESRD PPS expenditures will increase by approximately $300 million in CY 2023 compared to CY 2022. This reflects a $300 million increase from the payment rate update, approximately $2.5 million in estimated TPNIES payment amounts and approximately $2.3 million in estimated TDAPA payment amounts, as further described in the next paragraph. Because of the projected 3.1 percent overall payment increase, we estimate there will be an increase in beneficiary coinsurance payments of 3.1 percent in CY 2023, which translates to approximately $60 million.

Section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. Under this authority, CMS implemented § 413.234 to establish the TDAPA, a transitional drug add-on payment adjustment for certain new renal dialysis drugs and biological products and § 413.236 to establish the TPNIES, a transitional add-on payment adjustment for new and innovative equipment and supplies, which are not budget neutral.

As discussed in section II.D. of this final rule, the TPNIES payment period for the Tablo® System will continue in CY 2023. We estimate that the TPNIES payment amounts for the Tablo® System in CY 2023 would be approximately $2.5 million, of which, approximately $490,000 would be attributed to beneficiary coinsurance amounts. As discussed in section II.E. of this final rule, the TDAPA payment period for KORSUVA™ (difelikefalin) will continue in CY 2023. We estimate that the overall TDAPA payment amounts in CY 2023 would be approximately $2.3 million, of which, approximately $468,000 would be attributed to beneficiary coinsurance amounts.

2. Impacts of the Final Payment for Renal Dialysis Services Furnished to Individuals With AKI

The impact table in section VII.D.5.b of this final rule displays the estimated change in payments to ESRD facilities in CY 2023 compared to estimated payments in CY 2022. The overall impact of the CY 2023 changes is projected to be a 2.9 percent increase in payments for individuals with AKI. Hospital-based ESRD facilities have an estimated 2.8 percent increase in payments compared with freestanding ESRD facilities with an estimated 2.9 percent increase. The overall impact reflects the effects of the final update to the labor-related share, final CY 2023 wage index, final permanent cap on wage index decreases, final increase to the wage index floor, and the final payment rate update. We estimate that the aggregate payments made to ESRD facilities for renal dialysis services furnished to patients with AKI, at the final CY 2023 ESRD PPS base rate, will increase by $2 million in CY 2023 compared to CY 2022.

3. Impacts of the ESRD QIP

In the CY 2021 ESRD PPS final rule, we estimated that the overall economic impact of the PY 2023 ESRD QIP would be approximately $224 million as a result of the policies we had finalized at that time (85 FR 71400). The $224 million figure for PY 2023 included costs associated with the collection of information requirements, which we estimated would be approximately $208 million, and $16 million in estimated payment reductions across all facilities. In the CY 2023 ESRD PPS proposed rule, we estimated that the overall economic impact of the PY 2023 ESRD QIP would be approximately $218 million (87 FR 38467). In that proposed rule, we estimated that the $218 million figure for PY 2023 included costs associated with the collection of

information requirements and recalculated estimated payment reductions based on the six measures we proposed to suppress for PY 2023. However, as a result of the policies impacting the PY 2023 ESRD QIP that we are finalizing in this final rule, including the additional suppression of the Standardized Fistula Rate clinical measure, we are modifying our previous estimate. We now estimate that the overall economic impact of the PY 2023 ESRD QIP will be approximately $213.5 million. The $213.5 million figure for PY 2023 includes costs associated with the collection of information requirements, which we estimate will be approximately $208 million, and recalculated estimated payment reductions of approximately $5.5 million across all facilities based on the seven measures we are finalizing for suppression for PY 2023. Although we are updating the way we express the SHR clinical measure and the SRR clinical measure results beginning with PY 2024, these technical updates will not impact our previously estimated economic impact for the PY 2024 ESRD QIP.

In the CY 2023 ESRD PPS proposed rule, we estimated that the overall economic impact of the PY 2025 ESRD QIP would be approximately $252 million as a result of the policies we have previously finalized and the proposals in the proposed rule (87 FR 38467). The $252 million figure for PY 2025 included costs associated with the collection of information requirements, which we estimated would be approximately $215 million, and $37 million in estimated payment reductions across all facilities. In this final rule, we continue to estimate that the overall economic impact of the PY 2025 ESRD QIP will be approximately $252 million as a result of the policies we have previously finalized and the proposals we are finalizing in this final rule. However, we have updated our estimated costs associated with collection of information requirements and payment reductions across all facilities. The $252 million figure for PY 2025 includes costs associated with the collection of information requirements, which we estimate would be approximately $220 million, and $32 million in estimated payment reductions across all facilities. We are also updating our estimate that the overall economic impact of the PY 2026 ESRD QIP would be approximately $252 million as a result of the policies we have previously finalized. The $252 million figure for PY 2026 includes costs associated with the collection of information requirements, which we estimate would be approximately $220 million, and $32 million in estimated payment reductions across all facilities.

4. Impacts of the Final Changes to the ETC Model

The impact estimate in section VII.D.5.d of this final rule describes the estimated change in anticipated Medicare program savings arising from the ETC Model over the duration of the ETC Model as a result of the changes in this final rule. We estimate that the ETC Model will result in $28 million in net savings over the 6.5 year duration of the ETC Model. We also estimate that the changes in this final rule will produce no change in net savings for the ETC Model.

II. Calendar Year (CY) 2023 End Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, CMS implemented the ESRD PPS, a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Act, as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act), established that beginning with CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket increase factor reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014, to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule, we finalized $29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. Section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for—(1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Finally, under the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295).), Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA provides that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single per-treatment payment is made to an ESRD facility for all the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definition of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD

PPS payment policies. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, and four comorbidity categories (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, myelodysplastic syndrome). A different set of case-mix adjusters are applied for the pediatric population. Pediatric patient-level adjusters include two age categories (under age 22, or age 22 to 26) and two dialysis modalities (that is, peritoneal or hemodialysis) (§ 413.235(a) and (b)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (§ 413.232). The second payment adjustment reflects differences in area wage levels developed from core-based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

There are four additional payment adjustments under the ESRD PPS. The ESRD PPS provides adjustments, when applicable, for: (1) a training add-on for home and self-dialysis modalities (§ 413.235(c)); (2) an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care (§ 413.237); (3) a TDAPA for certain new renal dialysis drugs and biological products (§ 413.234(c)); and (4) a TPNIES for certain qualifying, new and innovative renal dialysis equipment and supplies (§ 413.236(d)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010 in the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011 in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

We published a final rule, which appeared in the November 8, 2021 issue of the **Federal Register**, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model,'' referred to herein as the ''CY 2022 ESRD PPS final rule.'' In that rule, we updated the ESRD PPS base rate, wage index, and outlier policy for CY 2022. We also updated the average per treatment offset amount for the TPNIES for CY 2022. In addition, we announced our approval of one application for the TPNIES for CY 2022 payment. For further detailed information regarding these updates, see 86 FR 61874.

B. Provisions of the Proposed Rule, Public Comments, and Responses to the Comments on the CY 2023 ESRD PPS

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'' (87 FR 38464 through 38586), referred to as the ''CY 2023 ESRD PPS proposed rule,'' appeared in the June 28, 2022 version of the **Federal Register**, with a comment period that ended on August 22, 2022. In that proposed rule, we proposed to make a number of annual updates for CY 2023, including updates to the ESRD PPS base rate, wage index, outlier policy, and the TPNIES offset amount. We also proposed several policy changes, including increasing the wage index floor, establishing a permanent cap on wage index decreases, modifying the outlier methodology, changing the definition of oral-only drug, and revising the descriptions of several ESRD PPS functional categories. The proposed rule included a summary of the three CY 2023 TPNIES applications that we received by the February 1, 2022 deadline and our preliminary analysis of the applicants' claims related to substantial clinical improvement and other eligibility criteria for the TPNIES. In addition, the rule included a request for information regarding potential payment adjustments for certain new renal dialysis drugs and biological products as well as health equity issues under the ESRD PPS with a focus on pediatric dialysis payment.

We received 291 public comments on our proposals, including comments from kidney and dialysis organizations, such as large dialysis organizations (LDOs), small dialysis organizations, for-profit and non-profit ESRD facilities, ESRD networks, and a dialysis coalition. We also received comments from patients; healthcare providers for adult and pediatric ESRD beneficiaries; home dialysis services and advocacy organizations; provider and legal advocacy organizations; administrators and insurance groups; a non-profit dialysis association, a professional association, and alliances for kidney care and home dialysis stakeholders; drug and device manufacturers; health care systems; a health solutions company; and the Medicare Payment Advisory Commission (MedPAC).

We received several comments related to issues that we either did not discuss in the CY 2023 ESRD PPS proposed rule or that we discussed for the purpose of background or context, but for which we did not propose changes. These include, for example, concerns about infections, comments on comorbidities that should or should not be considered for payment adjustments, suggestions for changes to payments for drugs and biological products, and suggestions for additional screenings for Medicare beneficiaries to detect kidney disease earlier. In addition, we received several comments regarding the TDAPA and TPNIES payment adjustments and length of the payment period. We also received comments regarding the TPNIES application process, implementation challenges from the CY 2022 TPNIES approval for the Tablo® System, and requests to amend the ESRD facility cost report and align Medicare Advantage plans with the ESRD PPS. While we are not providing detailed responses to those comments in this final rule because they are either out of scope of the proposed rule or concern topics for which we did not propose changes, we thank the commenters for their input and will potentially consider the recommendations in future rulemaking.

We received various comments requesting changes to Medicare payments for home dialysis. Some of these suggestions were to increase payments for home dialysis training, to increase the number of training sessions for home dialysis, to increase payments for home dialysis treatments, and to allow clinics to bill for telemedicine related to home dialysis. We thank the commenters for their recommendations regarding home dialysis; however, these comments are out of scope given that we did not propose to make any changes to the Medicare payment for home dialysis. Nevertheless, we will review and assess the feasibility of the commenters' recommendations and, if warranted, consider proposing changes to our policies in future rulemaking.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and

the policies we are finalizing for the CY 2023 ESRD PPS.

1. CY 2023 ESRD PPS Update

a. CY 2023 ESRD Bundled (ESRDB) Market Basket Rebasing and Revision; Market Basket Increase Factor; Productivity Adjustment; and Labor-Related Share

(1) Rebasing and Revising of the ESRDB Market Basket

(a) Background

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. Section 1881(b)(14)(F)(i) of the Act also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD Bundled (ESRDB) input price index using CY 2008 as the base year (75 FR 49151 through 49162). We subsequently revised and rebased the ESRDB input price index to a base year of CY 2012 in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136). In the CY 2019 ESRD PPS final rule (83 FR 56951 through 56964), we finalized a rebased ESRDB input price index to reflect a CY 2016 base year. Effective for CY 2023, we proposed to rebase and revise the ESRDB market basket to a base year of CY 2020.

Although ''market basket'' technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term ''ESRDB market basket,'' as used in this document, refers to the ESRDB input price index.

The ESRDB market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index is constructed in three steps. First, a base period is selected where total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called ''cost weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted previously, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services purchased to provide renal dialysis services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, an ESRD facility hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the ESRD facility, but would not be factored into the price change measured by a fixed-weight ESRD market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect changes between base periods in the mix of goods and services that ESRD facilities purchase to furnish ESRD treatment.

We last rebased the ESRDB market basket cost weights effective for CY 2019 (83 FR 56951 through 56964), with 2016 data used as the base period for the construction of the market basket cost weights. In the CY 2023 ESRD PPS proposed rule (87 FR 38468 through 38480), we proposed to use 2020 as the base year for the rebased ESRDB market basket cost weights. The cost weights for this ESRDB market basket are based on the cost report data for independent ESRD facilities. We refer to the market basket as a CY market basket because the base period for all price proxies and weights are set to CY 2020 (that is, the average index level for CY 2020 is equal to 100). The major source data for the ESRDB market basket is the 2020 MCRs (Form CMS–265–11, OMB NO. 0938–0236), supplemented with 2012 data from the United States (U.S.) Census Bureau's Services Annual Survey (SAS) inflated to 2020 levels. The 2012 SAS data is the most recent year of detailed expense data published by the Census Bureau for North American International Classification System (NAICS) Code 621492: Kidney Dialysis Centers. We also proposed to use May 2020 Occupational Employment Statistics data from the U.S. Department of Labor's Bureau of Labor Statistics (BLS) to estimate the weights for the Wages and Salaries and Employee Benefits occupational blends. We provide more detail on our methodology in section II.B.1.a.(1)(b) of this final rule.

The terms ''rebasing'' and ''revising,'' while often used interchangeably, actually denote different activities. The term ''rebasing'' means moving the base year for the structure of costs of an input price index (that is, in the CY 2023 ESRD PPS proposed rule, we proposed to move the base year cost structure from 2016 to 2020) without making any other major changes to the methodology. The term ''revising'' means changing data sources, cost categories, and/or price proxies used in the input price index. For CY 2023, we proposed to rebase the ESRDB market basket to reflect the 2020 cost structure of ESRD facilities and to revise the index, that is, make changes to cost categories or price proxies used in the index.

We proposed to use CY 2020 as the new base year because 2020 is the most recent year for which relatively complete MCR data were available. We analyzed the cost weights for the years 2017 through 2020 and found that the expenses reported in the ESRD facility MCRs for 2020 were consistent with those in the prior years. Additionally, given the nature of renal dialysis services, any impacts on utilization due to the COVID–19 Public Health Emergency (PHE) were minimal, as dialysis is not an optional treatment and must continue even during the PHE. In developing the proposed market basket, we reviewed ESRD expenditure data from ESRD MCRs (CMS Form 265–11, OMB NO. 0938–0236) for 2020 for each freestanding ESRD facility that reported expenses and payments. The 2020

MCRs are for those ESRD facilities whose cost reporting period began on or after October 1, 2019, and before October 1, 2020. Of the 2020 MCRs, approximately 91 percent of freestanding ESRD facilities had a begin date on January 1, 2020, approximately 5 percent had a begin date prior to January 1, 2020, and approximately 4 percent had a begin date after January 1, 2020. We explained that using this methodology allowed our sample to include ESRD facilities with varying cost report years including, but not limited to, the Federal fiscal year (FY) or CY.

We proposed to maintain our policy of using data from freestanding ESRD facilities (which account for over 90 percent of total ESRD facilities in CY 2020) because freestanding ESRD facility data reflect the actual cost structure faced by the ESRD facility itself. In contrast, expense data for hospital-based ESRD facilities reflect the allocation of overhead from the entire institution.

We developed cost category weights for the 2020-based ESRDB market basket in two stages. First, we derived base year cost weights for ten major categories (Wages and Salaries, Employee Benefits, Pharmaceuticals, Supplies, Laboratory Services, Housekeeping, Operations & Maintenance, Administrative & General, Capital-Related Building and Fixtures, and Capital-Related Moveable Equipment) from the ESRD MCRs. Second, we divided the Administrative & General cost category into further detail using 2012 SAS data for the industry Kidney Dialysis Centers NAICS 621492 inflated to 2020 levels. We applied the estimated 2020 distributions from the SAS data to the 2020 Administrative & General cost weight to yield the more detailed 2020 cost weights in the proposed market basket. This is the same methodology we used in the CY 2019 ESRD PPS rulemaking to break the Administrative & General costs into more detail for the 2016-based ESRDB market basket (83 FR 56951 through 56964).

We included a total of 21 detailed cost categories for the 2020-based ESRDB market basket, whereas the 2016-based ESRDB market basket had 20 detailed cost categories. A detailed discussion of the provisions is provided in section II.B.1.a.(1)(b) of this final rule.

(b) Cost Category Weights

Using Worksheets A and B from the 2020 MCRs, we first computed cost shares for ten major expenditure categories: Wages and Salaries, Employee Benefits, Pharmaceuticals, Supplies, Laboratory Services, Housekeeping, Operations & Maintenance, Administrative and General, Capital-Related Building and Fixtures, and Capital-Related Moveable Equipment. Edits were applied to include only cost reports that had total costs greater than zero. Total costs as reported on the MCR include those costs payable under the ESRD PPS. For example, we excluded expenses related to vaccine costs from total expenditures since these are not paid for under the ESRD PPS.

To reduce potential distortions from outliers in the calculation of the individual cost weights for the major expenditure categories for each cost category, values less than the 5th percentile or greater than the 95th percentile were excluded from the major cost weight computations. The proposed data set, after removing cost reports with total costs equal to or less than zero and excluding outliers, included information from approximately 6,625 independent ESRD facilities' cost reports from an available pool of 7,413 cost reports.

Table 1 presents the 2020-based ESRDB and 2016-based ESRDB market basket major cost weights as derived directly from the MCR data.

TABLE 1: The 2020-based ESRDB Market Basket Major Cost Weights Derived from the Medicare Cost Report Data

Cost Category	2020-based ESRDB Market Basket (%)	2016-based ESRDB Market Basket (%)
Wages and Salaries	34.5	32.6
Employee Benefits	7.7	7.0
Pharmaceuticals	10.1	12.4
Supplies	11.0	10.4
Laboratory Services	1.3	2.2
Housekeeping*	0.5	3.9
Operations & Maintenance	3.7	n/a
Administrative & General	17.5	18.5
Capital-related Building and Fixtures	9.4	9.2
Capital-related Moveable Equipment	4.4	3.8

Note: Totals may not sum to 100.0 percent due to rounding.

* For the 2016-based ESRDB market basket, this category was referred to as the Housekeeping and Operations cost category. For the 2020-based ESRDB market basket, the Housekeeping and Operations cost category is split into two detailed cost categories: Housekeeping and Operations & Maintenance.

We proposed to disaggregate the Administrative & General major cost category developed from the MCR into more detail to more accurately reflect ESRD facility costs. Those categories include: Benefits, Professional Fees, Telephone, Utilities, and All Other Goods and Services. We describe below how the initially computed categories and weights from the cost reports were modified to yield the proposed 2020 ESRDB market basket expenditure

categories and weights presented in the CY 2023 ESRD PPS proposed rule.

Wages and Salaries

The Wages and Salaries cost weight is comprised of direct patient care wages and salaries and non-direct patient care wages and salaries. Direct patient care wages and salaries for 2020 was derived from Worksheet B, column 5, lines 8 through 17 of the MCR. Non-direct patient care wages and salaries includes all other wages and salaries costs for non-health workers and physicians, which we derived using the following steps:

Step 1: To capture the salary costs associated with non-direct patient care cost centers, we calculated salary percentages for non-direct patient care from Worksheet A of the MCR. The estimated ratios were calculated as the ratio of salary costs (Worksheet A, columns 1 and 2) to total costs (Worksheet A, column 4). The salary percentages were calculated for seven distinct cost centers: 'Operations and Maintenance of Plant' combined with 'Capital Related Costs-Renal Dialysis Equipment' (line 3 and 6), Housekeeping (line 4), Employee Health and Wellness (EH&W) Benefits for Direct Patient Care (line 8), Supplies (line 9), Laboratory (line 10), Administrative & General (line 11), and Pharmaceuticals (line 12).

Step 2: We then multiplied the salary percentages computed in step 1 by the total costs for each corresponding reimbursable cost center totals as reported on Worksheet B. The Worksheet B totals were based on the sum of reimbursable costs reported on lines 8 through 17. For example, the salary percentage for Supplies (as measured by line 9 on Worksheet A) was applied to the total expenses for the Supplies cost center (the sum of costs reported on Worksheet B, column 7, lines 8 through 17). This provided us with an estimate of Non-Direct Patient Care Wages and Salaries.

Step 3: The estimated Wages and Salaries for each of the cost centers on Worksheet B derived in step 2 were subsequently summed and added to the direct patient care wages and salaries costs.

Step 4: The estimated non-direct patient care wages and salaries (see step 2) were then subtracted from their respective cost categories to avoid double-counting their values in the total costs.

Using this methodology, we derived a proposed Wages and Salaries cost weight of 34.5 percent, reflecting an estimated direct patient care wages and salaries cost weight of 25.7 percent and non-direct patient care wages and salaries cost weight of 8.9 percent, as seen in Table 2.

The final adjustment made to this category was to include Contract Labor costs. These costs appear on the MCR; however, they are embedded in the Other Costs from the trial balance reported on Worksheet A, Column 3 and cannot be disentangled using the MCRs. To avoid double counting of these expenses we proposed to move the estimated cost weight for the contract labor costs from the Administrative and General category (where we believed the majority of the contract labor costs would be reported) to the Wages and Salaries category. We used data from the SAS (2012 data inflated to 2020), which reported 2.4 percent of total expenses were spent on contract labor costs. We allocated 80 percent of that contract labor cost weight to the Wages and Salaries category. At the same time, we subtracted that same amount from the Administrative and General category, where the majority of contract labor expenses would likely be reported on the MCR. The 80 percent figure that was used was determined by taking salaries as a percentage of total compensation (excluding contract labor) from the 2020 MCR data. This is the same method that was used to allocate contract labor costs to the Wages and Salaries cost category for the 2016-based ESRDB market basket.

The resulting cost weight for Wages and Salaries increased to 36.5 percent when contract labor wages were added. The calculation of the Wages and Salaries cost weight for the 2020-based ESRDB market basket is shown in Table 2 along with the similar calculation for the 2016-based ESRDB market basket.

TABLE 2: The 2020 and 2016 ESRD Wages and Salaries Cost Weight Determination

Components	2020 Cost Weight	2016 Cost Weight	Source
Wages and Salaries Direct Patient Care	25.2%	25.1%	MCR
Wages and Salaries Non-direct Patient Care	8.9%	7.5%	MCR
Contract Labor (Wages)	1.9%	1.9%	80% of SAS Contract Labor weight
Total Wages and Salaries	**36.5%**	**34.5%**	

Employee Benefits

The proposed Employee Benefits cost weight was derived from the MCR data for direct patient care and supplemented with data from the SAS (2012 data inflated to 2020) to account for non-direct patient care Employee Benefits. The MCR data only reflects Employee Benefit costs associated with health and wellness; that is, it does not reflect retirement benefits.

To reflect the benefits related to non-direct patient care for employee health and wellness, we estimated the impact on the benefit weight using SAS. Unlike the MCR, the SAS collects detailed expenses for employee benefits including expenses related to the retirement and pension benefits. Incorporating the SAS data produced an Employee Benefits (both direct patient care and non-direct patient care) weight that was 1.3 percentage points higher (9.0 vs. 7.7) than the Employee Benefits weight for direct patient care calculated directly from the MCR. To avoid double-counting and to ensure all of the market basket weights still totaled 100 percent, we removed this additional 1.3 percentage points for Non-Direct Patient Care Employee Benefits from the

Administrative and General cost category.

The final adjustment made to this category was to include contract labor benefit costs. Once again, we noted, these costs appear on the MCR; however, they are embedded in the Other Costs from the trial balance reported on Worksheet A, Column 3 and cannot be disentangled using the MCR data. Identical to our methodology previously discussed for allocating Contract Labor Costs to Wages and Benefits, we applied 20 percent of total Contract Labor Costs, as estimated using the SAS, to the Benefits cost weight calculated from the cost reports. The 20 percent figure was determined by taking benefits as a percentage of total compensation (excluding contract labor) from the 2020 MCR data. The resulting cost weight for Employee Benefits increased to 9.5 percent when contract labor benefits were added. This is the same method that was used to allocate contract labor costs to the Benefits cost category for the 2016-based ESRDB market basket.

Table 3 compares the 2016-based Benefits cost share derivation as detailed in the CY 2019 ESRD PPS final rule (83 FR 56954) to the proposed 2020-based Benefits cost share derivation.

TABLE 3: The 2020 and 2016 ESRD Employee Benefits Cost Weight Determination

Components	2020 Cost Weight	2016 Cost Weight	Source
Employee Benefits Direct Patient Care	7.7%	7.0%	MCR
Employee Benefits Non-Direct Patient Care	1.3%	1.6%	SAS
Contract Labor (Benefits)	0.5%	0.5%	20% of SAS Contract Labor weight
Total Employee Benefits	**9.5%**	**9.1%**	

Pharmaceuticals

The proposed 2020-based ESRDB market basket included expenditures for all drugs, including formerly separately billable drugs and all other ESRD-related drugs that were covered under Medicare Part D before the ESRD PPS was implemented. We calculated a Pharmaceuticals cost weight from the following cost centers on Worksheet B, the sum of lines 8 through 17, for the following columns: column 11, ''Drugs Included in Composite Rate,'' column 12, ''Erythropoiesis stimulating agents (ESAs)''; and column 13, ''ESRD-Related and AKI -Related Drugs.'' We did not include the drug expenses for Non-ESRD Related Drugs, Supplies, and Labs as reported on line 5, column 10 or the AKI Non-Renal Related Drugs, Supplies, & Lab as reported on line 5.01 column 10 as these expenses are not included in the ESRD PPS bundled payment amount. Section 1842(o)(1)(A)(iv) of the Act requires that influenza, pneumococcal, COVID–19, and hepatitis B vaccines described in paragraph (A) or (B) of section 1861(s)(10) of the Act be paid based on 95 percent of average wholesale price (AWP) of the drug. Since these vaccines are not paid for under the ESRD PPS, we did not include expenses reported on worksheet B, column 9 line 7 in the 2020-based ESRDB market basket.

Finally, to avoid double-counting, the weight for the Pharmaceuticals category was reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with the applicable pharmaceutical cost centers referenced previously. This resulted in an ESRDB market basket weight for Pharmaceuticals of 10.1 percent. ESA expenditures accounted for 6.0 percentage points of the Pharmaceuticals cost weight, and All Other Drugs accounted for the remaining 4.1 percentage points.

The Pharmaceuticals cost weight decreased 2.3 percentage points from the 2016-based ESRDB market basket to the 2020-based ESRDB market basket (12.4 percent to 10.1 percent). Most ESRD facilities experienced a decrease in their Pharmaceuticals cost weight since 2016.

Supplies

We calculated the Supplies cost weight using the costs reported in the Supplies cost center (Worksheet B, line 5 and the sum of lines 8 through 17, column 7) of the MCR. To avoid double-counting, the Supplies costs were reduced to exclude the estimated share of Non-Direct patient care Wages and Salaries associated with this cost center. The resulting proposed 2020-based ESRDB market basket weight for Supplies was 11.0 percent, approximately 0.6 percentage point higher than the weight for the 2016-based ESRDB market basket.

Laboratory Services

We calculated the proposed Laboratory Services cost weight using the costs reported in the Laboratory cost center (Worksheet B, line 5 and the sum of line 8 through 17, column 8) of the MCR. To avoid double-counting, the Laboratory Services costs were reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with this cost center. The 2020-based ESRDB market basket weight for Laboratory Services was estimated at 1.3 percent, which is a 0.9 percentage point decrease from the 2016-based ESRDB market basket.

Housekeeping

We calculated the proposed Housekeeping cost weight using the costs reported on Worksheet A, line 4, column 8, of the MCR. To avoid double-counting, the weight for the Housekeeping category was reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with this cost center. These costs were divided by total costs to derive a 2020-based ESRDB market basket weight for Housekeeping of 0.5 percent. For the 2016-based ESRDB market basket the cost category weight for both Housekeeping and Operations costs were combined into a single cost weight. The Housekeeping cost weight in the 2016-based ESRDB market basket

would have been 0.5 percent if it had been broken out separately.

Operations & Maintenance

We proposed a new Operations & Maintenance cost category that includes the direct expenses incurred in the operation and maintenance of the plant and equipment such as heat, light, water (excluding water treatment for dialysis purposes), air conditioning, and air treatment; the maintenance and repair of building, parking facilities, and equipment; painting; elevator maintenance; performance of minor renovation of buildings and equipment; and protecting employees, visitors, and facility property. As previously discussed, these costs had formerly been combined with the Housekeeping expenses in a single cost category for Housekeeping and Operations. The proposed 2020-based ESRDB market basket Operations & Maintenance cost category reflects the expenses for Operations & Maintenance, which also includes the costs for Water and Sewerage that was a stand alone cost category in the 2016-based ESRDB market basket. We calculated the Operations & Maintenance cost weight using the costs reported on Worksheet A, line 3, column 8, of the MCR. To avoid double-counting, the weight for the Operations & Maintenance category was reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with this cost center. The resulting proposed 2020-based ESRDB market basket weight for Operations & Maintenance was 3.7 percent.

Capital

We developed a market basket weight for the Capital category using data from Worksheet B of the MCRs. Capital-related costs include depreciation and lease expenses for buildings, fixtures and movable equipment, property taxes, insurance costs, the costs of capital improvements, and maintenance expense for buildings, fixtures, and machinery. The MCR captures Capital-related Costs including: (1) Capital-Related- Building and Fixtures (2) Capital-Related Costs—Moveable Equipment and (3) Housekeeping, and Operations & Maintenance costs in Worksheet B, column 2. Since we developed separate expenditure categories for Housekeeping, and Operations & Maintenance, as detailed previously, we excluded these costs from the propose Capital cost weights. To calculate the Capital-related Buildings and Fixtures cost weight we summed expenses reported in Worksheet B lines 8 through 17, column 2 less Housekeeping, Operations & Maintenance (as derived from expenses reported on Worksheet A, as described previously), and less Capital-related Moveable equipment costs (calculated as Worksheet A, column 8, line 2 divided by the sum of Worksheet A, column 8, lines 1 and 2). The Capital-related moveable equipment cost weight is equal to Capital-related Renal Dialysis Equipment costs (Worksheet B, the sum of lines 8 through 17, column 4 plus Capital-Related Moveable Equipment (as described in the prior sentence)). We reasoned this delineation was particularly important given the critical role played by dialysis machines. Likewise, because price changes associated with Buildings and Fixtures could move differently than those associated with Machinery, we stated that we continue to believe that two capital-related cost categories are appropriate. The resulting proposed 2020-based ESRDB market basket weights for Capital-related Buildings and Fixtures and Capital-related Moveable Equipment were 9.4 and 4.4 percent, respectively.

Administrative & General

We proposed to compute the proportion of total Administrative & General expenditures using the Administrative and General cost center data from Worksheet B, the sum of lines 8 through 17, (column 9) of the MCRs. Additionally, we removed contract labor from this cost category and apportioned these costs to the Wages and Salaries and Employee Benefits cost weights. Similar to other expenditure category adjustments, we then reduced the computed weight to exclude Wages and Salaries and Benefits associated with the Administrative and General cost center for Non-direct Patient Care as estimated from the SAS data. The resulting proposed Administrative and General cost weight was 13.7 percent.

We proposed to further disaggregate the Administrative and General cost weight to derive detailed cost weights for Electricity, Natural Gas, Telephone, Professional Fees, and All Other Goods and Services. These detailed cost weights were derived by inflating the detailed 2012 SAS data forward to 2020 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that were obtained from the 2012 SAS data. We repeated this practice for each year to 2020. We then calculated the cost shares that each cost category represents of the 2012 data inflated to 2020. These resulting 2020 cost shares were applied to the Administrative and General cost weight derived from the MCR (net of contract labor and additional benefits) to obtain the detailed cost weights for the proposed 2020-based ESRDB market basket. This method is similar to the method used for the 2016-based ESRDB market basket.

Table 4 lists all of the cost categories and cost weights in the proposed 2020-based ESRDB market basket compared to the 2016-based ESRDB market basket.

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TABLE 4: Comparison of the 2020-based and the 2016-based ESRDB Market Basket Cost Categories and Weights

2020 Cost Category	2020 Cost Weights (percent)	2016 Cost Weights (percent)
Total	100.0	**100.0**
Compensation	**45.9**	**43.6**
Wages and Salaries	36.5	34.5
Employee Benefits	9.5	9.1
Utilities	**1.4**	**2.0**
Electricity	1.2	1.1
Natural Gas	0.1	0.1
Water and Sewerage	n/a	0.8
Medical Supplies & Laboratory Services	**22.4**	**24.9**
Pharmaceuticals	10.1	12.4
ESAs	6.0	10.0
Other Drugs (except ESAs)	4.1	2.4
Supplies	11.0	10.4
Laboratory Services	1.3	2.2
All Other Goods and Services	**16.6**	**16.4**
Telephone & Internet Services	0.5	0.5
Housekeeping	0.5	3.9
Operations & Maintenance	3.7	n/a
Professional Fees	0.8	0.7
All Other Goods and Services	11.1	11.3
Capital Costs	**13.8**	**13.0**
Capital Related-Building and Fixtures	9.4	9.2
Capital Related-Machinery	4.4	3.8

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and, therefore, the detail may not add to the total due to rounding.

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We received several comments regarding the proposed methodology for deriving the detailed cost weights of the 2020-based ESRDB market basket. The comments and our responses are set forth below.

Comment: Many commenters, including LDOs, a coalition of dialysis organizations, and a professional association supported the proposal to rebase and revise the ESRDB market basket base year to 2020. These commenters agreed that the data from 2016 no longer reflect the current mix of goods and services for providing ESRD care, and some also expressed agreement with the proposed major cost categories and weights as well as the disaggregation of the Administrative & General cost category. While many commenters supported the proposed rebased market basket, several commenters stated that the 2020 revised cost weights do not adequately capture the trends in the health care labor market that have continued into 2022, and that the proposed 2020 cost weights, particularly for labor and related costs, are likely underrepresented as a portion of the market basket. These commenters requested that CMS continue to monitor the effects of the COVID–19 PHE on freestanding ESRD facilities' costs moving forward and consider rebasing the ESRDB market basket more frequently (than every four years) if these trends change and the cost category weights no longer accurately represent freestanding ESRD facilities' costs.

Response: We appreciate the commenters' support for rebasing and revising the ESRDB market basket to a 2020 base year. We also understand the commenters' concerns that the data from 2020 do not necessarily reflect the current relative cost share weights that ESRD facilities may be experiencing in 2022. However, the 2020 data reflect the latest available data available to estimate the ESRDB market basket cost share weights at the time of the CY 2023 ESRD PPS proposed rule. We will continue to monitor the cost share weights for potential effects of the COVID–19 PHE on freestanding ESRD facilities' costs and, if technically appropriate, consider rebasing the ESRDB market basket more frequently than usual should the cost weights change significantly.

Comment: MedPAC requested that CMS's rebasing of the ESRDB market basket should reflect the findings from the agency's most recent audit of

freestanding ESRD facilities, which found that cost reports have included costs that are not allowable under Medicare.

Response: We understand MedPAC's concerns regarding the 2018 audited cost report data; [1] however, we do not agree that the results of the audited data can be directly utilized for determining the ESRDB market basket cost weights in the 2020 cost report data. Although the audited cost report data identified potential areas where cost levels were misreported by some facilities, we do not believe that slightly different cost levels will result in substantial variation to the relative cost share weights derived from the unaudited data, since the cost weights are based on relative shares of the total. Additionally, the weights are derived from all facilities and, therefore, for an audited report to impact the overall market basket cost shares, the misreporting will have to be prevalent across a significant percentage of facilities. Finally, the audit was performed on a sample of cost reports for 2018 and we proposed to use data from 2020 cost reports; any inaccuracies in the 2018 data do not necessarily mean that 2020 data will be impacted in the same way.

Final Rule Action: After consideration of the public comments we received, we are finalizing the methodology for deriving the detailed cost weights of the 2020-based ESRDB market basket as proposed without modification.

(c) Price Proxies for the 2020-Based ESRDB Market Basket

After developing the cost weights for the 2020-based ESRDB market basket, we proposed to select the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. We based the price proxies on BLS data and grouped them into one of the following BLS categories:

- *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).
- *Producer Price Indexes.* Producer Price Indexes (PPIs) measure price changes for goods sold in other than retail markets. PPIs are used when the purchases of goods or services are made at the wholesale level.
- *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by consumers. CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the wholesale level, or if no appropriate PPIs are available.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance:

Reliability. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)

Timeliness. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe, as stated in the CY 2023 ESRD PPS proposed rule, that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.

Availability. Availability means that the proxy is publicly available. As stated in the CY 2023 ESRD PPS proposed rule, we prefer that our proxies are publicly available because this helps to ensure that our market basket increase factors are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.

Relevance. Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs that we have selected meet these criteria. Therefore, as stated in the CY 2023 ESRD PPS proposed rule, we believe that they continue to be the best measure of price changes for the cost categories to which they will be applied.

Table 7 lists all proposed price proxies for the 2020-based ESRDB market basket. We note that we proposed to use the same proxies as those used in the 2016-based ESRDB market basket, except for the price proxy for the Other Drugs (except ESAs) cost category. Below is a detailed explanation of the proposed price proxies used for each cost category.

Wages and Salaries

We proposed to continue using a blend of ECIs to proxy the Wages and Salaries cost weight in the 2020-based ESRDB market basket, and to continue using four occupational categories and associated ECIs based on full-time equivalents (FTE) data from ESRD MCRs and ECIs from BLS. We calculated occupation weights for the blended Wages and Salaries price proxy using 2020 FTE data from the MCR data multiplied by the associated 2020 Average Mean Wage data from the Bureau of Labor Statistics' Occupational Employment Statistics. This is similar to the methodology used in the 2016-based ESRDB market basket to derive these occupational wages and salaries categories.

Health Related Wages and Salaries

We proposed to continue using the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code #CIU1026220000000I) as the price proxy for health-related occupations. Of the two health-related ECIs that we considered (''Hospitals'' and ''Health Care and Social Assistance''), the wage distribution within the Hospital NAICS sector (622) is more closely related to the wage distribution of ESRD facilities than it is to the wage distribution of the Health Care and Social Assistance NAICS sector (62).

The Wages and Salaries—Health Related subcategory weight within the Wages and Salaries cost category accounts for 79.4 percent of total Wages and Salaries in 2020. The ESRD MCR FTE categories used to define the Wages and Salaries—Health Related subcategory include ''Physicians,'' ''Registered Nurses,'' ''Licensed Practical Nurses,'' ''Nurses' Aides,'' ''Technicians,'' and ''Dieticians''.

Management Wages and Salaries

We proposed to continue using the ECI for Wages and Salaries for Private

[1] Details on the audit process and findings, as well as adjustments for unallowable costs based on its findings, can be found in the CY 2022 ESRD PPS proposed rule (86 FR 36322).

Industry Workers in Management, Business, and Financial (BLS series code #CIU2020000110000I). As we stated in the CY 2023 ESRD PPS proposed rule, we believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of management personnel at ESRD facilities.

The Wages and Salaries—Management subcategory weight within the Wages and Salaries cost category is 9.0 percent in 2020. The ESRD MCR FTE category used to define the Wages and Salaries—Management subcategory is ''Management.''

Administrative Wages and Salaries

We proposed to continue using the ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support (BLS series code #CIU2020000220000I). As we stated in the CY 2023 ESRD PPS proposed rule, we believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of administrative support personnel at ESRD facilities.

The Wages and Salaries—Administrative subcategory weight within the Wages and Salaries cost category is 5.3 percent in 2020. The ESRD MCR FTE category used to define the Wages and Salaries—Administrative subcategory is ''Administrative.''

Services Wages and Salaries

We proposed to continue using the ECI for Wages and Salaries for Private Industry Workers in Service Occupations (BLS series code #CIU2020000300000I). As we stated in the CY 2023 ESRD PPS proposed rule, we believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of all other non-health related, non-management, and non-administrative service support personnel at ESRD facilities.

The Services subcategory weight within the Wages and Salaries cost category is 6.3 percent in 2020. The ESRD MCR FTE categories used to define the Wages and Salaries—Services subcategory are ''Social Workers'' and ''Other.''

Table 5 lists the four ECI series and the corresponding weights used to construct the proposed ECI blend for Wages and Salaries compared to the 2016-based weights for the subcategories. As we stated in the CY 2023 ESRD PPS proposed rule, we believe this ECI blend is the most appropriate price proxy to measure the growth of wages and salaries faced by ESRD facilities.

TABLE 5: ECI Blend for Wages and Salaries in the 2020-Based and 2016-Based ESRDB Market Baskets

Cost Category	ECI Series	2020 Weight	2016 Weight
Health Related	ECI for Wages and Salaries for All Civilian Workers in Hospitals	79.4%	79.9%
Management	ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial	9.0%	6.7%
Administrative	ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support	5.3%	7.7%
Services	ECI for Wages and Salaries for Private Industry Workers in Service Occupations	6.3%	5.7%

Employee Benefits

We proposed to continue using an ECI blend for Employee Benefits in the 2020-based ESRDB market basket where the components match those of the Wage and Salaries ECI blend. The occupation weights for the blended Benefits price proxy (Table 6) are the same as those for the wages and salaries price proxy blend as shown in Table 5. BLS does not publish ECI for Benefits price proxies for each Wage and Salary ECI; however, where these series are not published, they can be derived by using the ECI for Total Compensation and the relative importance of wages and salaries with total compensation as published by BLS for each detailed ECI occupational index.

Health Related Benefits

We proposed to continue using the ECI for Benefits for All Civilian Workers in Hospitals to measure price growth of this subcategory. This is calculated using the ECI for Total Compensation for All Civilian Workers in Hospitals (BLS series code #CIU10162200000000I) and the relative importance of Wages and Salaries within Total Compensation as published by BLS. As we stated in the CY 2023 ESRD PPS proposed rule, we believe this constructed ECI series is technically appropriate for the reason stated in the Wages and Salaries price proxy section.

Management Benefits

We proposed to continue using the ECI for Benefits for Private Industry Workers in Management, Business, and Financial to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU2010000110000I) and the relative importance of wages and salaries within total compensation. As we stated in the CY 2023 ESRD PPS proposed rule, we believe this constructed ECI series is technically appropriate for the reason stated in the Wages and Salaries price proxy section.

Administrative Benefits

We proposed to continue using the ECI for Benefits for Private Industry Workers in Office and Administrative Support to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code #CIU2010000220000I) and the relative importance of Wages and Salaries within Total Compensation. As we stated in the CY 2023 ESRD PPS proposed rule, we believe this constructed ECI series is technically appropriate for the reason stated in the wages and salaries price proxy section.

Services Benefits

We proposed to continue using the ECI for Total Benefits for Private Industry Workers in Service Occupations (BLS series code #CIU2030000300000I) to measure price growth of this subcategory. As we stated in the CY 2023 ESRD PPS proposed rule, we believe this ECI series is

technically appropriate for the reason stated in the Wages and Salaries price proxy section. We also stated we believe the proposed benefits ECI blend continues to be the most appropriate price proxy to measure the growth of benefits prices faced by ESRD facilities. Table 6 lists the four ECI series and the corresponding weights used to construct the proposed benefits ECI blend.

TABLE 6: ECI Blend for Benefits in the 2020-Based and 2016-Based ESRDB Market Baskets

Cost Category	ECI Series	2020 Weight	2016 Weight
Health Related	ECI for Benefits for All Civilian Workers in Hospitals.	79.4%	79.9%
Management	ECI for Benefits for Private Industry Workers in Management, Business, and Financial.	9.0%	6.7%
Administrative	ECI for Benefits for Private Industry Workers in Office and Administrative Support.	5.3%	7.7%
Services	ECI for Benefits for Private Industry Workers in Service Occupations.	6.3%	5.7%

Electricity

We proposed to continue using the PPI Commodity for Commercial Electric Power (BLS series code #WPU0542) to measure the price growth of this cost category.

Natural Gas

We proposed to continue using the PPI Commodity for Commercial Natural Gas (BLS series code #WPU0552) to measure the price growth of this cost category.

Pharmaceuticals

ESAs: We proposed to continue using the PPI Commodity for Biological Products, Excluding Diagnostic, for Human Use (which we will abbreviate as PPI–BPHU) (BLS series code #WPU063719) as the price proxy for the ESA drugs in the market basket. The PPI–BPHU measures the price change of prescription biologics, and ESAs will be captured within this index, if they are included in the PPI sample. Since the PPI relies on confidentiality with respect to the companies and drugs/biologicals included in the sample, we explained that we do not know if these drugs are indeed reflected in this price index. However, as we stated in the CY 2023 ESRD PPS proposed rule, we believe the PPI–BPHU is an appropriate proxy to use because although ESAs may be a small part of the fuller category of biological products, we can examine whether the price increases for the ESA drugs are similar to the drugs included in the PPI–BPHU. We did this by comparing the historical price changes in the PPI–BPHU and the average sales price (ASP) for ESAs and found the cumulative growth to be consistent over the past 4 years. We stated that we will continue to monitor the trends in the prices for ESA drugs as measured by other price data sources to ensure that the PPI–BPHU is still an appropriate price proxy.

Other Drugs (except ESA): For all other drugs included in the ESRD PPS bundled payment other than ESAs, we proposed to use a blend of 50 percent of the PPI Commodity for Vitamin, Nutrient, and Hematinic Preparations (which we will abbreviate as PPI–VNHP) (BLS series code #WPU063807), and 50 percent of the PPI Commodity for Pharmaceuticals for human use, prescription (which we will abbreviate as PPI-Pharmaceuticals) (BLS series code #WPUSI07003). As we stated in the CY 2023 ESRD PPS proposed rule, we continue to believe that the PPI–VNHP is an appropriate price proxy for the iron supplements commonly used in the treatment of ESRD, and an analysis of claims data indicated that iron supplement costs account for about half of the All Other ESRD-related Drugs costs. For the remaining drugs represented in the non-ESA drug category (such as calcimimetics and Vitamin D analogs) we believed a different price proxy would be more appropriate and we proposed to use the PPI Commodity for Pharmaceuticals for human use, prescription, which captures the inflationary price pressures for all types of prescription drugs rather than a single therapeutic category of drugs. Though this PPI measure includes a wide variety of prescription drugs, we noted that we believe it is technically appropriate to use a broad indicator of prescription drug price trends for three key reasons: (1) the more detailed PPI measure where we believe these types of non-ESA drugs will be captured will more likely reflect price trends not faced by ESRD facilities, such as cancer drugs, (2) there have been notable changes to the types and mix of drugs paid for under the ESRD PPS bundled payment since 2016, such as the inclusion of formerly oral-only calcimimetics and the addition of AKI-related drugs, and (3) the potential for future changes to the types and mix of drugs that may be paid for under the ESRD PPS bundled payment, such as when other drugs that are currently oral-only drugs are included in the ESRD PPS beginning for CY 2025. For these reasons, as we stated in the CY 2023 ESRD PPS proposed rule, we believe that a broader drug index representing a larger mix of prescription drugs is a technical improvement to the proposed price proxy for this cost category. We stated that we will continue to monitor the relative share of expenses for iron supplements and other types of drugs for this cost category to determine if the 50/50 PPI blend warrants an adjustment, and if so, we will propose such an adjustment in future rulemaking.

Supplies

We proposed to continue using the PPI Commodity for Surgical and Medical Instruments (BLS series code #WPU1562) to measure the price growth of this cost category.

Laboratory Services

We proposed to continue using the PPI Industry for Medical Laboratories (BLS series code #PCU621511621511) to measure the price growth of this cost category.

Telephone Service

We proposed to continue using the CPI U.S. city average for Telephone Services (BLS series code #CUUR0000SEED) to measure the price growth of this cost category.

Housekeeping

We proposed to continue using the PPI Commodity for Cleaning and Building Maintenance Services (BLS series code #WPU49) to measure the price growth of this cost category.

Operations & Maintenance

For the Operations & Maintenance cost category, we proposed to use the ECI for Total compensation for All Civilian workers in Installation, maintenance, and repair (BLS series code #CIU1010000430000I) to measure the price growth of this cost category. This price proxy accounts for the compensation expenses related to maintenance and repair workers. As we stated in the CY 2023 ESRD PPS proposed rule, we believe the majority of expenses for maintenance and repair to be labor-related costs and therefore, believe that this ECI is the most technically appropriate price proxy for this cost category.

Professional Fees

We proposed to continue using the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code #CIU2010000120000I) to measure the price growth of this cost category.

All Other Goods and Services

We proposed to continue using the PPI Commodity for Final demand—Finished Goods Less Foods and Energy (BLS series code #WPUFD4131) to measure the price growth of this cost category.

Capital-Related Building and Fixtures

We proposed to continue using the PPI Industry for Lessors of Nonresidential Buildings (BLS series code #PCU531120531120) to measure the price growth of this cost category.

Capital-Related Moveable Equipment

We proposed to continue using the PPI Commodity for Electrical Machinery and Equipment (BLS series code #WPU117) to measure the price growth of this cost category.

Table 7 shows all the proposed price proxies and cost weights for the 2020-based ESRDB Market Basket.

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TABLE 7: Price Proxies and associated Cost Weights for the 2020-based ESRDB Market Basket

Cost Category	Price Proxy	2020 Cost Weight
Total ESRDB Market Basket		100.0%
Compensation		**45.9%**
Wages and Salaries		36.5%
Health-related	ECI for Wages and Salaries for All Civilian Workers in Hospitals.	28.9%
Management	ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial.	3.3%
Administrative	ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support.	1.9%
Services	ECI for Wages and Salaries for Private Industry Workers in Service Occupations.	2.3%
Employee Benefits		9.5%
Health-related	ECI for Total Benefits for All Civilian workers in Hospitals.	7.5%
Management	ECI for Total Benefits for Private Industry workers in Management, Business, and Financial.	0.9%
Administrative	ECI for Total Benefits for Private Industry workers in Office and Administrative Support.	0.5%
Services	ECI for Total Benefits for Private Industry workers in Service Occupations.	0.6%
Utilities		**1.4%**
Electricity	PPI Commodity for Commercial Electric Power.	1.2%
Natural Gas	PPI Commodity for Commercial Natural Gas.	0.1%
Medical Materials and Supplies		**22.4%**
Pharmaceuticals		10.1%
ESAs	PPI Commodity for Biological Products, Excluding Diagnostics, for Human Use.	6.0%
Other Drugs	50/50 blend of the PPI Commodity for Vitamin, Nutrient, and Hematinic Preparations, and the PPI Commodity for Pharmaceuticals for human use, prescription	4.1%
Supplies	PPI Commodity for Surgical and Medical Instruments.	11.0%

Cost Category	Price Proxy	2020 Cost Weight
Laboratory Services	PPI Industry for Medical Laboratories.	1.3%
All Other Goods and Services		**16.6%**
Telephone Service	CPI-U for Telephone Services.	0.5%
Housekeeping	PPI Commodity for Cleaning and Building Maintenance Services.	0.5%
Operations & Maintenance	ECI for Total compensation for All Civilian workers in Installation, maintenance, and repair	3.7%
Professional Fees	ECI for Total Compensation for Private Industry Workers in Professional and Related.	0.8%
All Other Goods and Services	PPI for Final demand - Finished Goods less Foods and Energy.	11.1%
Capital Costs		**13.8%**
Capital Related Building and Fixtures	PPI Industry for Lessors of Nonresidential Buildings.	9.4%
Capital Related Moveable Equipment	PPI Commodity for Electrical Machinery and Equipment.	4.4%

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and therefore, the detail may not add to the total due to rounding.

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We received several comments regarding the proposed price proxies in the 2020-based ESRDB market basket. The comments and our responses are set forth below.

Comment: Several commenters, including a coalition of dialysis organizations, supported the proposal to adopt the PPI Commodity for Pharmaceuticals for human use, prescription (BLS series code #WPUSI07003) within the blended price proxy for Non-ESA drugs in the ESRDB market basket. They stated that they believe the majority of the non-ESA drugs in the ESRD PPS bundled payment align with this proxy and not the PPI Commodity data for Chemicals and allied products-Vitamin, nutrient, and hematinic preparations. The commenters requested for CMS to monitor the impact of this change and adjust the weight of the blended proxy in future years, if appropriate, and for CMS to potentially consider breaking out the weight for the non-ESA blend formally into two separate market basket categories in the future.

Response: We appreciate the commenters' support for the proposed 50/50 blended price proxy for the Non-ESA drug cost category. We will continue to monitor the mix of the expenses for the non-ESA drugs accounted for in this category and consider if it may be appropriate to propose to adjust the cost weights of this blended price proxy through future notice and comment rulemaking.

Comment: One LDO expressed that they believe the process and indices used by CMS to capture year over year growth in the ESRDB market basket have worked relatively well since the ESRD PPS was implemented in 2011. The commenter stated that they do not object to CMS's use of the ECI for Wages and Salaries for All Civilian Workers in Hospitals as the price proxy for the ESRDB market basket's health-related occupations; however, they have concerns that the ECI is not designed to accurately capture rapid changes in inflation and market dynamics of the type seen as a result of the COVID–19 PHE. Specifically, the commenter stated that ESRD facilities have experienced dramatic increases in overtime pay, dramatic increases in hiring bonuses, increases in travel costs, and a higher dependency on travel nurses and staffing agencies, which demand hourly rates that far exceed the average. One LDO and a non-profit dialysis association cited a study by Altarum that showed that between July 2021 and June 2022, healthcare wages grew by an average of 6.9 percent, compared to 5.1 percent for all private sector jobs. The same study showed that average hourly earnings in healthcare grew 7.4 percent, compared to 5.2 percent across all private sector jobs. The study also showed that the quantity of healthcare workers has decreased relative to the levels from before the COVID–19 PHE, reporting 78,000 fewer workers in July 2022 compared to February 2020. The nonprofit dialysis association noted that while other industries outside of healthcare may be able to fund the rising costs of labor by increasing their prices or improving efficiency, ESRD facilities are unable to do so because the majority of ESRD patients are Medicare beneficiaries, and therefore the majority of ESRD facilities' revenue is determined by the Federal government. The nonprofit dialysis association further noted that ESRD facilities have specialized requirements—many of which are codified in Federal regulations—for dialysis nurses, home

dialysis nurse specialists, and dialysis patient care technicians, that require additional education, training, experience, and certification beyond what is often required of clinical staff in other healthcare settings. As a result, the commenter stated, ESRD facilities can be easily outbid for clinical workers by better financed hospitals, health plans, clinical practices, and other healthcare settings that may also have fewer clinical requirements.

Response: The ESRDB market basket reflects changes over time in the price of providing renal dialysis services and will not reflect increases in costs associated with changes in the volume or intensity of input goods and services. To measure price growth for ESRD facility wages and salaries costs, the ESRDB market basket relies on a blend of ECIs reflecting the occupational skill mix of FTEs as reported on the 2020 Medicare cost report forms. The majority of the weight for compensation costs is for health-related occupations, and accounts for approximately 80 percent of the ESRD facility compensation costs. The health-related workers' Wages and Salaries, and Benefits, cost categories use the ECI for wages and salaries and the ECI for benefits for civilian hospital workers, respectively. We believe that these ECIs are the best available price proxies to account for the health-related workers' occupational skill mix within ESRDs. The BLS Occupational Employment and Wage Statistics (OEWS) data are one of the primary data sources used to derive the weights for the ECI. In 2020, which we proposed as the base year of the ESRDB market basket, a little over 56 percent of total employment for NAICS 622100 was attributed to Health Professional and Technical occupations, and approximately 13 percent was attributed to Health Service occupations. Therefore, in the absence of ESRD-specific data, we believe that the highly skilled hospital workforce captured by the ECI for hospital workers (inclusive of therapists, nurses, and other clinicians) is a reasonable proxy for the compensation component of the ESRDB market basket. Additionally, we believe that by utilizing the relative distribution of workers based on the FTE data reported on the ESRD cost report, the occupational distribution of the compensation costs weights is technically appropriate.

Comment: One LDO encouraged CMS to provide more transparency regarding the ESRDB market basket price proxies forecasting models' methodologies and underlying assumptions, and stated that greater transparency could better inform stakeholder feedback and help identify opportunities to improve the models' capacity to capture economic anomalies that facilities have encountered in recent years.

Response: We appreciate the commenter's feedback on improving the forecasting model capacity of the price proxies used in the ESRDB market basket. CMS uses independent forecasts of the price proxies for the CMS market baskets from IHS Global Inc. (IGI), a nationally recognized economic and financial forecasting firm. The rationale for using an independent forecaster is to ensure neutrality in the annual ESRDB market basket increase and productivity adjustment while reflecting comprehensive economic and health sector forecasting model capabilities that extend beyond CMS' expertise. As the forecasting models are proprietary in nature, we are not licensed to share information related to the detailed models. More information on the IGI economic forecasts can be found at the following website, *https://ihsmarkit.com/products/US-economic-modeling-forecasting-services.html*.

Final Rule Action: After consideration of the public comments we received, we are finalizing the 2020-based ESRDB market basket price proxies as proposed.

(d) Rebasing Results

As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38479), a comparison of the yearly differences of increase factors from CY 2019 to CY 2023 for the 2016-based ESRDB market basket and the 2020-based ESRDB market basket showed that the CY 2023 ESRDB market basket increase factor would be 0.2 percentage point lower if we continued to use the 2016-based ESRDB market basket. For the years prior to CY 2023 the annual market basket increase factors were the same, except for CY 2021 where the 2020-based market basket was 0.1 percentage point lower. We did not receive any comments related to the comparison of the ESRDB market basket updates comparing the 2016-based and 2020-based ESRDB market baskets.

(2) Labor-Related Share for the ESRD PPS

We define the labor-related share (LRS) as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market.

We proposed to use the 2020-based ESRDB market basket cost weights to determine the proposed labor-related share for ESRD facilities. Specifically, effective for CY 2023, we proposed a labor-related share of 55.2 percent, compared to the current 52.3 percent that was based on the 2016-based ESRDB market basket, as shown in Table 8. These figures represent the sum of Wages and Salaries, Benefits, Housekeeping, Operations & Maintenance, 87 percent of the weight for Professional Fees (details discussed later in this subsection), and 46 percent of the weight for Capital-related Building and Fixtures expenses (details discussed later in this subsection). We used the same methodology for the 2016-based ESRDB market basket.

TABLE 8: Labor-Related Share of Current and ESRD Bundled Market Baskets

Cost Category	2020-based ESRDB Market Basket Weights	2016-based ESRDB Market Basket Weights
Wages and Salaries	36.5	34.5
Employee Benefits	9.5	9.1
Housekeeping*	0.5	3.9
Operations & Maintenance	3.7	n/a
Professional Fees (Labor-Related)	0.7	0.6
Capital Labor-Related	4.3	4.2
Total Labor-Related Share	55.2	52.3

*The 2016-based ESRDB labor-related share had a combined category weight for Housekeeping and Operations

As discussed in the CY 2023 ESRD PPS proposed rule, the proposed labor-related share for Professional Fees reflects the proportion of ESRD facilities' professional fees expenses that we believe vary with local labor market (87 percent). We conducted a survey of ESRD facilities in 2008 to better understand the proportion of contracted professional services that ESRD facilities typically purchase outside of their local labor market. These purchased professional services include functions such as accounting and auditing, management consulting, engineering, and legal services. Based on the survey results, we determined that, on average, 87 percent of professional services are purchased from local firms and 13 percent are purchased from businesses located outside of the ESRD's local labor market. Thus, we included 87 percent of the cost weight for Professional Fees in the labor-related share (87 percent is the same percentage as used in prior years).

As discussed in the CY 2023 ESRD PPS proposed rule, the proposed labor-related share for capital-related expenses reflects the proportion of ESRD facilities' capital-related expenses that we believe varies with local labor market wages (46 percent of ESRD facilities' Capital-related Building and Fixtures expenses). Capital-related expenses are affected in some proportion by variations in local labor market costs (such as construction worker wages) that are reflected in the price of the capital asset. However, many other inputs that determine capital costs are not related to local labor market costs, such as interest rates. The 46-percent figure is based on regressions run for the inpatient hospital capital PPS in 1991 (56 FR 43375). We noted that we use a similar methodology to calculate capital-related expenses for the labor-related shares for rehabilitation facilities (70 FR 30233), psychiatric facilities, long-term care facilities, and skilled nursing facilities (66 FR 39585).

We received several comments regarding our calculation of the proposed labor-related share based on the 2020-based ESRDB market basket. The comments and our responses are set forth below.

Comment: Several commenters, including a coalition of dialysis organizations, a nonprofit dialysis association, and a provider advocacy organization, supported the proposed increase of the labor share from 52.3 percent to 55.2 percent, and stated that their experience is that the costs of labor are rising exponentially. The commenters further stated that they do not believe that shifting the market basket percentage alone will address the labor shortage's impact on payments and costs.

Response: We appreciate the commenters' support of the proposed labor-related share. This increase in the ESRD PPS labor-related share reflects the relative increase in labor-related costs compared to non-labor-related costs that ESRD facilities have experienced since 2016 and through 2020. We will continue to monitor the ESRD cost report data for significant changes to the ESRD cost share weights.

Final Rule Action: After consideration of the public comments we received, we are finalizing the 2020-based labor-related share of 55.2 percent effective for CY 2023, as proposed.

(3) CY 2023 ESRD Market Basket Increase Factor, Adjusted for Productivity

Under section 1881(b)(14)(F)(i) of the Act, beginning in CY 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. We proposed to use the 2020-based ESRDB market basket as described in section II.B.1 of this final rule to compute the CY 2023 ESRDB market basket increase factor and labor-related share based on the best available data. Consistent with historical practice, we proposed to estimate the ESRDB market basket increase factor based on IGI's forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets.

(a) CY 2023 Market Basket Increase Factor

Based on IGI's first quarter 2022 forecast, the proposed 2020-based ESRDB market basket increase factor for CY 2023 was projected to be 2.8 percent. We also proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket update or productivity adjustment), we would use such data, if appropriate, to determine the CY 2023 market basket update in this final rule. Based on the more recent data available for this CY 2023 ESRD PPS final rule (that is, IGI's third quarter 2022 forecast of the 2020-based ESRDB market basket with historical data through the second quarter of 2022), we

estimate that the ESRD PPS CY 2023 market basket update is 3.1 percent.

(b) Productivity Adjustment

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the ''productivity adjustment''). MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The detailed methodology for deriving the MFP projection was finalized in the CY 2012 ESRD PPS final rule (76 FR 70232 through 70235).

BLS publishes the official measures of productivity for the U.S. economy. As we noted in the CY 2023 ESRD PPS proposed rule, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act previously was published by BLS as private nonfarm business MFP. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term ''multifactor productivity'' with ''total factor productivity'' (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology.[2] As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business TFP; however, as mentioned previously, the data and methods are unchanged. We referred readers to *https://www.bls.gov/productivity/* 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, in the CY 2022 ESRD PPS final rule (86 FR 61879), we noted that effective for CY 2022 and future years, CMS will be changing the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment. We stated this was not a change in policy, as we will continue to use the same methodology for deriving the adjustment and rely on the same underlying data.

As discussed in the CY 2023 ESRD PPS proposed rule, based on IGI's first quarter 2022 forecast with historical data through the fourth quarter of 2021, the proposed productivity adjustment for CY 2023 (the 10-year moving average of TFP for the period ending CY 2023) was projected to be 0.4 percentage point. Furthermore, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the market basket and/or productivity adjustment), we would use such data, if appropriate, to determine the CY 2023 market basket update and productivity adjustment in this final rule. Based on the more recent data available from IGI's third quarter 2022 forecast, the current estimate of the productivity adjustment for CY 2023 is 0.1 percentage point.

(c) CY 2023 Market Basket Increase Factor Adjusted for Productivity

In accordance with section 1881(b)(14)(F)(i) of the Act, we proposed to base the CY 2023 market basket update, which is used to determine the applicable percentage increase for the ESRD PPS payments, on IGI's first quarter 2022 forecast of the 2020-based ESRDB market basket. We proposed to then reduce this percentage increase by the estimated productivity adjustment for CY 2023 of 0.4 percentage point (the 10-year moving average growth of TFP for the period ending CY 2023 based on IGI's first quarter 2022 forecast). Therefore, the proposed CY 2023 ESRDB update was equal to 2.4 percent (2.8 percent market basket update reduced by the 0.4 percentage point productivity adjustment). Furthermore, as noted previously, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the market basket and/or productivity adjustment), we would use such data, if appropriate, to determine the CY 2023 market basket update and productivity adjustment in this final rule.

We invited public comment on our proposals for the CY 2023 market basket update and productivity adjustment. The following is a summary of the public comments received on the proposed CY 2023 market basket update and productivity adjustment and our responses:

Comment: Many commenters, including an LDO, a provider advocacy organization, a nonprofit dialysis association, a coalition of dialysis organizations, a network of dialysis organizations, and a professional organization, generally supported the utilization of the most recent data available (for example, a more recent estimate of the market basket and/or productivity adjustment) to determine the final CY 2023 ESRD PPS update. MedPAC recommended that the ESRD PPS base rate increase for CY 2023 should be updated by the amount determined under current law, and that analysis reported in the March 2022 Report to the Congress: Medicare Payment Policy [3] concluded that this increase is warranted based on analysis of payment adequacy (which includes an assessment of beneficiary access, supply and capacity of facilities, facilities' access to capital, quality, and financial indicators for the sector). At the same time, other commenters expressed their concern that the CY 2023 ESRD PPS update insufficiently captures the rising costs that ESRD facilities have experienced and continue to experience, particularly the impact of the health-related compensation costs. However, commenters expressed different views about the scope and nature of the staffing challenges facing ESRD facilities. A provider advocacy organization claimed that the ongoing COVID–19 PHE is creating significant and lasting effects on staffing and supply costs. In contrast, a patient-led dialysis organization maintained that the current labor shortages are not a temporary phenomenon related to the ongoing COVID–19 PHE, but the result of a demographic shift in labor market conditions in the healthcare industry. This commenter stated that the American workforce as a whole has shrunk, and mentioned a 2008 report from the Institute of Medicine that further described the demographic shift the commenter identified.[4] Many commenters requested that CMS consider using its statutory authority to apply a labor add-on payment adjustment to the ESRD PPS for CY 2023.

Many commenters, including LDOs, ESRD facilities, professional associations, patients, provider advocacy organizations, and a coalition of dialysis organizations, stated that a labor add-on payment adjustment factor is needed because ESRD facilities have

[2] Total Factor Productivity in Major Industries—2020. Available at: *https://www.bls.gov/news.release/prod5.nr0.htm.*

[3] *https://www.medpac.gov/document/march-2022-report-to-the-congress-medicare-payment-policy/.*

[4] *https://pubmed.ncbi.nlm.nih.gov/25009893/.*

had to contend with rising costs in labor, medical supplies, and rent. They noted that the largest contributor to higher input costs is accelerating labor costs, which have been exacerbated by the nation-wide shortages in qualified clinical staff, and that they need to increasingly rely on contract labor, which has led to a significant, permanent increase in labor costs.

Response: We are required to update ESRD PPS bundled payments by the market basket update adjusted for productivity under section 1881(b)(14)(F)(i) of the Act, which states that the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. We believe the 2020-based ESRDB market basket increase adequately reflects the average change in the price of goods and services ESRD facilities purchase to provide renal dialysis services, and is technically appropriate to use as the ESRD PPS payment update factor. The ESRDB market basket is a fixed-weight, Laspeyres-type index that reflects changes over time in the price of providing renal dialysis services and will not reflect increases in costs associated with changes in the volume or intensity of input goods and services. As such, the ESRDB market basket update will reflect the prospective price pressures described by the commenters as increasing during a high inflation period (such as faster wage growth or higher energy prices), but inherently will not reflect other factors that might increase the level of costs, such as the quantity of labor used. However, as we note in section II.B.1.a.(2) of this CY 2023 ESRD PPS final rule, the 2020-based ESRDB market basket reflects an increase to the cost category weights for labor-related costs. Therefore, the final CY 2023 ESRDB market basket update reflects the most recent available data regarding both prices and the quantity of labor used to provide renal dialysis services.

We agree with the commenters who stated that recent higher inflationary trends have impacted the outlook for price growth over the next several quarters. At the time of the CY 2023 ESRD PPS proposed rule, based on the IGI first quarter 2022 forecast with historical data through the fourth quarter of 2021, the 2020-based ESRDB market basket update was forecasted to be 2.8 percent for CY 2023, reflecting forecasted compensation prices of about 3.9 percent (by comparison, compensation growth in the ESRDB market basket averaged 2.2 percent from 2012 through 2021). In the CY 2023 ESRD PPS proposed rule, we proposed that if more recent data became available, we would use such data, if appropriate, to derive the final CY 2023 ESRDB market basket update for the final rule. For this final rule, we now have an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the U.S. economy and expected price inflation for CY 2023 for ESRD facilities. Based on the IGI third quarter 2022 forecast with historical data through the second quarter of 2022, we are projecting a CY 2023 ESRDB market basket update of 3.1 percent (reflecting forecasted compensation growth of 4.5 percent) and productivity adjustment of 0.1 percentage point. Therefore, for CY 2023, a final productivity adjusted ESRDB market basket update of 3.0 percent (3.1 percent less 0.1 percentage point) will be applicable, compared to the 2.4 percent productivity adjusted ESRDB market basket update that was proposed.

As for commenters' suggestions for alternatives to the productivity-adjusted ESRDB market basket update for CY 2023, as noted previously, we are required by statute to update ESRD PPS payments by the market basket update adjusted for productivity. Any change to the productivity adjusted-market basket update would require legislation to amend the statute. While we acknowledge the commenters' suggestions that we apply an add-on payment adjustment to the ESRD PPS for CY 2023 to account for increasing labor costs, we note that we did not propose to establish an add-on payment adjustment for labor under section 1881(b)(14)(D)(iv) of the Act or to use other methods or data sources to update ESRD PPS payment rates for CY 2023, and we are not finalizing such an approach for this final rule. We proposed to update ESRD PPS payments by the market basket update, which is consistent with the statute and our longstanding policy for updating the ESRD PPS base rate. We do not believe it would be appropriate to apply additional adjustments to the ESRD PPS base rate to circumvent the statutorily-required market basket update. Further, as discussed earlier in this section of this final rule, we are finalizing our proposal to rebase the ESRDB market basket to reflect more recent data on ESRD facility cost structures, and we believe this rebased ESRDB market basket appropriately reflects the prospective price pressures described by the commenters as increasing during a high inflation period. Consistent with our proposal, we have used more recent data to calculate a final ESRDB productivity-adjusted market basket update of 3.0 percent for CY 2023.

Comment: Several commenters, including an LDO and a coalition of dialysis organizations, recognized that CMS does not have the authority to eliminate the productivity adjustment from the annual ESRD PPS update calculation, but stated that they continue to be concerned by the historically small and even negative Medicare margins, and that the experience of ESRD facilities is contrary to the idea that productivity can be improved year-over-year. The commenters also stated their view that the current productivity adjustment does not capture factors unique to ESRD facilities, such as required staffing structures or operational changes required due to the impact of the COVID–19 PHE, including establishing cohort clinics to minimize disruptions in care that can impede improvements in productivity.

One LDO stated that CMS's current approach, which applies the same adjustment across the board to other sectors subject to a reduction for productivity, is a blunt instrument. This commenter recommended that CMS work with the kidney care community and policymakers to revisit this policy and devise a productivity adjustment that: (1) better reflects factors over which ESRD facilities have control and that affect opportunity for productivity gains, and (2) accounts for the statutory reductions to the ESRD PPS already in place to account for expected gains in efficiency.

Response: We acknowledge the commenters' concerns regarding productivity growth at the economy-wide level and its application to ESRD facilities; however, as the commenters acknowledge, section 1881(b)(14)(F)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the ESRD PPS market basket increase factor for 2012 and subsequent years. As required by statute, the CY 2023 productivity adjustment is derived based on the 10-year moving average growth in economy-wide productivity for the period ending CY 2023. We will continue to monitor the impact of the ESRD PPS updates, including the effects of the productivity adjustment, on ESRD facility margins as well as beneficiary access to care as reported by MedPAC in their annual Report to the Congress.

Comment: Many commenters, including LDOs, ESRD facilities,

professional associations, patients, provider advocacy organizations, and a coalition of dialysis organizations, requested that CMS apply a forecast error payment adjustment to the ESRD PPS base rate to support ESRD facilities during this inflationary period, particularly accounting for what commenters state is an error in the forecasted payment updates for CYs 2021 and 2022. The commenters stated that forecasted payment updates that they view as incorrect, coupled with the impact of the workforce shortage, have put them in financial difficulty. The commenters suggested that CMS should apply the actual percent increase in the market basket for the two CYs, 2021 and 2022, where the forecast missed its mark. The commenters highlighted that CMS has applied this type of an adjustment in other parts of the Medicare program historically, such as for SNFs, and could do so for the ESRD PPS on a temporary or even permanent basis. A couple of commenters recommended that the forecast error correction could be designed and implemented in a manner similar to the SNF market basket forecast error correction, triggered by positive and negative forecast errors that exceed 0.5 percentage points.

One provider advocacy organization stated that they understand that this is not a customary practice for CMS, but these extraordinary times call for extraordinary measures and CMS has discretion to implement a forecast error adjustment based on section 1881(b)(14)(D)(iv) of the Act, which states that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. This commenter further stated that while they recognize that updates to the ESRD market basket are set prospectively, and some degree of forecast error is inevitable, ESRD facilities should not be financially disadvantaged as a result of CMS market basket forecasting errors. This commenter, along with one LDO, stated that they believe establishing a forecast error payment adjustment in the ESRD PPS is within CMS' existing statutory authority under section 1881(b)(F)(i)(I) of the Act.

Several commenters, including an LDO, a coalition of dialysis organizations, and a nonprofit dialysis association, stated that failure to correct for the missed IGI forecast error projections of the market basket updates for CYs 2021 and 2022 will result in chronic underfunding of the ESRD PPS going forward. These commenters stated that each successive update to the ESRD PPS base rate will be building on a previous rate that has never accounted for the large and rapid inflationary trends in CY 2021 through CY 2023. One LDO and a coalition of dialysis organizations further expressed that a forecast error payment adjustment is imperative given the Medicare ESRD PPS's current narrow margins and the fact that over 90 percent of the ESRD beneficiaries rely on Medicare coverage.

Response: As discussed previously, the ESRDB market basket updates are set prospectively, which means that the update relies on a mix of both historical data for part of the period for which the update is calculated, and forecasted data for the remainder. For instance, the CY 2023 market basket update in this final rule reflects historical data through the second quarter of CY 2022 and forecasted data through the fourth quarter of CY 2023. While there is no precedent to adjust for market basket forecast error in the annual ESRD PPS update, the forecast error for a market basket update is calculated as the actual market basket increase for a given year less the forecasted market basket increase.[5] Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative. For example, the CY 2017 ESRDB forecast error was −0.8 percentage point, while the CY 2021 ESRDB forecast error was +1.2 percentage point; CY 2022 historical data is not yet available to calculate a forecast error for CY 2022.

As discussed earlier in this section of this final rule, our longstanding policy since the inception of the ESRD PPS has been to update ESRD PPS payments based on an appropriate market basket in accordance with section 1881(b)(14)(F)(i) of the Act. For this final rule, we have incorporated more recent historical data and forecasts, which utilize the most current projections of expected future price and wage pressures likely to be faced by ESRD facilities to provide renal dialysis services. We did not propose a forecast error payment adjustment for CY 2023, and we are not finalizing such an adjustment for this final rule. As we have discussed in past rulemaking (85 FR 71434; 80 FR 69031) and in section II.B.1.b.(2) of this final rule, predictability in Medicare payments is important to enable ESRD facilities to budget and plan their operations. As we noted earlier in this section, forecast error calculations are unpredictable, and can be both positive and negative. We note that over longer periods of time, the positive differences between the actual and forecasted market basket increase in prior years can offset negative differences; therefore, we do not believe it is necessary to implement a forecast error payment adjustment for the ESRD PPS based solely on a positive CY 2021 forecast error.

Final Rule Action: After consideration of the comments we received, we are finalizing a CY 2023 ESRDB productivity-adjusted market basket increase of 3.0 percent based on the most recent data available. As noted previously, based on the more recent data available for this CY 2023 ESRD PPS final rule (that is, IGI's third quarter 2022 forecast of the 2020-based ESRDB market basket with historical data through the second quarter of 2022), the CY 2023 ESRDB market basket update is 3.1 percent. Based on the more recent data available from IGI's third quarter 2022 forecast, the current estimate of the productivity adjustment for CY 2023 is 0.1 percentage point. Therefore, the current estimate of the CY 2023 ESRD productivity-adjusted market basket increase factor is equal to 3.0 percent (3.1 percent market basket update reduced by 0.1 percentage point productivity adjustment).

b. CY 2023 ESRD PPS Wage Indices

(1) Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. We use OMB's CBSA-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The bulletins are available online at *https://www.whitehouse.gov/omb/information-for-agencies/bulletins/*.

For CY 2023, we proposed to update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We proposed to use the most recent pre-floor, pre-reclassified

[5] FAQ—Market Basket Definitions and General Information. Available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/info.pdf*.

hospital wage data collected annually under the inpatient PPS. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d) (10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. For CY 2023, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2018, and before October 1, 2019 (FY 2019 cost report data).

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For a full discussion, see the CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the State to serve as a reasonable proxy for the wage index of that urban CBSA, that is, we use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. We applied the statewide urban average based on the average of all urban areas within the State to Hinesville-Fort Stewart, Georgia (78 FR 72173), and we applied the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172).

A wage index floor value (0.5000) is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico. However, the wage index floor value is applicable for any area that may fall below the floor. A description of the history of the wage index floor under the ESRD PPS can be found in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967).

An ESRD facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2019 ESRD PPS final rule (83 FR 56963), we finalized a labor-related share of 52.3 percent, which was based on the 2016-based ESRDB market basket. In the CY 2021 ESRD PPS final rule (85 FR 71436), we updated the OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, beginning with the CY 2021 ESRD PPS wage index. In addition, we finalized the application of a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. We finalized that the transition would be phased in over 2 years, such that the reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022. For CY 2023, as discussed in section II.B.1.a(2) of this final rule, the labor-related share to which the wage index will be applied is 55.2 percent, based on the 2020-based ESRDB market basket.

For CY 2023, we proposed to update the ESRD PPS wage index to use the most recent hospital wage data. The CY 2023 ESRD PPS wage index is set forth in Addendum A and is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.* Addendum A provides a crosswalk between the CY 2022 wage index and the CY 2023 wage index. Addendum B provides an ESRD facility level impact analysis. Addendum B is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.*

We received several comments on our proposal to update the ESRD PPS wage index. The comments and our responses are set forth below.

Comment: Four commenters, including an ESRD facility, a physician, and a dialysis administrator, expressed concerns that the ESRD PPS wage index does not reflect the realities faced by dialysis clinics and would lead to too low payments to hire and retain staff. These commenters pointed to inflation and the COVID–19 PHE as main factors driving the increase in healthcare wages. Several commenters representing a network of rural ESRD facilities indicated that they thought the wage index was too low for their area, not accurately reflecting the cost of labor.

Response: We appreciate the concerns that commenters raised; however, we did not propose to change the wage index methodology for CY 2023 and are not finalizing any changes to that methodology in this final rule. The wage data used to construct the ESRD PPS wage index are updated annually, based on the most current data available, and are based on OMB's CBSA delineations when applying the rural definitions and corresponding wage index values. As discussed in CY 2011 ESRD PPS final rule (75 FR 49200), the wage index reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. Because the wage index is scaled relative to the national average, it does not reflect changes over time to the cost of labor. Rather, it is the market basket increase which accounts for national trends, including inflation. As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38480), we proposed to increase the ESRD PPS base rate for CY 2023 by the market basket increase factor in accordance with section 1881(b)(14)(F)(i) of the Act, which provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services that reflect the costs of furnishing renal dialysis services. As discussed in section II.B.1.a.(3) of this CY 2023 ESRD PPS final rule, the final productivity-adjusted market basket update for CY 2023 is 3.0 percent based on the latest available data. We note that this final update is 0.6 percentage point higher than the proposed update and reflects a revised outlook regarding the U.S. economy and expected price inflation for CY 2023 for ESRD facilities. We believe the final productivity adjusted market basket update will address some of the commenters' concerns regarding rising wages due to inflation.

Comment: Several commenters suggested changes to the wage index methodology. One professional association and one non-profit dialysis facility suggested CMS use a wage index methodology for the ESRD PPS that is consistent with the inpatient payment wage index policies, including using a different labor-related share for ESRD facilities with a low wage index. A non-profit health insurance organization in Puerto Rico suggested CMS implement a payment adjustment for clinics with wage index values in the lowest quartile, similar to the system used by IPPS. A non-profit health insurance organization in Puerto Rico and a healthcare group in Puerto Rico expressed a desire for CMS to create a new wage index based only on data from ESRD facilities. These commenters claimed that the current wage index based on hospital data is inadequate given the differences in staffing needs between ESRD facilities and hospitals.

Response: We appreciate the commenters' suggestions for modifying the methodology for the ESRD PPS wage index. We did not propose changes to the ESRD PPS wage index methodology for CY 2023, and therefore we are not finalizing any changes to that methodology in this final rule. As discussed in section II.B.1.b.(2) of this final rule, we are finalizing a permanent 5-percent cap on any decrease to an ESRD facility's wage index from its

wage index in the prior year, and as discussed in section II.B.1.b.(3) of this final rule, we are finalizing an increase to the wage index floor from 0.5000 to 0.6000. We believe that these final policies will address some of the underlying concerns of the commenters by assisting in the higher labor costs affecting low wage index areas, maintaining the ESRD PPS wage index as a relative measure of the value of labor in prescribed labor market areas, increasing predictability of ESRD PPS payments for ESRD facilities, and mitigating instability and significant negative impacts to ESRD facilities resulting from significant changes to the wage index. We did not propose and are not finalizing other methodological changes that commenters suggested; however, we will take these comments into consideration to potentially inform future rulemaking.

Final Rule Action: We are finalizing our proposal to update the ESRD PPS wage index for CY 2023 to use the most recent hospital wage data, as proposed.

(2) Permanent Cap on Wage Index Decreases

As discussed in section II.B.1.b.(1) of this final rule and in previous ESRD PPS rules, under the authority of section 1881(b)(14)(D)(iv)(II) of the Act, we have proposed and finalized temporary, budget-neutral transition policies in the past to help mitigate negative impacts on ESRD facilities following the adoption of certain ESRD PPS wage index changes. In the CY 2015 ESRD PPS final rule (79 FR 66142), we implemented revised OMB area delineations using a 2-year transition, with a 50/50 blended wage index for all ESRD facilities in CY 2015 [6] and 100 percent of the wage index based on the new OMB delineations in CY 2016. In the CY 2021 ESRD PPS proposed rule (85 FR 42160 through 42161), we proposed a transition policy to help mitigate any negative impacts that ESRD facilities may experience due to our proposal to adopt the 2018 OMB delineations under the ESRD PPS. We noted that because the overall amount of ESRD PPS payments would increase slightly due to the 2018 OMB delineations, the effect of the wage index budget neutrality factor would be to reduce the ESRD PPS per treatment base rate for all ESRD facilities paid under the ESRD PPS, despite the fact that the majority of ESRD facilities would be unaffected by the 2018 OMB delineations. Thus, we explained that we believed it would be appropriate to provide for a transition period to mitigate the resulting short-term instability of a lower ESRD PPS base rate as well as consequential negative impacts to ESRD facilities that experience reduced payments. We proposed to apply a 5-percent cap on any decrease in an ESRD facility's wage index from its final wage index from the prior calendar year, that is, CY 2020. We explained that we believed the 5-percent cap would provide greater transparency and would be administratively less complex than the prior methodology of applying a 50/50 blended wage index (85 FR 71478). We proposed that no cap would be applied to the reduction in the wage index for the second year, that is, CY 2022 (85 FR 42161).

Several commenters to the CY 2021 ESRD PPS proposed rule supported the wage index transition policy that we proposed for CY 2021; however, as discussed in the CY 2021 ESRD PPS final rule (86 FR 71434 through 71436), some commenters expressed concerns about the large negative effects of the new labor market area delineations on certain areas. A patient organization suggested that the 5 percent cap may not provide an adequate transition for labor market areas that would experience a decrease in their wage index of greater than 10 percent. Similarly, a national non-profit dialysis organization recommended that CMS provide an extended transition period, beyond the proposed 5 percent limit for 2021, for at least 3 years. Some commenters, including MedPAC, suggested alternatives to the methodology. MedPAC suggested that the 5 percent cap limit should apply to both increases and decreases in the wage index.

We stated in the CY 2021 ESRD PPS final rule that we believed a 5 percent cap on the overall decrease in an ESRD facility's wage index value would be an appropriate transition, as it would effectively mitigate any significant decreases in an ESRD facility's wage index for CY 2021. With respect to extending the transition period for at least 3 years, we stated that we believed this would undermine the goal of the wage index policy, which is to improve the accuracy of payments under the ESRD PPS, and would serve to further delay improving the accuracy of the ESRD PPS by continuing to pay certain ESRD facilities more than their wage data suggest is appropriate. We also stated that the transition policies are not intended to curtail the positive impacts of certain wage index changes, so it would not be appropriate to also apply the 5 percent cap on wage index increases. We acknowledged that a transition policy was necessary to help mitigate initial significant negative impacts from revised OMB delineations, but expressed that this mitigation must be balanced against the importance of ensuring accurate payments. We finalized the transition policy for CY 2021 as proposed. We did not propose to extend the transition policy for CY 2022 or future years, however, as we discussed in the CY 2022 ESRD PPS final rule (86 FR 61881), we received comments acknowledging and supporting the final phase-in of the updated OMB delineations for CY 2022.

In the CY 2023 ESRD PPS proposed rule (87 FR 38482), we noted that based on our past wage index transition policies and public comments, we recognized that certain changes to our wage index policy may significantly affect Medicare payments to ESRD facilities. Commenters have raised concerns about scenarios in which changes to wage index policy may have significant negative impacts on ESRD facilities. Therefore, in the CY 2023 ESRD PPS proposed rule, we considered how best to address those scenarios.

We explained that in the past, we have established transition policies of limited duration to phase in significant changes to labor market areas, such as revised OMB delineations. In taking this approach in the past, we sought to mitigate short-term instability and fluctuations that can negatively impact ESRD facilities due to wage index changes. In accordance with the ESRD PPS wage index regulations at § 413.231(a), we adjust the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index that is established by CMS, and which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. Our policy is generally to use the most current hospital wage data and analysis available to ensure the accuracy of the ESRD PPS wage index, in accordance with § 413.196(d)(2). As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38482) as well as earlier in this section of the final rule, we believe that past wage index transition policies have helped mitigate initial significant negative impacts from changes such as revised OMB delineations. However, we recognized that changes to the wage index have the potential to create instability and significant negative impacts on certain ESRD facilities even when labor market areas do not change as a result of revised OMB delineations.

[6] ESRD facilities received 50 percent of their CY 2015 wage index value based on the OMB delineations for CY 2014 and 50 percent of their CY 2015 wage index value based on the newer OMB delineations. 79 FR 66142.

In addition, we noted in the proposed rule that year-to-year fluctuations in an area's wage index can occur due to external factors beyond an ESRD facility's control, such as the COVID–19 PHE, and for an individual ESRD facility, these fluctuations can be difficult to predict. While we have maintained that temporary transition policies provide sufficient time for facilities to make operational changes for future CYs and have noted separate agency actions to address certain external factors, such as the issuance of waivers and flexibilities during the COVID–19 PHE (85 FR 71435), we also recognized that predictability in Medicare payments is important to enable ESRD facilities to budget and plan their operations.

In light of these considerations, we proposed a permanent mitigation policy to smooth the impact of year-to-year changes in ESRD PPS payments related to decreases in the ESRD PPS wage index. We proposed a policy that we believed would increase the predictability of ESRD PPS payments for ESRD facilities; mitigate instability and significant negative impacts to ESRD facilities resulting from changes to the wage index; and use the most current data to maintain the accuracy of the ESRD PPS wage index.

In the CY 2023 ESRD PPS proposed rule, we stated that we believed our transition policy that applied a 5-percent cap on wage index decreases for CY 2021 provided greater transparency and was administratively less complex than prior transition methodologies. In addition, we stated that we believed this methodology mitigated short-term instability and fluctuations that can negatively impact ESRD facilities due to wage index changes. We also stated that we believed the 5-percent cap we applied to all wage index decreases for CY 2021 provided an adequate safeguard against significant and unpredictable payment reductions in that year, related to the adoption of the revised OMB delineations. However, we recognized there are circumstances that a 2-year transition policy, like the one adopted for CY 2021, would not effectively address for future years in which ESRD facilities continue to be negatively affected by significant wage index decreases. Therefore, we proposed a permanent policy that we believed 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 ESRD facilities' control (for example, public health or other emergencies, or the adoption of future OMB revisions to the CBSA delineations through rulemaking).

As we noted in the CY 2023 ESRD PPS proposed rule (87 FR 38482), typical year-to-year variation in the ESRD PPS wage index has historically been within 5 percent, and we expected this would continue to be the case in future years. We explained that, because ESRD facilities are usually experienced with this level of wage index fluctuation, we believed applying a 5-percent cap on all wage index decreases each year, regardless of the reason for the decrease, would effectively mitigate instability in ESRD PPS payments due to any significant wage index decreases that may affect ESRD facilities in a year. Therefore, we stated, we believed this approach would address concerns about instability that commenters raised in response to the CY 2021 ESRD PPS proposed rule. In addition, we stated that we believed applying a 5-percent cap on all wage index decreases would support increased predictability about ESRD PPS payments for ESRD facilities, enabling them to more effectively budget and plan their operations. Lastly, 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 stated that we believed it would still ensure the wage index is a relative measure of the value of labor in prescribed labor market areas. We noted that with a permanent cap, we would be able to continue to update the wage index with the most current hospital wage data as required under § 413.196(d)(2) to more accurately align the use of labor resources with ESRD PPS payment while mitigating the instability in payments to individual ESRD facilities that such updates may otherwise cause. We discussed that we would compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. We estimated that applying a 5-percent cap on all wage index decreases would have a very small effect on the wage index budget neutrality factor for CY 2023, and therefore would have a small effect on the ESRD PPS base rate. We stated that this small effect on budget neutrality also demonstrates that this policy would have a minimal impact on the ESRD PPS wage index overall. The wage index [7] is a measure of the value of labor (wage and wage-related costs) in a prescribed labor market area relative to the national average. Therefore, we anticipated that in the absence of any proposed wage index policy changes such as changes to OMB delineations, most ESRD facilities would not experience year-to-year wage index declines greater than 5 percent in any given year. Therefore, we anticipated that the impact to the wage index budget neutrality factor in future years would continue to be minimal. We also stated that we believed that when the 5-percent cap would be applied under this policy, it likely would be applied similarly to all ESRD facilities 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 this policy may result in ESRD facilities in a CBSA receiving a higher wage index than others in the same area (such as in situations when OMB delineations change), we stated that we believed the impact would be temporary, as the average hourly wage of facilities in a labor market would tend to converge to the mean average hourly wage of the CBSA.

As noted previously, section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. Under our regulations at § 413.231(a), we must use an appropriate wage index to adjust the labor-related portion of the base rate to account for geographic differences in the area wage levels. We stated in the CY 2023 ESRD PPS proposed rule that we believed a 5-percent cap on wage index decreases would be appropriate for the ESRD PPS. Therefore, for CY 2023 and subsequent years, we proposed to apply a 5-percent cap on any decrease to an ESRD facility's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. That is, an ESRD facility's wage index for CY 2023 would not be less than 95 percent of its final wage index for CY 2022, regardless of whether the ESRD facility is part of an updated CBSA, and for subsequent years, an ESRD facility's wage index would not be less than 95 percent of its wage index calculated in the prior CY. We noted this also would mean that if an ESRD facility's prior CY 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 ESRD facility's capped wage index in the prior CY. For example, if an ESRD facility's wage index for CY

[7] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/wageindex#:~:text=A%20labor%20market%20area's%20wage,portion%20of%20the%20standardized%20amounts.*

2023 is calculated with the application of the 5-percent cap, then its wage index for CY 2024 would not be less than 95 percent of its capped wage index in CY 2023. Lastly, we stated that a newly opened or newly certified ESRD facility would be paid the wage index for the area in which it is geographically located for its first full or partial CY with no cap applied, because a new ESRD facility would not have a wage index in the prior CY. We proposed to reflect the permanent cap on wage index decreases in our regulations at § 413.231(c).

We received several comments on our proposal to establish a permanent cap on wage index decreases for the ESRD PPS. The comments and our responses are set forth below.

Comment: Commenters broadly supported the proposed 5-percent cap on wage index decreases. A coalition of dialysis organizations expressed appreciation that CMS recognized the need for greater predictability to avoid negative impacts on ESRD facilities, but noted that the wage index continues to raise concern among many of its members and that a conversation around the wage index and the implications of the budget neutrality requirement should take place. One LDO encouraged CMS to also engage with the kidney care community and use its statutory authority to develop and apply an alternative to the hospital wage index.

Response: We thank the commenters for their support. We also appreciate the general concerns that commenters raised about the wage index. We did not propose for CY 2023 any of the changes to the ESRD PPS wage index that these commenters suggested, but we will take these suggestions into consideration to potentially inform future rulemaking.

Comment: MedPAC supported the proposal to cap wage index decreases at 5 percent, but suggested also applying a cap to wage index increases of more than 5 percent.

Response: We appreciate MedPAC's suggestion that the cap on wage index changes of more than 5 percent should also be applied to increases in the wage index. However, as we discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38482), one purpose of the proposed policy is to help mitigate the significant negative impacts of certain wage index changes. As we noted in the proposed rule, we believe that applying a 5-percent cap on all wage index decreases would support increased predictability about ESRD PPS payments for ESRD facilities, enabling them to more effectively budget and plan their operations. That is, we proposed to cap decreases because we believe that an ESRD facility would be able to more effectively budget and plan when there is predictability about its expected minimum level of ESRD PPS payments in the upcoming CY. We did not propose to limit wage index increases because we do not believe such a policy is needed to enable ESRD facilities to more effectively budget and plan their operations. For these reasons, we believe it is appropriate for ESRD facilities that experience an increase in their wage index value to receive that wage index value.

Comment: Several commenters, including a nonprofit dialysis association, an LDO, and a couple of independent ESRD facilities encouraged CMS to implement the proposed 5-percent cap in a way that would protect facilities that experienced substantial reductions to their wage index due to the adoption of the new CBSA delineations in CY 2021.

Response: As we noted earlier in this final rule, we stated in the CY 2021 ESRD PPS final rule that we believed a 5-percent cap on the overall decrease in an ESRD facility's wage index value would be an appropriate transition, as it would effectively mitigate any significant decreases in an ESRD facility's wage index for CY 2021. We indicated that no cap would be applied to the reduction in the second year, CY 2022. We did not propose to extend the transition policy for CY 2022 or future years, however, as we discussed in the CY 2022 ESRD PPS final rule (86 FR 61881), we received comments acknowledging and supporting the final phase-in of the updated OMB delineations for CY 2022. We have historically implemented transitions of limited duration, such as in the CY 2015 ESRD PPS final rule (79 FR 66142), to address CBSA changes due to substantial updates to OMB delineations. As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38482) and earlier in this final rule, our policy is generally to use the most current hospital wage data and analysis available to ensure the accuracy of the ESRD PPS wage index, in accordance with § 413.196(d)(2). In accordance with this general policy, we proposed to use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS and the most recent prior-year ESRD PPS wage index to determine the facilities to which the 5-percent cap would apply in CY 2023. We proposed that the CY 2023 ESRD PPS 5-percent cap wage index policy would be prospective to mitigate any significant decreases beginning in CY 2023.

Final Rule Action: After consideration of the comments received, for CY 2023 and subsequent years, we are finalizing as proposed a permanent 5-percent cap on any decrease to an ESRD facility's wage index from its wage index in the prior year, which we will apply in a budget-neutral manner. This means that an ESRD facility's wage index for CY 2023 will not be less than 95 percent of its final wage index for CY 2022, and for subsequent years, an ESRD facility's wage index will not be less than 95 percent of its wage index calculated in the prior CY. Also, if an ESRD facility's prior CY wage index is calculated with the application of the 5 percent cap, the following year's wage index will not be less than 95 percent of the ESRD facility's capped wage index in the prior CY. We are also finalizing as proposed that a newly opened or newly certified ESRD facility will be paid the wage index for the area in which it is geographically located for its first full or partial CY with no cap applied, because a new ESRD facility would not have a wage index in the prior CY. We will reflect the permanent cap on wage index decreases in our regulations at § 413.231(c) by stating that beginning January 1, 2023, CMS applies a cap on decreases to the wage index, such that the wage index applied to an ESRD facility is not less than 95 percent of the wage index applied to that ESRD facility in the prior calendar year.

As previously discussed in this final rule, we believe this mitigation policy will maintain the ESRD PPS wage index as a relative measure of the value of labor in prescribed labor market areas, increase predictability of ESRD PPS payments for ESRD facilities, and mitigate instability and significant negative impacts to ESRD facilities resulting from significant changes to the wage index. In section VII.D.5 of this final rule, we estimate the impact to payments for ESRD facilities in CY 2023 based on this policy. We also note that we will examine the effects of this policy on an ongoing basis in the future to assess its continued appropriateness.

(3) Update to ESRD PPS Wage Index Floor

(a) Background

A wage index floor value is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico; however, the wage index floor value is applicable for any area that may fall below the floor.

In the CY 2011 ESRD PPS final rule (75 FR 49116 through 49117), we finalized a policy to reduce the wage index floor by 0.05 for each of the remaining years of the ESRD PPS transition, that is, until CY 2014. We applied a 0.05 reduction to the wage index floor for CYs 2012 and 2013, resulting in a wage index floor of 0.5500 and 0.5000, respectively (CY 2012 ESRD PPS final rule, 76 FR 70241). We continued to apply and reduce the wage index floor by 0.05 in CY 2013 (77 FR 67459 through 67461). Although we only intended to provide a wage index floor during the 4-year transition in the CY 2014 ESRD PPS final rule (78 FR 72173), we decided to continue to apply the wage index floor and reduce it by 0.05 per year for CY 2014 and for CY 2015, resulting in a wage index floor of 0.4500 and 0.4000, respectively.

In the CY 2016 ESRD PPS final rule (80 FR 69006 through 69008), however, we decided to maintain a wage index floor of 0.4000, rather than further reduce the floor by 0.05. We stated that we needed more time to study the wage indices that are reported for Puerto Rico to assess the appropriateness of discontinuing the wage index floor (80 FR 69006).

In the CY 2017 ESRD PPS proposed rule (81 FR 42817), we presented the findings from analyses of ESRD facility cost report and claims data submitted by facilities located in Puerto Rico and mainland facilities. We solicited public comments on the wage index for CBSAs in Puerto Rico as part of our continuing effort to determine an appropriate policy. We did not propose to change the wage index floor for CBSAs in Puerto Rico, but we requested public comments and feedback on the suggestions that were submitted in the CY 2016 ESRD PPS final rule (80 FR 69007). After considering the public comments we received regarding the wage index floor, in the CY 2017 ESRD PPS final rule, we finalized a wage index floor of 0.4000 (81 FR 77858).

In the CY 2018 ESRD PPS final rule (82 FR 50747), we finalized a policy to permanently maintain the wage index floor of 0.4000, because we believed it was set at an appropriate level to provide additional payment support to the lowest wage areas. This policy also obviated the need for an additional budget-neutrality adjustment that would reduce the ESRD PPS base rate, beyond the adjustment needed to reflect updated hospital wage data, to maintain budget neutrality for wage index updates.

In the CY 2019 ESRD PPS proposed rule (83 FR 34328 through 34330), we proposed to increase the wage index floor from 0.4000 to 0.5000. We conducted various analyses to support our proposal to increase the wage index floor from 0.4000 to 0.5000. We calculated alternative wage indexes for Puerto Rico that combined labor quantities, that is FTEs, from cost reports with BLS wage information to create two regular Laspeyres price indexes [8] (ranging between 0.510 and 0.550). We discuss this analysis in detail in the following paragraphs, however, the complete discussion can be found in the CY 2019 ESRD PPS proposed rule at 83 FR 34328 through 34330.

In response to the CY 2019 wage index floor proposal, we received several comments. One commenter opposed the proposal and expressed concern over the data sources used to develop the wage indexes in general. This commenter requested additional documentation of our analysis to determine the two alternative wage indices for Puerto Rico. Several commenters expressed support for the proposal to increase the wage index from 0.40 in 2018 to 0.50 for CY 2019 and subsequent years, because they believed it would assist ESRD facilities in providing access to high-quality care particularly in rural areas where access challenges may be present. Some commenters expressed support for CMS's position that the then-current wage index floor was too low; however, they recommended CMS set the wage index floor higher than 0.5000 (specifically, at 0.5936, which was identified as the lower boundary of CMS's statistical outlier analysis as discussed further in this section of the final rule).

In response to these comments, in the CY 2019 ESRD PPS final rule (83 FR 56967), we stated that we continued to believe that a wage index floor of 0.5000 struck an appropriate balance between providing additional payments to areas that fell below the wage floor while minimizing the impact on the ESRD PPS base rate. We noted that the purpose of the wage index adjustment is to recognize differences in ESRD facility resource use for wages specific to the geographic area in which facilities are located. While a wage index floor of 0.5000 continued to be the lowest wage index nationwide, we noted that the areas subject to the floor continued to have the lowest wages compared to mainland facilities. We noted that the increase to the wage index floor to 0.5000 was a 25 percent increase over the then-current floor and would provide a higher wage index for all facilities in Puerto Rico where wage indexes, based on hospital reported data, range from .3300 to .4400. For these reasons, we stated that we believed a wage index floor of 0.5000 was appropriate and would support labor costs in low wage areas.

Therefore, in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967), we finalized an increase to the wage index floor from 0.4000 to 0.5000 for CY 2019 and subsequent years. We explained that we revisited our evaluation of payments to ESRD facilities located in the lowest wage areas to be responsive to comments from interested parties and to ensure payments under the ESRD PPS are appropriate. We provided statistical analyses that supported a higher wage index floor and finalized an increase from 0.4000 to 0.5000 to safeguard access to care in affected areas.

As noted previously in this final rule, currently, all areas with wage index values that fall below the floor are located in Puerto Rico; however, the wage index floor value is applicable for any area that may fall below the floor. The wage index floor of 0.5000 has been in effect since January 1, 2019.

We did not include any wage index floor proposals in the CY 2022 ESRD PPS proposed rule, however, we received several public comments regarding the wage index floor. As discussed in the CY 2022 ESRD PPS final rule (86 FR 61881), three commenters, including a large dialysis organization, a non-profit health insurance organization in Puerto Rico, and a healthcare group in Puerto Rico, commented on the wage index for ESRD facilities located in Puerto Rico. These commenters recommended that CMS increase the wage index floor from 0.5000 to 0.5500, noting that in the CY 2019 ESRD PPS proposed rule, CMS reported that its own analysis indicated that Puerto Rico's wage index likely lies between 0.5100 and 0.5500. They noted that CMS further stated that any wage index values less than 0.5936 are considered outlier values. They also pointed out that CMS still finalized a floor at 0.5000 and that we characterized it as a balance between providing additional payments to affected areas while minimizing the impact on the ESRD PPS base rate. Another commenter recommended that CMS evaluate policy inequities between the ESRD PPS wage index for ESRD

[8] A Laspeyres index is an index formula used in price statistics for measuring price development of the basket of goods and services consumed in the base period (*https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:Laspeyres_price_index#:~:text=The%20Laspeyres%20price%20index%20is,cost%20in%20the%20current%20period*).

facilities located in Puerto Rico compared to other states and territories, taking into consideration the unique circumstances that affect Puerto Rico, including its shortage of healthcare specialists and labor work force, remote geography, transportation and freighting costs, drug pricing, and lack of transitional care services.

In response to these comments, we stated in the CY 2022 ESRD PPS final rule that we would not finalize any changes to those policies since we did not propose any changes to the wage index floor or wage index methodology for CY 2022, but would take these suggestions into account when considering future rulemaking.

(b) CY 2023 Wage Index Floor Proposal

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. Based on this authority, in the CY 2023 ESRD PPS proposed rule (87 FR 38483 through 38486), we proposed to increase the wage index floor in accordance with the Secretary's efforts to account for geographic differences in an area's wage levels using an appropriate wage index which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located.

For CY 2023 and subsequent years, we proposed to increase the wage index floor to 0.6000. We stated that we believed that this wage floor increase is responsive to comments from interested parties, safeguards access to care in areas at the lowest end of the current wage index distribution, and is supported by data and analyses that support a higher wage index floor, as discussed in the following subsections.

(i) Analysis of Puerto Rico Cost Reports for the CY 2019 ESRD PPS Rulemaking

We explained that for the CY 2019 ESRD PPS proposed rule (83 FR 34329 through 34330), we performed an analysis using ESRD facility cost reports and wage information specific to Puerto Rico from the BLS (*https://www.bls.gov/oes/2015/may/oes_pr.htm*). The analysis utilized data from cost reports for freestanding facilities and for hospital-based facilities in Puerto Rico for CYs 2013 through 2015.

Using these data, we calculated alternative wage indexes for Puerto Rico that combined labor quantities, that is FTEs, from cost reports with BLS wage information to create two regular Laspeyres price indexes. In the context of this analysis, a Laspeyres price index can be viewed as a relative, weighted average wage of labor in each geographical area. This average combines the wages of various labor categories according to certain weights. The two indexes we considered used the same BLS-derived wages but different weights. The first index used quantity weights derived from the overall U.S. use of labor inputs. The second index used quantity weights derived from the Puerto Rico use of labor inputs. The alternative wage indexes derived from the analysis indicated that Puerto Rico's wage index likely lies between 0.5100 and 0.5500. As noted earlier in this section of this final rule and discussed in the CY 2019 ESRD PPS final rule (83 FR 56967), commenters have noted that both values are above the current wage index floor and suggest that the current 0.5000 wage index floor may be too low. Commenters pointed out CMS's analysis shows that Puerto Rico's wage index likely lies between 0.51 and 0.55, while additional analyses note that any wage index values less than 0.5936 are considered outlier values, with 0.5936 therefore as the lower wage index boundary. They expressed concern that in the CY 2019 ESRD PPS proposed rule CMS proposed a new floor of only 0.5000 even though the present methodology applied to Puerto Rico has created the only outlier in the U.S. As we stated in the CY 2019 ESRD PPS final rule (83 FR 56967), at that time, we believed that a wage index floor of 0.5000 struck an appropriate balance between providing additional payments to areas that fall below the wage floor while minimizing the impact on the ESRD PPS base rate. At the time, we conducted analyses to gauge the appropriateness of the then-current wage index floor of 0.4000 and determine whether it was too low. We did not propose to use these analyses to determine the exact value for a new wage index floor.

Specifically, as we explained in the CY 2019 ESRD PPS final rule, CMS performed a statistical outlier analysis to identify the upper and lower boundaries of the distribution of the current wage index values and remove outlier values at the edges of the distribution. In the general sense, an outlier is an observation that lies outside a defined range from other values in a population. In this case, the population of values is the various wage indexes within the CY 2019 wage index. The lower and upper quartiles (the 25th and 75th percentiles) are also used. The lower quartile is Q1 and the upper quartile is Q3. The difference (Q3 − Q1) is called the interquartile range (IQR). The IQR is used in calculating the inner and outer fences of a data set. The inner fences are needed for identifying mild outlier values in the edges of the distribution of a data set. Any values in the data set that are outside of the inner fences are identified as an outlier. The standard multiplying value for identifying the inner fences is 1.5. First, we identified the Q1 and Q3 quartiles of the CY 2018 wage index, which are as follows: Q1 = 0.8303 and Q3 = 0.9881. Next, we identified the IQR: IQR = 0.9881 − 0.8303 = 0.1578. Finally, we identified the inner fence values as shown below. Lower inner fence: Q1 − 1.5*IQR = 0.8303 − (1.5 × 0.1578) = 0.5936. This statistical outlier analysis demonstrated that any wage index values less than 0.5936 are considered outlier values, and 0.5936 as the lower boundary also suggested that the current wage index floor could be appropriately reset at a higher level.

Based on these analyses, we finalized a wage index floor of 0.5000 in the CY 2019 ESRD PPS final rule. We continued to apply the wage index floor of 0.5000 per year through CY 2022. Although we did not propose specific policies relating to the wage index floor in the CY 2022 ESRD PPS proposed rule, commenters on that rule noted that past hurricanes and the COVID–19 PHE have created infrastructure challenges that lead to high costs of dialysis care. These commenters requested CMS increase the wage index floor. In the CY 2023 ESRD PPS proposed rule, we stated that in response to comments and our continued concern regarding access, we were revisiting the CY 2019 analysis, and believed that the statistical analysis of the CY 2019 data indicated that a wage index floor as high as 0.5936 would be appropriate.

(ii) Analysis of the CY 2023 ESRD PPS Final Rule Analytic File

As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38385 through 38486), we performed an analysis to compare the impact of three options to adjust the wage index floor upward using the CY 2023 ESRD PPS final rule analytic file. The analytic file included qualifying data for beneficiaries for whom a 72x claim for renal dialysis services was submitted in the outpatient file setting during CY 2021. We analyzed the impact of three options for adjustment for the wage index floor: (1) wage index floor of 0.5000 (that is, no change), (2) wage index floor of 0.5500, and (3) wage index floor of 0.6000. Specifically, we examined how these three options would potentially impact the base rate,

outlier thresholds, and average payment rates for all ESRD facilities.

Among the three options, we considered the wage index floor of 0.5000 as the baseline or starting point used for comparisons. We then compared the impact on various aspects of the ESRD PPS under the alternative options using the 0.5500 and 0.6000 wage index floor.

First, we examined the potential impact on the proposed base rate for CY 2023 (87 FR 38485). Under the baseline (wage index value of 0.5000), the proposed base rate for CY 2023 would be $264.14. The remaining two options (0.5500 floor and 0.6000 floor) would result in a proposed base rate of $264.11 and $264.09, respectively. We noted that these options would decrease the ESRD PPS base rate due to the application of the budget neutrality factor for each option, however as discussed in the following paragraph, we noted that the overall impact to ESRD PPS payments would be negligible.

Next, we examined the potential impact to the proposed outlier thresholds for CY 2023. Relative to the baseline (wage index floor value of 0.5000), all options would have little or no impact on either the proposed outlier MAP or the FDL. Lastly, we examined the potential impact to overall ESRD facility payments. After accounting for all payment adjustments under the ESRD PPS and applying the proposed budget neutrality factor for each option, we noted in the proposed rule that all options would be associated with a 3.00 percent increase in projected payments for CY 2023 due to the proposed market basket update and proposed outlier FDL and MAP amounts. We estimated that the change in overall payments attributable to increasing the wage index floor would be less than 0.01 percentage point. However, we estimated that there would be a significant increase in payments to ESRD facilities located in Puerto Rico. Under the 0.5500 wage index floor option, we estimated that payments to ESRD facilities in Puerto Rico would increase by approximately 3.8 percent relative to the 0.5000 wage index floor option. Under the 0.6000 wage index floor option, we estimated that payments to Puerto Rico facilities would increase by approximately 7.6 percent relative to the 0.5000 floor. In other words, increasing the wage index floor to 0.6000 would maximize the positive impacts for ESRD facilities located in Puerto Rico while continuing to minimize the impact to overall ESRD PPS payments.

As noted previously, the statistical analysis presented in the CY 2019 ESRD PPS rulemaking resulted in values for the lower and upper fences for appropriate wage index values (lower = 0.5936, upper = 0.7514). Any values in the data set that are outside of the fences are identified as an outlier. Therefore, we stated, the analysis indicated that a wage index floor of 0.5936 would be appropriate, because any wage index values less than 0.5936 or greater than 0.7514 would be considered outlier values, and a wage index value within the fences could be appropriate. For greater simplicity and public understanding, we proposed to round the lower fence of 0.5936 to the nearest 0.05, to align with the increment of change that we previously adopted in the CY 2011 ESRD PPS final rule (75 FR 49116 through 49117) for historical reductions to the ESRD PPS wage index floor. As a result, after rounding to the nearest 0.05, a wage index floor of 0.6000 would be in line with the data.

We noted that we strive for a wage index floor value that maintains the accuracy of payments under the ESRD PPS, that is, has minimal impact on the base rate, outlier thresholds, and average payment rates for all ESRD facilities. Based on our analysis of several options using the most recent analytic file for this final rule, we identified that a value near the lower fence of 0.5936 as described in the prior paragraph would maximize the positive impacts for ESRD facilities with wage indexes below the floor while continuing to minimize the impact to overall ESRD PPS payments.

(iii) Wage Index Floor Proposed Action

Based on our re-evaluation the CY 2019 analysis and subsequent analysis of several options using the most recent analytic file for the CY 2023 ESRD PPS proposed rule, we proposed to increase the wage index floor to 0.6000. We stated that we believed our analyses supported that wage index floor value and would strike the right balance between providing increased payment to areas for which labor costs are higher than the current wage index for the relevant CBSAs indicate, while maintaining the accuracy of payments under the ESRD PPS and minimizing the overall impact to all ESRD facilities. In addition, we proposed to amend § 413.231 by adding new paragraph (d) to reflect this change and to codify the wage index floor policy. We stated we believed this increase from the current 0.5000 wage index floor value would minimize the impact to the base rate while providing increased payment to areas that need it.

Currently, only rural Puerto Rico and 8 urban CBSAs in Puerto Rico receive the wage index floor of 0.5000. The next lowest wage index is the Virgin Islands CBSA with a value of 0.6002. All CBSAs in Puerto Rico would be subject to the wage index floor of 0.6000. Though the wage index floor value currently would only affect areas in Puerto Rico, we noted that, consistent with our established policy, the proposed wage index floor value of 6.000 would be applicable for any area that may fall below the floor.

We solicited comment on the proposal to increase the wage index floor from 0.5000 to 0.6000. The comments and our responses are set forth below.

Comment: MedPAC expressed opposition to the proposed wage index floor increase and expressed that wage index floors and related policies distort area wage indexes. MedPAC recommended that CMS establish an ESRD PPS wage index for all ESRD facilities using wage data that represents all employers and industry-specific occupational weights, rather than the hospital wage data currently used. Several commenters also agreed with MedPAC's recommendation to establish a wage index specific to ESRD facilities.

Response: We appreciate MedPAC's comments, but we do not agree with the suggestion that the proposed wage index floor would distort area wage indexes under the ESRD PPS. As our analysis shows, wage indexes below the lower fence of 0.5936 are statistical outliers, so the application of the floor would serve to improve rather than distort the accuracy of the ESRD PPS wage index overall. Further, our analysis of the impact to the ESRD PPS base rate indicates that the proposed wage index floor would strike the right balance between providing increased payment to areas for which labor costs are higher than the current wage index for the relevant CBSAs indicate, while maintaining the accuracy of payments under the ESRD PPS and minimizing the overall impact to all ESRD facilities.

We appreciate the feedback that we should use wage data that represents all employers and industry-specific occupational weights for the ESRD PPS wage index. We note that for our analysis to determine if the wage index floor could be appropriately set at a higher value, we used wage data from the BLS and FTEs by occupation reported on the cost reports for independent ESRD facilities. Specifically, we calculated labor weights by occupation for Puerto Rico and the greater U.S. as the treatment weighted average of the FTEs reported on independent facility cost reports. We did not include hospital-based cost

report data because the occupations for which the FTEs were reported were not identical between independent and hospital-based cost reports. Although an ESRD facility wage index that more specifically targets the labor mix applicable to ESRD facilities could potentially identify more granular cost differences between labor market areas, some commenters expressed concern that it could increase the reporting burden on ESRD facilities. We appreciate MedPAC's suggestions for establishing a new wage index for the ESRD PPS and may consider these recommendations for potential future rulemaking.

Comment: Several commenters, including a national dialysis provider, an LDO, and an insurance organization, expressed support for finalizing the wage index floor policy as proposed. The commenters who supported our proposal stated that a wage index floor increase to 0.6000 would improve access and quality of care for Medicare ESRD beneficiaries in Puerto Rico, given that all areas with wage index values below the floor are in Puerto Rico. These commenters stated that a wage index floor of 0.6000 would improve equality amongst all ESRD facilities given that the next lowest wage index value outside of Puerto Rico is the Virgin Islands, with a proposed wage index value of 0.6004. These commenters stated that health equity in the Medicare program would be served by minimizing payment disparities between the lowest and highest paid ESRD facilities.

Response: We thank the commenters for their support of the wage index floor proposal. We are aiming to strike a balance between providing increased payment to areas where actual labor costs are higher than the current wage index indicates while minimizing the overall impact to all ESRD facilities. We believe a wage index floor of 0.6000 is appropriate and will support labor costs in low wage areas.

Comment: While most commenters supported finalizing the wage index floor policy as proposed, these same commenters also stated that CMS should consider future refinements to the wage index floor policy. Commenters claimed that the current analysis is based on the data from cost reports from the years 2013 through 2015. Commenters explained that since 2015, the economic situation in Puerto Rico has worsened due to natural disasters, PHEs, post COVID–19 inflation, and new economic measures imposed under the Puerto Rico Oversight, Management, and Economic Stability Act. The commenters stated that CMS should conduct new analysis of cost reports for free-standing and hospital-based ESRD facilities in Puerto Rico and increase the wage index floor to 0.7000.

Response: As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38483 through 38486), we revisited our analysis using ESRD facility cost reports and wage information specific to Puerto Rico from the BLS utilizing data from cost reports for freestanding facilities and for hospital-based facilities in Puerto Rico for CYs 2013 through 2015. We used this data to determine if the wage index floor could be appropriately set at a higher value. We did not propose to use these analyses to determine the exact value for a new wage index floor. Instead, we considered the cost report analyses, along with the analysis of the CY 2023 ESRD PPS proposed rule analytic file, to determine a higher wage index floor, which assists ESRD facilities in areas with low wage index levels while maintaining the accuracy of payments under the ESRD PPS. We appreciate these recommendations regarding our wage index floor analysis and may consider these suggestions for potential future rulemaking.

In our efforts to strike a balance between resource use and payment, we also stated in the CY 2023 ESRD PPS proposed rule (87 FR 38484 through 38486) that our analysis of several options using the most recent analytic file for the CY 2023 proposed rule showed that a higher wage index floor will slightly decrease the ESRD PPS base rate for all ESRD facilities due to the application of the budget neutrality factor. Given that increasing the wage index floor results in proportional decrease in the base rate for all facilities, we must establish a value that that maintains the accuracy of payments under the ESRD PPS. An increase to the wage index floor to 0.6000 is a 20 percent increase over the current wage index floor and will provide a higher wage index for all facilities in areas that fall below the floor, which are currently all located in Puerto Rico, and will assist in the higher labor costs affecting low wage index areas. We continue to believe that a wage index floor of 0.6000 strikes an appropriate balance between providing additional payments to areas that fall below the wage index floor while minimizing the impact on average payment rates for all ESRD facilities.

Comment: Some commenters made additional comments regarding Puerto Rico and the staffing difficulties ESRD facilities face there. Commenters expressed their belief that failing economic factors have led to a relocation of health care professionals from Puerto Rico to the U.S. mainland. Commenters expressed their belief that ESRD facilities have had to increase wages to retain qualified staff. Commenters stated that under local regulation, Puerto Rico ESRD facilities can only employ Registered Nurses (RNs) rather than technicians for medical care. Commenters also stated that under local regulation, RNs and other ESRD facility staff in Puerto Rico must be bilingual. Commenters explained that for these reasons ESRD facility staff are costlier in Puerto Rico.

Response: We thank commenters for the additional information regarding ESRD facilities in Puerto Rico. We have codified the wage index policy and our methodology at § 413.231. As discussed previously, we adjust the labor-related portion of the base rate to account for geographic difference is area wage using an appropriate wage index which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. To acquire such data to develop the wage index annually, changes in labor costs are captured in the survey of wages and wage-related costs derived from the MCRs, the Hospital Wage Index Occupational Mix Survey, hospitals' payroll records, contracts, and other wage-related documentation. This process is utilized by other Medicare prospective payment systems. We appreciate the additional information regarding the staffing costs in Puerto Rico; however, we believe that Puerto Rico's labor costs should be captured in the wage-related documentation used for the development of the annual wage index.

Regarding concerns raised about the need to hire bilingual RNs, the need for bilingual staff occurs in both inpatient and outpatient settings and hospital cost reports should reflect those additional costs. As stated in the CY 2019 ESRD PPS final rule (83 FR 56967), we note that in every analysis we conducted, the average salary of RNs in Puerto Rico was approximately half that of mainland facilities and none of the analyses produced a 0.7000 wage index value.

Regarding the use of RNs in Puerto Rico facilities, we have received conflicting information from Puerto Rico about the how local scope of practice for RNs and other staff impact ESRD facility costs. We are continuing to explore alternative methodologies for accounting for the labor-related costs of all ESRD facilities and we may revisit the use of a wage index floor under the ESRD PPS in that context in future rulemaking. We note that any changes to the ESRD PPS wage index floor would

be proposed through notice and comment rulemaking.

Comment: Commenters expressed their belief that health disparities in the patient population in Puerto Rico justify a higher wage index floor than proposed. Commenters stated that diabetes is rampant in Puerto Rico and that its prevalence is higher in the Puerto Rican population compared to the U.S. The commenters further stated that diabetes is a primary cause of kidney failure, heart disease, and cardiac chronic related conditions. Commenters stated that Puerto Rico has prominent levels of disease burden resulting in higher complex care needs and higher costs.

Response: The wage index payment adjustment is intended to recognize geographic differences in wage levels in areas in which ESRD facilities are located. We do not believe it would be appropriate to raise the wage index floor to mitigate other issues such as non-labor costs or costs associated with issues of disease burden disparities.

Final Rule Action: After considering the public comments we received regarding the wage index floor, we are finalizing an increase to the wage index floor from 0.5000 to 0.6000 for CY 2023 and subsequent years as proposed. In addition, we are amending § 413.231 by adding new paragraph (d) to reflect this change and to codify the wage index floor policy. Section 413.231(d) will provide that beginning January 1, 2023, CMS applies a floor of 0.6000 to the wage index, such that the wage index applied to an ESRD facility is not less than 0.6000.

c. CY 2023 Update to the Outlier Policy

(1) Background

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of ESAs necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty and obesity. A patient's specific medical condition, such as secondary hyperparathyroidism, may result in higher per treatment costs. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237.

Section 413.237(a)(1) enumerates the following items and services that are eligible for outlier payments as ESRD outlier services: (i) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (ii) Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iii) Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iv) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025; and (v) renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.[9]

In the CY 2011 ESRD PPS final rule (75 FR 49142), CMS stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as ESRD outlier services were specified in Transmittal 2134, dated January 14, 2011.[10] We use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. For example, we use these issuances to identify renal dialysis oral drugs that were or would have been covered under Part D prior to 2011 to provide unit prices for determining the imputed MAP amounts. In addition, we use these issuances to update the list of ESRD outlier services by adding or removing items and services that we determined, based our monitoring efforts, are either incorrectly included or missing from the list.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its imputed (that is, calculated) MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average estimated expenditure per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted MAP amount per treatment plus the FDL amount. As described in the following paragraphs, the facility's predicted MAP amount is the national adjusted average ESRD outlier services MAP amount per treatment, further adjusted for case-mix and facility characteristics applicable to the claim. We use the term ''national adjusted average'' in this section of this final rule to more clearly distinguish the calculation of the average ESRD outlier services MAP amount per treatment from the calculation of the predicted MAP amount for a claim. The average ESRD outlier services MAP amount per treatment is based on utilization from all ESRD facilities, whereas the calculation of the predicted MAP amount for a claim is based on the individual ESRD facility and patient characteristics of the monthly claim. In accordance with § 413.237(c), ESRD facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and codified in § 413.220(b)(4), using 2007 data, we established the outlier percentage, which is used to reduce the per treatment base rate to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments, at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters

[9] Under § 413.237(a)(1)(vi), as of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

[10] Transmittal 2033 issued August 20, 2010, was rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which included one technical correction. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2134CP.pdf*

applicable using the outlier services payment multipliers developed from the regression analysis used to compute the payment adjustments. We discuss the details of our current methodology for calculating the MAP and FDL amounts in the following section.

(2) Overview of Current Outlier Methodology

We update the national adjusted average MAP amounts and FDL amounts each year using the latest available data in the annual regulatory updates to the ESRD PPS, in accordance with our longstanding policy (75 FR 49174). As noted earlier in this section of the final rule, based on our longstanding policy finalized in the CY 2011 ESRD PPS final rule (75 FR 49139 through 49140), the national adjusted average MAP amounts represent the national average estimated expenditure per treatment for ESRD outlier services, adjusted by a standardization factor. As detailed in the following paragraph, when evaluating outlier eligibility for a particular patient treated in a particular facility for a particular month, this national adjusted average is further adjusted to reflect the patient-specific case-mix severity and facility characteristics. We refer to this further adjusted MAP amount as the predicted MAP amount. Unlike the national average outlier MAP amount per treatment, the predicted MAP amount varies across patients (and even across patient-months). The national adjusted average MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140).

Under the methodology finalized in the CY 2011 ESRD PPS final rule (75 FR 49174), each year, using the latest available ESRD PPS data, we compute the national average MAP amount, and establish the FDL amount at a level that results in projected outlier payments that equal 1.0 percent of total payments under the ESRD PPS. When setting the outlier thresholds for the ESRD PPS rule, we first identify all ESRD outlier services for all beneficiaries using the most recently complete 72x claims data, which is claims from 2 years prior. For example, for the CY 2022 ESRD PPS rulemaking (86 FR 61882), we used 2020 claims. For items billed using HCPCS codes, we include injectable drugs as eligible ESRD outlier services if they belong to one of the ESRD PPS functional categories but are not in one of the composite rate drug categories (both are described in Chapter 11, Section 20.3 of the Medicare Benefit Policy Manual).[11] We do not include composite rate items because they are not eligible for outlier payments, in accordance with our longstanding ESRD PPS policy of including only formerly separately billable items and services as eligible ESRD outlier services (75 FR 49138). For items billed using National Drug Codes (NDCs), we include all oral drugs included on the ESRD outlier services list, which includes oral calcimimetics (starting January 1, 2021), and oral vitamin D analogs. We also include laboratory services that are on the list of eligible ESRD outlier services published by CMS.[12] Two supply HCPCS codes are eligible for outlier payments (A4657 syringe and A4913 miscellaneous supplies).

(a) Methodology for Calculating Imputed MAP Amounts and Predicted MAP Amounts

As we explained in the CY 2011 ESRD PPS final rule (75 FR 49142), the ESRD facility must identify all ESRD outlier services furnished to the patient by line item on the monthly claim that it submits to Medicare to receive the outlier payment adjustment. We estimate the imputed MAP amount for these services by applying the established pricing methodologies described in the following paragraph of this final rule. The imputed MAP amounts for each of these services are summed and divided by the corresponding number of treatments identified on the claim to yield the imputed ESRD outlier services MAP amount per treatment.

We multiply the utilization (that is, units of ESRD outlier services reported on the 72X claim) with prices to obtain the outlier-eligible amount. We obtain the utilization only from claim lines that are fully covered by Medicare (that is, claim lines that do not include any non-covered charge amount) containing ESRD outlier services. Separately billable services that are performed in the ESRD facility during dialysis that are not related to the treatment of ESRD are not included in the outlier-eligible amount. In the CY 2011 ESRD PPS final rule (75 FR 49142), we finalized the basis for estimating imputed MAP amounts as follows: For pricing of ESRD outlier services that are Part B renal dialysis drugs reported with HCPCS codes, we use the latest Average Sales Price (ASP) data, which is updated quarterly. ESRD outlier services that are renal dialysis drugs formerly covered under Part D and reported with NDCs are priced based on the national average pricing data retrieved from the Medicare Prescription Drug Plan Finder, which reflect pharmacy dispensing and administration fees. For ESRD outlier services that are laboratory tests billed using HCPCS codes, we use the latest payment rates from the Clinical Laboratory Fee Schedule. For renal dialysis supplies used to administer ESRD outlier services Part B drugs (for example, syringes), we estimate MAP amounts based on the predetermined fees that apply to these items, that is, we pay $0.50 for each syringe identified on an ESRD facility's claims form. For other medical/surgical supplies such as intravenous sets and gloves, the Medicare Claims Processing Manual currently allows Medicare contractors to elect among various options to price these supplies, such as the Drug Topics Red Book, Med-Span, or First Data Bank (CMS Pub. 100–04, Chapter 8, § 60.2.1). We sum up the outlier-eligible amounts for drugs, laboratory tests, and supplies separately.

Next, we inflate the outlier-eligible amounts calculated for drugs, laboratory tests, and supplies from the latest available prices to forecasted prices for the rule year.[13] For example, in the CY 2022 ESRD PPS rulemaking (86 FR 61882), we used 2021 prices inflated to the forecasted prices for CY 2022. Then, we add the inflated drug, laboratory test, and supply amounts and multiply the total amount by 0.98, in accordance with the budget neutrality requirement under section 153(b) of MIPPA. Lastly, we divide the amount by the number of treatments reported on the claim to obtain imputed MAP amount per treatment.

After calculating the imputed MAP amount per treatment, we then compute the predicted MAP amount for the claim. As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the patient-specific predicted MAP amount is equal to the national adjusted average MAP amount multiplied by the patient-specific case-mix adjusters. The national average MAP amount is adjusted by applying a standardization factor that reflects the

[11] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf.*

[12] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Outlier_Services.*

[13] We use a blended 4-quarter moving average of the ESRDB market basket price proxies for pharmaceuticals to inflate drug prices to the rule year. We inflate laboratory test prices to the rule year based on the estimated change in payment rates under the Clinical Laboratory Fee Schedule, using a CPI forecast to estimate changes for years in which a new survey will be implemented. For supplies, we apply a 0 percent inflation factor, because these prices are based on predetermined fees or prices established by the Medicare contractor.

national average of patients' outlier services case-mix severity. We apply this standardization factor to avoid systematically biasing the national average MAP amount calculation, which would result in setting the FDL amounts at a level that is too low. By applying the standardization factor to the national average MAP amount when calculating the patient-specific predicted MAP amount, we ensure that total imputed MAP dollars equal total predicted MAP dollars. The methodology for calculating this standardization factor is discussed in detail in the following section.

(b) Methodology for Calculating Case-Mix Standardization Factor and National Adjusted Average MAP Amount

We publish the national adjusted average MAP amount each year in the ESRD PPS proposed and final rule along with the adjustment factor. We currently use the ESRD outlier services multipliers that are the separately billable (SB) multipliers developed from the regression analysis used in the CY 2016 ESRD PPS refinement (80 FR 68993 and 80 FR 69002). As discussed in the CY 2016 ESRD PPS final rule (80 FR 68970), in accordance with section 632(c) of ATRA, we analyzed the case-mix payment adjustments under the ESRD PPS using more recent data. We revised the adjustments by changing the adjustment payment amounts based on our updated regression analysis using CYs 2012 and 2013 ESRD claims and cost report data. There was no change in the ESRD PPS outlier methodology for CY 2016, however, we updated the ESRD outlier services multipliers (80 FR 69008). The current ESRD outlier services multipliers are presented in Tables 9 and 10 in this section. A more detailed description of the steps is provided in the following paragraphs.

TABLE 9: Adult Outlier Services Multipliers

Variable	Outlier Services Multipliers
Age	
18-44	1.044
45-59	1.000
60-69	1.005
70-79	1.000
80+	0.961
Body surface area (BSA) (per 0.1 m^2)	1.000
Underweight (BMI < 18.5)	1.090
Time since onset of renal dialysis < 4 months	1.409
Facility low volume status	0.955
Comorbidities	
Pericarditis (acute)	1.209
Gastro-intestinal tract bleeding (acute)	1.426
Bacterial pneumonia (acute)	---
Hereditary hemolytic or sickle cell anemia (chronic)	1.999
Myelodysplastic syndrome (chronic)	1.494
Monoclonal gammopathy (chronic)	---
Rural	0.978

TABLE 10: PEDIATRIC OUTLIER SERVICES MULTIPLIERS

Patient Characteristics	Outlier Services Multipliers			
Age	Modality	Population %	Separately Billable Multiplier	Expanded Bundle Payment Multiplier
>13	PD	27.62	0.410	1.063
>13	HD	19.23	1.406	1.306
13–17	PD	20.19	0.569	1.102
13–17	HD	32.96	1.494	1.327

As discussed in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49140), to calculate the predicted MAP amount per treatment, we first compute the weighted mean of the imputed MAP amounts per treatment, separately for adult and pediatric patients, at the national level. Then, for each claim, we identify the patient's case-mix adjustments that are applicable for the month based on conditions recorded on the 72x claims, and multiply all applicable ESRD outlier services multipliers together to obtain the combined ESRD outlier services multiplier. For pediatric patients, the ESRD outlier services multipliers are the age and modality adjusters; for adults, the ESRD outlier services multipliers include all case-mix and facility-level adjusters. We then calculate the national per-treatment weighted mean of the combined outlier services multipliers for adult and pediatric patients separately. We calculate one standardization factor for adult patients and one for pediatric patients. Each standardization factor is calculated as follows:

1/(weighted mean of the combined outlier services multipliers).

We calculate the adjusted national average outlier MAP amount per treatment by multiplying the per-treatment weighted mean of the imputed outlier MAP amount per treatment by the standardization factor, separately for adults and pediatric patients.

To calculate the predicted outlier MAP amount per treatment for each claim, we multiply the national adjusted average MAP amount per treatment, separate for adults and pediatrics, by all applicable outlier services multipliers for that claim.

(c) Methodology for Calculating FDL Amounts

In accordance with our longstanding methodology, FDL amounts are calculated separately for adult and pediatric patients so that projected outlier payments equal 1.0 percent of total ESRD PPS payments (75 FR 49142 through 49144). For the FDL amounts, we begin by computing total payments for the particular rule year separately for adults and pediatric patients. We include all anticipated updates such as the wage index, market basket update, and productivity adjustment. For each claim, we compute:

Outlier payment per Treatment = Outlier loss share amount * (Imputed MAP amount per Treatment—(Threshold per Treatment)) = 0.8 * (Imputed MAP amount per Treatment—(Predicted MAP amount per Treatment + FDL))

A claim is eligible for an outlier payment if the imputed MAP amount per treatment—(Threshold per Treatment) >0.

We simulate total outlier payments, separately for adult and pediatric patients, starting with the prior rule year's FDL amounts. If the sum of projected outlier payments for the particular rule year is higher than 1.0 percent of total payments, we increase the FDL amounts to decrease the amount of outlier payments. In contrast, if projected outlier payments are lower than 1.0 percent of total payments, we decrease the FDL amounts to increase the amount of outlier payments. We determine the separate adult and pediatric FDL amounts that bring projected adult and pediatric outlier payments to 1.0 percent of total payments for each patient population. We announce the proposed and final MAP amounts and FDL amounts in the annual ESRD PPS proposed and final rules, respectively.

(d) Example of Outlier Calculation

The following is an example of the calculation of the outlier payment. John, a 68-year-old male Medicare beneficiary, is 187.96 cm. in height and weighs 95 kg. John receives hemodialysis 3 times weekly. In January 2022, he was hospitalized for 4 days for a compound ankle fracture. During the hospitalization John did not undergo any dialysis treatments. After discharge John resumed his dialysis treatments, but required additional laboratory testing and above-average doses of several injectable drugs, particularly EPO, to return his hemoglobin levels to the normal range. During January 2022, John received 9 hemodialysis treatments at his usual ESRD facility. The facility submitted a claim for eligible ESRD outlier services including drugs and biological products, laboratory tests, and supplies totaling $3,000.00.

We begin by computing the predicted MAP amount per treatment based on the ESRD outlier services case-mix adjustment factors applicable to John. These factors are age and BSA. John's BSA is 2.2161. Following the methodology adopted in the CY 2016 ESRD PPS final rule (80 FR 68989), we calculate the exponent of the PM for BSA by subtracting the national average BSA from John's BSA and dividing by 0.1. Applying the ESRD outlier services multiplier set forth in Table 9 of this final rule for BSA, John's ESRD outlier services payment multiplier (PM) for BSA is computed as follows:

$1.000^{(2.2161-1.9)/0.1} = 1.000^{3.16135} = 1.000$

Using this calculated PM for BSA and the PM for age from Table 9, John's outlier services PM is calculated as:

1.005 *1.000 = 1.005

For CY 2022, the national average MAP amount per treatment for adult patients is $42.75. Therefore, the predicted MAP amount per treatment for John is: $42.75 * 1.005 = $42.96.

Next, we determine the imputed MAP amount per treatment which reflects the estimated expenditure for ESRD outlier services incurred by the ESRD facility. John's imputed MAP amount per treatment is equal to the total amount of drugs and biological products, laboratory tests, and supplies submitted on the claim, divided by the number of treatments. We calculate this as:

$3000.00 / 9 = $333.33.

Next, we must determine if John's ESRD facility is entitled to outlier payments for John's January claim by comparing the predicted MAP amount to the threshold per treatment. We calculate the threshold per treatment by adding the CY 2022 FDL amount to the predicted MAP amount for John.

The threshold amount for John is calculated to reflect the case-mix adjustments for age and BSA.

Threshold = Predicted MAP amount ($42.96) + FDL ($75.39) = $118.35

Because John's imputed MAP amount per treatment was $333.33, which exceeds the sum of the predicted MAP amount and FDL amount ($118.35), John's ESRD facility is eligible for outlier payments.

The outlier payments for John's 9 treatments are calculated as the amount by which the imputed MAP amount exceeds the threshold, then multiplied by the 80 percent loss-sharing ratio.

Imputed MAP amount minus Threshold: $333.33 − $118.35 = $214.98

Outlier payments per treatment: $214.98 * .80 = $171.98

Total outlier payments: $171.98 * 9 = $1,547.82

(3) Current Issue and Concerns From Interested Parties

As we discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38493), for several years, outlier payments have consistently landed below the target of 1.0 percent of total ESRD PPS payments. Commenters have raised concerns that the methodology we currently use to calculate the outlier payment adjustment results in underpayment to ESRD facilities, as money was removed from the base rate to balance the outlier payment (85 FR 71409, 71438 through

71439; 84 FR 60705 through 60706; 83 FR 56969). Therefore, they have urged us to adopt an alternative modeling approach that accounts for declining trends in spending for eligible ESRD outlier services over time.

MedPAC echoed these concerns in a comment in response to the CY 2021 ESRD PPS proposed rule (85 71438 through 71440), and also suggested that the introduction of calcimimetics as an eligible ESRD outlier service could perpetuate this issue. MedPAC predicted that if calcimimetic use decreases between 2019 (when the products were paid under the ESRD PPS using the TDAPA) and 2021 (when the products would be paid as part of the ESRD PPS base rate), the outlier threshold would be set too high, and outlier payments would be lower than the target of 1.0 percent of total CY 2021 payments.

We explained in the CY 2023 ESRD PPS proposed rule (87 FR 38490 through 38491) that, in response to the concerns raised by MedPAC and others, CMS has been conducting research in conjunction with its contractor, including holding three technical expert panels (TEPs), to investigate possible improvements to the ESRD PPS payment methodologies. As discussed in the CY 2022 ESRD PPS proposed rule (86 FR 36401 through 36402), during the second and third TEP meetings convened by the CMS contractor in 2019 and 2020, panelists discussed their specific concerns regarding the current outlier policy and alternative methodologies to achieve the 1.0 percent outlier target. Some TEP panelists and interested parties have strongly advocated that we establish a new outlier methodology using alternative modeling approaches that account for trends in formerly separately billable spending over time. Other interested parties advocated for changing the outlier percentage. Overall, panelists expressed support for any change to outlier calculations that result in total outlier payments being closer to the target.

In the CY 2022 ESRD PPS proposed rule (86 FR 36402), we stated that we were considering potential revisions to the calculation of the outlier threshold to address concerns from interested parties. In that rule, we presented the information that was previously provided to the TEP to solicit comments from interested parties in the dialysis community and the public (86 FR 36402). We published an RFI to solicit comments on the approaches noted in the previous paragraph and any information that would better inform future modifications to the methodology (86 FR 36402). In addition to generally seeking input regarding calculating the outlier payment adjustment, we specifically requested responses to the following questions:

- An alternative approach could be to estimate the retrospective FDL trend by using historical utilization data. How many years of data should be included in calculation of this trend to best capture changes in treatment patterns?
- The simulation of the FDL can be improved by better anticipating changes in utilization of ESRD outlier services. What are the factors that affect the use of ESRD outlier services over time, and to what extent should CMS try to forecast the effect of these factors?
- As ESRD beneficiaries can now choose to enroll in Medicare Advantage (MA), please describe any anticipated effects of this enrollment change on the use of ESRD outlier services in the ESRD PPS.
- Adoption of the suggested methodology may account for systematic changes in the use of high cost outlier items. However, inherently unpredictable changes may still push the outlier payment off the 1.0 percent target. Please comment on the acceptability of the following payment adjustment methods: Payment reconciliation in the form of an add-on payment adjustment or a payment reduction might be necessary to bring payments in line with the 1 percent target. An add-on payment adjustment would be distributed after sufficient data reveal the magnitude of the deviation (1 year after the end of the payment year). The distribution of these monies could be done via a lump sum or via a per-treatment payment add-on effective for 1 year. This add-on payment adjustment would be paid irrespective of the outlier claim status in that year. A payment reduction could take the form of a reduction in the base rate, also to be applied 1 year after the end of the payment year.

As discussed in the CY 2022 ESRD PPS final rule (86 FR 61996), we received numerous public comments in response to our RFI on payment reform under the ESRD PPS. As discussed in a more detailed comment summary on the CMS website,[14] we received comments from major national patient and provider organizations and MedPAC on the RFI regarding the outlier policy. Commenters reiterated their concerns that outlier payments under the ESRD PPS have not achieved the 1.0 percent target since the system was implemented. Commenters focused on three main suggestions for the outlier policy: (1) reducing the target outlier percentage to 0.5 or 0.6 percent, which commenters maintained would more closely align with the historical percentage that has been paid under the ESRD PPS; (2) changing the methodology used to calculate the FDL and MAP amounts to better account for not only historical trends in utilization but also changes in prices and utilization of new and innovative products; and (3) re-allocating money from the ESRD PPS that is not paid out for outliers—either by allowing unspent funds to apply to a subsequent year's withhold amount or establishing a payment mechanism to support ESRD facilities' activities aimed at reducing health disparities.

(4) Changes to the Outlier Methodology for CY 2023

In response to significant public comments received over many years, in the CY 2023 ESRD PPS proposed rule (87 FR 38491 through 38493), we proposed changes to the outlier policy for CY 2023 and subsequent years. As we discussed in the proposed rule, we considered the three main suggestions that commenters raised in response to the CY 2022 RFI in developing these proposed changes.

First, we considered the recommendation from commenters that CMS reduce the outlier percentage from 1.0 percent to 0.5 percent or 0.6 percent. Although this approach would allow us to potentially increase payment under the ESRD PPS base rate for treatment of those patients who do not qualify for outlier payments, we stated that we were chiefly concerned that this approach would not directly address the root cause of outlier payments totaling less than 1 percent of overall ESRD PPS payments in prior years. Although reducing the target outlier percentage would reduce the size of outlier payments relative to total ESRD PPS payments, we stated that we were concerned that if we do not change the methodology that we use to prospectively determine the outlier threshold, we may continue to not meet even the lower target outlier percentage.

Additionally, as discussed in the CY 2011 ESRD PPS final rule (75 FR 49134), we established the 1.0 percent outlier percentage because it struck an appropriate balance between our objective of paying an adequate amount for the most costly, resource-intensive patients while providing an appropriate level of payment for those patients who do not qualify for outlier payments. We stated that we were concerned that a

[14] *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/ESRDpayment/Educational_Resources.*

reduced outlier percentage may not provide the appropriate level of payment for outlier cases, and may not protect access for beneficiaries whose care is unusually costly. This is because if we were to decrease the target outlier percentage, we would need to significantly increase the FDL amounts, which would make it more difficult for ESRD facilities to receive outlier payment based on their claims. Therefore, after careful consideration, we did not propose to reduce the outlier percentage.

Next, we considered the recommendation to re-allocate money from the ESRD PPS that is not paid out for outliers. As explained earlier in this section of the final rule, we solicited comments in the CY 2022 ESRD PPS proposed rule (86 FR 36402) about a potential payment reconciliation in the form of an add-on payment adjustment or a payment reduction, which might be necessary to bring outlier payments in line with the 1.0 percent target. As we described in the detailed RFI comment summary document on the CMS website,[15] several commenters supported this idea, and recommended that CMS allow unspent outlier funds from the prior year to reduce the amount set aside for outliers in the next year. Other commenters suggested that unspent outlier funds could be used to fund initiatives that support health equity. One national dialysis organization pointed out that lags in the claims process and refiling of claims, often over different calendar years, will present challenges to such an approach. This organization noted that these challenges could make it difficult to accurately calculate the amount of the add-on payment adjustment or ''clawback'' payment amount for each year. In the CY 2023 ESRD PPS proposed rule, we stated that we agreed with the concerns this organization raised, and believed that these challenges would make it difficult to accurately operationalize commenters' recommendations that we allow unspent funds to apply to a subsequent year's withhold amount or establish a payment mechanism to support ESRD facilities' activities aimed at reducing health disparities. Therefore, after careful consideration, we did not propose to establish a payment reconciliation methodology for the ESRD PPS outlier policy.

Lastly, we discussed in the CY 2023 ESRD PPS proposed rule that we considered the feedback from interested parties and commenters in the past ESRD PPS TEPs and in comments to the RFI in the CY 2022 ESRD PPS proposed rule regarding the methodology used to calculate the FDL amounts. As commenters have previously noted, the current methodology that we use to prospectively calculate the FDL amounts has not been able to effectively account for declining use of eligible ESRD outlier services (that is, separately billable items and services prior to 2011) each year since the implementation of the ESRD PPS. For example, the CY 2021 FDL amounts ($48.33 for adult and $41.04 pediatric patients) were added to the predicted MAP amounts to determine the outlier thresholds using 2019 data. The outlier MAP amount continued to fall from 2019 to 2021. Consequently, in 2021 claims, outlier payments comprised approximately 0.4 percent of total ESRD PPS payments, demonstrating that the use of 2019 data resulted in thresholds too high to achieve the targeted 1.0 percent outlier payment.

Several organizations that commented in response to the RFI[16] in the CY 2022 ESRD PPS proposed rule expressed that using a retrospective FDL trend based on historical utilization data will provide a better calculation of the appropriate prospective FDL amounts. These organizations also cautioned that such a methodology will remain sensitive to changes in utilization or price increases for new and innovative products. Commenters suggested that such a methodology will likely not succeed in estimating the appropriate FDL amounts in years when there are significant changes to the ESRD PPS, such as in years that immediately follow the end of a period during which CMS has paid for a product using the TDAPA or TPNIES payment adjustments under the ESRD PPS. MedPAC suggested that CMS consider modeling alternative approaches to establishing the outlier threshold and use an approach that reflects the trend over time in spending for items in the ESRD PPS bundled payment that were separately billable prior to 2011.

We also noted that in the CY 2022 ESRD PPS final rule (86 FR 36402), we solicited comments on any anticipated effects enrollment changes in MA plans might have on the use of ESRD outlier services. National provider organizations pointed out that to the extent that MA plans are not permitted to systematically include healthier ESRD beneficiaries and exclude costly beneficiaries, there would seem to be little impact on the outlier pool. They expressed concern about the decision[17] to eliminate network adequacy standards that apply to ESRD facilities. They predicted these decisions would discourage many ESRD patients from enrolling in MA plans, especially those needing specialized treatment or requiring additional medications. To the extent this scenario may occur, commenters claimed that it could result in ''outlier'' patients, specifically, those sicker, costlier patients, remaining in traditional Medicare and the healthier, less costly patients enrolling in MA plans.

Based on these comments, in the CY 2023 ESRD PPS proposed rule, we proposed an approach that would account for the historical trend in spending for formerly separately billable items and services and would also effectively account for the introduction of new and innovative products under the ESRD PPS. We stated that we believed that our proposed methodology would also adapt to changes in the ESRD PPS patient population, such as the potential scenario that commenters raised in which costlier ''outlier'' patients might remain in traditional Medicare while healthier, less costly patients enroll in MA plans.

As we discussed earlier in this section of the final rule, our current methodology prospectively calculates the adult and pediatric FDL and MAP amounts based on simulated outlier payments. The utilization of outlier services for these simulated outlier payments comes from a single year of ESRD PPS claims, and the prices come from the pricing methodology described earlier in this section of the final rule

[15] *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/ESRDpayment/Educational_Resources.*

[16] *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/ESRDpayment/Educational_Resources.*

[17] We believe the commenters were referring to a CMS decision to remove outpatient dialysis from the list of facility types subject to network adequacy standards and require that MA organizations submit an attestation that it has as an adequate network that provides the required access and availability to dialysis services, including outpatient facilities. CMS indicated in the Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program (CMS–4190–F) final rule that we believe there is more than one way to access medically necessary dialysis care and that we wanted plans to exercise all of their options to best meet a beneficiary's health care needs. (85 FR 33796, 33852 through 33866). Further, regardless of whether a facility or provider specialty type is subject to network adequacy standards, MA organizations are required in § 422.112(a)(3) to arrange for health care services outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs. Section 422.112(a)(10) requires MA plans to ensure access and availability to covered services consistent with the prevailing community pattern of health care delivery in the areas served by the network. (85 FR 33858 through 33860).

using latest available prices inflated to forecasted prices for the rule year. Under the current methodology, we prospectively set the adult and pediatric FDL amounts so that simulated outlier payments for the rule year are estimated to equal 1.0 percent.

For CY 2023 and subsequent years, we proposed to continue to calculate the adult and pediatric MAP amounts for the rule year (CY 2023) following our established methodology, but we would prospectively calculate the adult FDL amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years. We also proposed to adjust the calculation of the historical FDL trend for years that immediately follow the end of a period during which CMS has paid for a product using the TDAPA or TPNIES payment adjustments under the ESRD PPS. We noted in the proposed rule that we did not propose to apply this method to pediatric FDL amount calculations, as the pediatric population is too small to reliably use this method.

As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38492 through 38493), we proposed the following steps for prospectively calculating the adult FDL amounts:

- *Step 1:* Use ESRD PPS claims from the 3 most recent available data years, relative to the rule year. For CY 2023, this would include data from CY 2019, CY 2020, and CY 2021. Using these claims, the projected base rate for the rule year, and the latest available prices of ESRD outlier services, we would use our established methodology to calculate the FDL amounts that would have achieved the 1.0 percent outlier target for each year. In the following steps, we refer to these calculated FDL amounts as the ''retrospective'' FDL amounts.
- *Step 2:* If any items or services that were previously paid for using the TDAPA or TPNIES in any of the 3 most recent available data years would be ESRD outlier services for the rule year, then we would also calculate an alternative series of retrospective FDL amounts. This alternative series would account for any new ESRD outlier services, that is, any ESRD outlier services for the rule year that were previously paid for using the TDAPA or TPNIES in any of the 3 most recent available data years. In the following steps, we refer to this alternative series of retrospective FDL amounts as the ''adjusted'' retrospective FDLs. Specifically, we would calculate the adjusted retrospective FDL amounts as follows:

++ If a new ESRD outlier service was paid for using the TDAPA or TPNIES in the most recent available data year, as in the case of calcimimetics in the CY 2020 data used for the CY 2022 ESRD PPS rulemaking, then we would calculate the first retrospective FDL amount for that year using the latest available prices and historical utilization of ESRD outlier services that includes TDAPA or TPNIES utilization for the new ESRD outlier service. We would also calculate a second retrospective FDL amount for that year that excludes the new ESRD outlier service. To calculate the adjusted retrospective FDLs for the preceding 2 data years, we would take the difference between the corresponding FDL amount with and without the new ESRD outlier service for the most recent data year, and add this amount to each retrospective FDL amount calculated in Step 1. For CY 2023, we would add the difference calculated for CY 2021 to the retrospective FDL amounts for CY 2020 and CY 2019.

++ If a new ESRD outlier service first became eligible in the most recent available data year, as in the case of calcimimetics in the CY 2021 data used for this CY 2023 ESRD PPS proposed rule, then we would calculate the first retrospective FDL amount for the most recent data year using the latest available prices and historical utilization of ESRD outlier services. We would also calculate a second retrospective FDL amount for that year that excludes the new ESRD outlier service. To calculate the adjusted retrospective FDL amounts for the preceding 2 data years, we would take the difference between the corresponding FDL amount with and without the new ESRD outlier service for the most recent data year, and add this amount to each retrospective FDL amount calculated in Step 1. For CY 2023, we would add the difference calculated for CY 2021 to the retrospective FDL amounts for CY 2020 and CY 2019.

++ If a new ESRD outlier service first became eligible in the second most recent available data year, as in the case of calcimimetics in the CY 2022 data that we would expect to use for the CY 2024 rulemaking, then we would calculate retrospective FDL amounts for the most recent two data years using the latest available prices and historical utilization of outlier services. For the earliest historical year, in which the new ESRD outlier service was still being paid for using the TDAPA or the TPNIES, we would also calculate a second retrospective FDL amount for that year that excludes the new ESRD outlier service. To calculate the adjusted retrospective FDL amount for the earliest historical year, we would take the difference between the corresponding FDL amount with and without the new ESRD outlier service in the second most recent available data year, and add this amount to the retrospective FDL amount calculated in Step 1. For CY 2023, we would add the difference calculated for CY 2020 to the retrospective FDL amount for CY 2019.

++ If a new ESRD outlier service first became outlier eligible earlier than any of the 3 most recent available data years, we would not calculate any adjusted retrospective FDL amounts for that item or service. For example, for CY 2025, we would not calculate any adjusted retrospective FDL amounts to account for calcimimetics in the CY 2021, CY 2022, and CY 2023 claims. We would calculate only the series of retrospective FDL amounts for these years in accordance with Step 1.

- *Step 3:* Using either the series of retrospective FDL amounts or adjusted retrospective FDL amounts, as appropriate, for the 3 most recent available data years, we would use a linear regression to calculate the historical trend in FDL amounts. We would project this trend forward to determine the appropriate FDL amount for the rule year.

We received several comments on our proposal to modify the outlier methodology. Those comments and our responses are set forth below.

Comment: Several commenters urged CMS to reduce the outlier percentage from 1.0 percent to 0.5 or 0.6 percent. A provider advocacy organization further claimed that even if CMS were to achieve the full 1 percent outlier target, $82 million in ESRD PPS expenditures would be withheld from ESRD facilities until a later date when outlier payment adjustments were processed and distributed. This commenter recommended that CMS reduce the percentage of payments allocated for the outlier pool from 1 percent to 0.5 percent to ensure the maximum amount of up-front funds flow to ESRD facilities during this time of crisis currently being driven by staffing shortages and inflationary pressures. A small and rural dialysis provider voiced similar concerns and claimed that reducing the outlier percentage to 0.5 percent would serve ESRD patients by helping to keep their units open.

Response: As discussed in the CY 2023 ESRD PPS proposed rule, we are concerned that a reduced outlier percentage may not provide the appropriate level of payment for outlier

cases, and may not protect access for beneficiaries whose care is unusually costly. If we were to reduce the outlier percentage, we would then need to increase the FDL amount which would make it more difficult for ESRD facilities to receive outlier payment based on their claims. Regarding the comment about money being withheld from ESRD facilities, we note that outlier payments are paid as an adjustment to the ESRD PPS base rate, so payment is made when the ESRD claim is paid. There is no reason that outlier payments would be processed or paid at a later date than any other payments under the ESRD PPS.

We appreciate the concerns commenters raised about staffing shortages and inflationary pressures, and we agree with the commenters who stated that recent higher inflationary trends have impacted the outlook for price growth over the next several quarters. As discussed in section II.B.1.a.(3)(c) of this final rule, we are finalizing a 3.0 percent increase to the productivity-adjusted ESRDB market basket for CY 2023. We believe that this final update to the market basket more accurately accounts for the recent inflationary pressures and changes in the cost of labor that commenters cited.

Comment: Several commenters expressed their belief that the outlier policy results in money being withheld from ESRD facilities and not returned to them, due to the fact that the ESRD PPS achieved less than the 1 percent outlier target in past years. A provider advocacy organization claimed that from 2019 to 2021, the outlier policy has resulted in over $150 million in Medicare dollars designated for the ESRD PPS outlier pool but not ultimately released to ESRD facilities. An LDO estimated that total ''leakage'' from the outlier pool exceeds $500 million as of CY 2021 and encouraged CMS to consider that a payment reconciliation methodology or other additional measures may be necessary to stem what they described as the loss of patient care dollars from the ESRD PPS. Some commenters suggested reducing a subsequent year's target percent or applying a mechanism to restore unspent outlier dollars to the ESRD PPS.

Response: While we appreciate the concerns that commenters raised, we note that ESRD PPS payment policy is set prospectively. That is, we establish the outlier FDL and MAP amounts each year at a level that our analysis indicates will effectively protect access for the costliest beneficiaries while maintaining an appropriate ESRD PPS base rate for all other beneficiaries. As discussed previously, we did not propose, nor are we finalizing, to establish a payment reconciliation methodology for the ESRD PPS outlier policy for CY 2023, because we considered that lags in the claims process and refiling of claims, often over different calendar years, would present challenges to such an approach.

Regarding the suggestion to reduce a subsequent year's target outlier percentage, we do not believe this approach would be appropriate at this time. As noted earlier in this final rule and discussed in the CY 2023 ESRD PPS proposed rule, we are concerned that a reduced outlier percentage may not provide the appropriate level of payment for outlier cases, and may not protect access for beneficiaries whose care is unusually costly. If we were to reduce the outlier percentage, we would then need to increase the FDL amount which would make it more difficult for ESRD facilities to receive outlier payment based on their claims. Rather, we believe the proposed methodology is the most appropriate, because it better aligns assumptions about future trends in prices and utilization of ESRD outlier services with actual trends in the utilization of such services.

Comment: A provider advocacy organization expressed concern about the impact of the outlier policy on pediatric ESRD facilities, and stated that instead of attempting to qualify more cases for outlier payments, CMS should analyze the cost of providing care in pediatric facilities and develop a pediatric-specific ESRD PPS base rate to appropriately compensate these specialized facilities for their work. A professional organization of pediatric nephrologists expressed similar concerns, and recommended that CMS adopt a pediatric modifier to appropriately reimburse for pediatric care, since the proposed continuation of the longstanding outlier policy applies to such a small number of pediatric patients that it does not adequately address costs.

Response: We appreciate the concerns these commenters raised about payment adequacy for pediatric patients. In the CY 2022 ESRD PPS proposed rule (86 FR 36402 through 36404), we solicited comments on ESRD PPS payment for pediatric patients. In the CY 2022 ESRD PPS final rule (86 FR 61997), we noted similar concerns from commenters that the total costs of ESRD care delivered to pediatric dialysis patients are not covered by the current ESRD PPS bundled payment and existing pediatric multipliers. Additionally, as discussed in section II.E of this final rule, we received comments in response to our RFI in the CY 2023 ESRD PPS proposed rule about ways to address payment disparities for pediatric patients. We appreciate the thoughtful responses that commenters provided to both of these comment solicitations, and will take them into consideration to potentially inform future rulemaking.

While we agree with commenters that the ESRD PPS outlier policy alone is not sufficient to account for the costs of furnishing renal dialysis services to pediatric beneficiaries, we continue to believe that an outlier policy is important for paying an adequate amount for the most costly, resource-intensive pediatric patients. As we noted in the CY 2011 ESRD PPS final rule (75 FR 49139), our longstanding methodology establishes separate FDL and MAP amounts for pediatric and adult beneficiaries so that the outlier thresholds for determining outlier payments for pediatric patients are not inappropriately high, resulting in fewer outlier payments for these beneficiaries.

Comment: Several commenters, including a network of dialysis organizations and regional offices, a nonprofit dialysis association, a coalition of dialysis organizations, MedPAC, and an LDO, expressed support for the proposed change to the outlier methodology. A network of dialysis organizations and regional offices further stated they support the outlier payment adjustment as an appropriate protection for patients who utilize significantly more services than the average patient.

MedPAC supported the proposed methodology and acknowledged that it is likely to improve outlier payment accuracy, but also urged CMS to refine its approach for applying the pricing data that the agency uses to project FDL amounts, particularly for drugs. MedPAC suggested CMS use a drug price inflation factor based on ASP values, and noted that the ASP data that CMS uses to determine facilities' actual outlier payments might be a more accurate data source on drug prices than the ESRDB market basket pharmaceutical price proxies that are currently used.

Lastly, one LDO encouraged CMS to monitor the performance of the outlier payment adjustment under the proposed methodology. A coalition of dialysis organizations expressed support for the proposed change to the outlier methodology and encouraged CMS to continue sharing any under- or over-payment from the outlier pool and consider ways to adjust the target outlier percentage as needed.

Response: We appreciate commenters' support for the proposed change to the

outlier methodology. We intend to continue to monitor the performance of the outlier policy on an ongoing basis and continue to publish information in our annual rules in the **Federal Register** about the performance of the outlier policy in the future. We appreciate the methodological suggestions that commenters provided. Although we are not finalizing those changes in this final rule, we will take these suggestions into consideration to potentially inform future rulemaking.

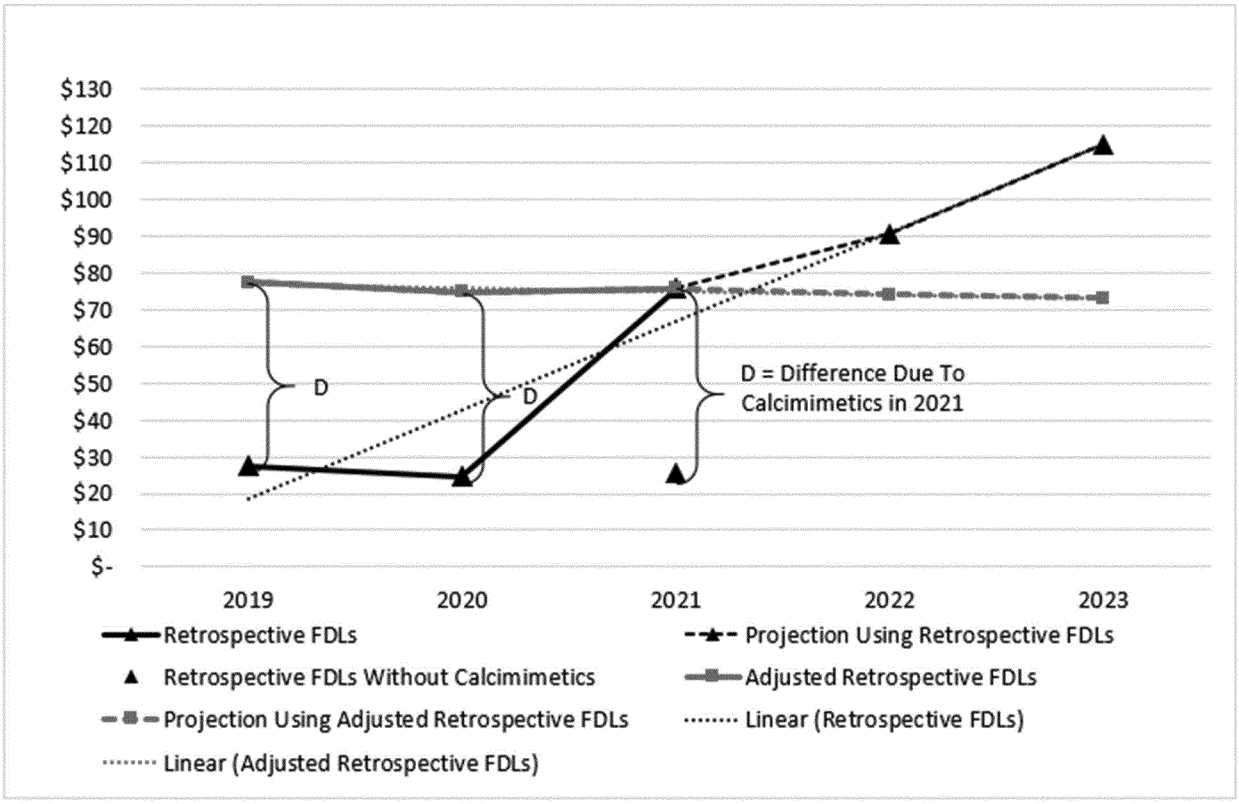
Comment: A nonprofit dialysis association and an LDO expressed concerns about using TDAPA and TPNIES expenditures in the calculation of the FDL and MAP amounts. The LDO claimed that the inclusion of these expenditures has the potential to increase the dollars withheld from the ESRD PPS base rate and result in the outlier pool paying less than the 1 percent target. The nonprofit dialysis association claimed that the proposed methodology would not succeed in estimating the outlier pool in years where there were significant changes to the ESRD PPS, such as in years when CMS incorporates new ESRD outlier services that were previously paid for using the TDAPA or the TPNIES into the ESRD PPS bundled payment.

Response: We believe that these commenters have misunderstood how TDAPA and TPNIES expenditures would be used in the proposed outlier methodology, as well as the effect that including these expenditures would have on outlier payments. As the commenters correctly noted, any renal dialysis service that is paid for using the TDAPA or the TPNIES would not be considered an eligible ESRD outlier service. However, following the conclusion of the TDAPA or TPNIES payment period, certain renal dialysis services would become eligible ESRD outlier services. Under our proposed methodology, which we are finalizing, we will only include expenditures for renal dialysis services that are in their final year of payment under the TDAPA or the TPNIES if those services would become eligible ESRD outlier services in the following (target) year. We did not propose to include any TDAPA or TPNIES expenditures in our estimates of ESRD outlier payments for setting the FDL and MAP amounts for any services that would not be eligible ESRD outlier services in the target year. We also proposed to account for the introduction of such new eligible ESRD outlier services by calculating a retrospective trend line based on prior years' TDAPA or TPNIES utilization. Because these expenditures will be added to the retrospective FDLs to calculate the adjusted retrospective FDLs under the proposed methodology, our inclusion of TDAPA or TPNIES utilization will always reduce the slope of the trend line of the adjusted retrospective FDL, as demonstrated in Figure 1. Therefore, contrary to the concerns that commenters raised, this inclusion of TDAPA and TPNIES utilization data will avoid overestimating ESRD outlier expenditures in years when new renal dialysis services are added to the ESRD PPS bundled payment and will reduce the likelihood of paying less than the 1 percent outlier target.

Final Rule Action: After careful consideration of the comments, we are finalizing our proposed methodology for prospectively calculating the adult FDL amounts for the outlier policy beginning for CY 2023.

For illustration purposes, Figure 1 presents an example of the adult retrospective FDL amounts and adjusted retrospective FDL amounts calculated for CY 2019, CY 2020, and CY 2021, as well as the projected FDL trend through CY 2023, under our final methodology. The adjusted retrospective FDL amounts shown in Figure 1 will account for the difference in retrospective FDL amounts calculated with and without calcimimetics, which became ESRD outlier services beginning January 1, 2021. Figure 1 illustrates how the methodology will incorporate data for new ESRD outlier services while continuing to account for the downward historical trend in spending for formerly separately billable items and services.

Figure 1. Retrospective FDL Amounts and Adjusted Retrospective FDL Amounts (CY 2019 through CY 2021) and Their Corresponding Projected FDLs through CY 2023 for Adults



(5) CY 2023 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2023, we proposed to update the MAP amounts for adult and pediatric patients using the latest available CY 2021 claims data. We proposed to update the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2021 claims data, and use the latest available claims data from CY 2019, CY 2020, and CY 2021 to calculate the FDL amount for adults, in accordance with the proposed methodology discussed in section II.B.1.c.(4) of this final rule.

We also stated that we recognize that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and FDL amounts every year under the ESRD PPS. CY 2021 claims data showed outlier payments represented approximately 0.5 percent of total payments. Accordingly, as discussed in section II.B.1.c.(4) of this final rule, we are changing our ESRD PPS outlier methodology to better target 1.0 percent of total payments.

For this final rule, the outlier services MAP amounts and pediatric FDL amounts for CY 2023 were updated based on claims data from CY 2021, consistent with our policy to base any adjustments made to the MAP amounts under the ESRD PPS upon the most recent data year available and our proposal for CY 2023. The adult FDL amounts for CY 2023 were derived from the projected FDL trend calculated according to the methodology described in section II.B.1.c.(4) of this final rule that we are finalizing for CY 2023.

The impact of this update is shown in Table 11, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2022 with the updated final estimates for this final rule. The estimates for the final CY 2023 MAP amounts, which are included in Column II of Table 11, were inflation adjusted to reflect projected 2023 prices for ESRD outlier services.

TABLE 11: Outlier Policy: Impact of Using Updated Data for the Outlier Policy

	Column I Final outlier policy for CY 2022 (based on 2020 data, price inflated to 2022)*		Column II Final outlier policy for CY 2023 (based on 2021 data, price inflated to 2023)**	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	$ 25.91	$ 44.49	$24.13	$41.36
Adjustments				
Standardization for outlier services	1.0693	0.9805	1.0819	0.9774
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$27.15	$42.75	$25.59	$39.62
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$26.02	$75.39	$23.29	$73.19
Patient-month-facilities qualifying for outlier payment	12.89%	7.08%	12.90%	5.90%

*Column I was obtained from Column II of Table 1 from the CY 2022 ESRD PPS final rule (86 FR 61883).
**The FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2019, 2020, and 2021.

As demonstrated in Table 11, the estimated FDL per treatment that determines the CY 2023 outlier threshold amount for adults (Column II; $73.19) is lower than that used for the CY 2022 outlier policy (Column I; $75.39). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $42.75 to $39.62. For pediatric patients, there is a decrease in the FDL amount from $26.02 to $23.29. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from $27.15 to $25.59.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2023 will be 5.90 percent for adult patients and 12.90 percent for pediatric patients, based on the 2021 claims data and methodology finalized in section II.B.1.c.(4) of this final rule. The outlier MAP and FDL amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of ESAs and other injectable drugs).

(6) Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. Based on the 2021 claims, outlier payments represented approximately 0.5 percent of total payments, which is below the 1 percent target due to declines in the use of outlier services.

As we stated in the CY 2023 ESRD PPS proposed rule (87 FR 38494), recalibration of the thresholds using 2021 data and the proposed methodology, which is further described in section II.B.1.c.(4) of this final rule, is expected to result in aggregate outlier payments closer to the 1 percent target in CY 2023. We stated in the CY 2023 ESRD PPS proposed rule that we believed finalizing the proposed update to the outlier MAP and FDL amounts for CY 2023 would increase payments for ESRD beneficiaries requiring higher resource utilization. This would move us closer to meeting our 1 percent outlier policy goal, because we are using more current data for computing the MAP and FDL amounts, which is more in line with current outlier services utilization rates. We also noted in the CY 2023 ESRD PPS proposed rule that recalibration of the FDL amounts would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments.

The comments and our responses to the comments on our proposed updates to the outlier policy are set forth below.

Comment: Several commenters noted that the outlier policy has historically achieved less than the 1 percent target, and recommended that CMS eliminate the ESRD PPS outlier policy. One small dialysis organization within a large health system stated that they appreciate CMS's willingness to address outlier payments but expressed concern that the outlier provision is not working as intended. Several commenters, including MedPAC, LDOs, and a network of dialysis organizations and regional offices, expressed support for the outlier policy and the proposed adjustment to the methodology for calculating the FDL amount for adults.

Response: We appreciate the support from commenters. Regarding the commenters who recommended the elimination of the outlier policy, we note that as we discussed earlier in this CY 2023 ESRD PPS final rule, we are concerned that reducing the outlier percentage to 0 would not provide the appropriate level of payment for outlier cases, and may not protect access for

beneficiaries whose care is unusually costly.

Final Rule Action: After considering the public comments, we are finalizing the updated outlier thresholds for CY 2023 displayed in Column II of Table 11 of this final rule and based on CY 2021 data.

d. Final Impacts to the CY 2023 ESRD PPS Base Rate

(1) ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), CMS established the methodology for calculating the ESRD PPS per-treatment base rate, that is, the ESRD PPS base rate, and calculating the per treatment payment amount, which are codified at § 413.220 and § 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, training adjustment add-on, TDAPA, and TPNIES.

(2) Annual Payment Rate Update for CY 2023

The final ESRD PPS base rate for CY 2023 is $265.57. This update reflects several factors, described in more detail as follows:

Wage Index Budget-Neutrality Adjustment Factor: We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2023, we did not propose any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the final CY 2023 wage index budget-neutrality adjustment factor using treatment counts from the 2021 claims and facility-specific CY 2022 payment rates to estimate the total dollar amount that each ESRD facility will have received in CY 2022. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2023. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the CY 2023 ESRD PPS wage index and labor-related share for CY 2023. As discussed in section II.B.1.b of this final rule, the ESRD PPS wage index for CY 2023 includes an update to the most recent hospital wage data and continued use of the 2018 OMB delineations. Additionally, as discussed in section II.B.1.b(3)(b)(iii) of this final rule, we are increasing the ESRD PPS wage index floor from 0.5000 to 0.6000 and applying a permanent 5-percent cap on any decrease to an ESRD facility's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. The total of these payments becomes the new CY 2023 amount of wage-adjusted expenditures for all ESRD facilities. The wage index budget-neutrality factor is calculated as the target amount divided by the new CY 2023 amount. When we multiplied the wage index budget neutrality factor by the applicable CY 2023 estimated payments, aggregate payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget neutrality adjustment factor ensures that wage index adjustments do not increase or decrease aggregate Medicare payments with respect to changes in wage index updates. The CY 2023 wage index budget-neutrality adjustment factor is 0.999730. This application would yield a CY 2023 ESRD PPS base rate of $257.83 prior to the application of the market basket increase factor ($257.90 × 0.999730 = $257.83). This CY 2023 wage index budget-neutrality adjustment factor reflects the impact of all wage index policy changes, including the CY 2023 ESRD PPS wage index and labor-related share, increase to the wage index floor, and permanent 5-percent cap on wage index decreases.

For purposes of illustration and analysis, we also calculated a separate budget neutrality factor to estimate the impact that the permanent 5-percent cap on wage index decreases would have on CY 2023 ESRD PPS payments. Following the steps described earlier in this section of the CY 2023 ESRD PPS final rule, we divided estimated payments without the 5-percent cap by estimated payments with the cap. We calculated the resulting budget neutrality factor as 0.999905. Applying this budget neutrality factor to the ESRD PPS base rate, we estimate that the permanent 5-percent cap would result in a $0.02 decrease to the ESRD PPS base rate ($257.90 × 0.999905 = $257.88). The overall CY 2023 wage index budget-neutrality adjustment factor is lower because of the effects on budget neutrality of the updated CY 2023 wage index data.

Market Basket Increase: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase factor. The latest CY 2023 projection of the ESRDB market basket percentage increase factor is 3.1 percent. In CY 2023, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As discussed previously in section II.B.1.a of this final rule, the productivity adjustment for CY 2023 is 0.1 percent, thus yielding an update to the base rate of 3.0 percent for CY 2023. Therefore, the CY 2023 ESRD PPS base rate is $265.57 ($257.90 × 0.999730 × 1.030 = $265.57).

The comments and our responses to the comments on our proposed updates to the ESRD PPS base rate are set forth below.

Comment: Several commenters expressed concerns with the proposed update to the ESRD PPS base rate for CY 2023. Many commenters, including LDOs, ESRD facilities, professional associations, patients, provider advocacy organizations, and a coalition of dialysis organizations, requested that CMS apply a forecast error payment adjustment to the ESRD PPS base rate to support ESRD facilities during this inflationary period, particularly accounting for what forecasters state is an error in the forecasted payment updates for CYs 2021 and 2022. The commenters stated that forecasted payment updates that they view as incorrect, coupled with the impact of the workforce shortage, have put them in financial difficulty. A coalition of dialysis organizations and a non-profit dialysis association both noted that if CMS were to adjust the CY 2022 base rate for forecast error, the CY 2022 base rate would have been $263.21, which would result in a calculated CY 2023 proposed base rate of $269.53 rather than the proposed $264.09.

Response: As we discussed in section II.B.1.a.(3)(c) of this CY 2023 ESRD PPS final rule, there is no precedent to adjust for market basket forecast error in the annual ESRD PPS update; however, the

forecast error for a market basket update is calculated as the actual market basket increase for a given year less the forecasted market basket increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative. For example, the CY 2017 ESRDB forecast error was −0.8 percentage point, while the CY 2021 ESRDB forecast error was +1.2 percentage point; CY 2022 historical data is not yet available to calculate a forecast error for CY 2022.

We further noted in section II.B.1.a.(3)(c) of this final rule that our longstanding policy since the inception of the ESRD PPS has been to update ESRD PPS payments based on an appropriate market basket in accordance with section 1881(b)(14)(F)(i) of the Act. For this final rule, we have incorporated more recent historical data and forecasts, which utilize the most current projections of expected future price and wage pressures likely to be faced by ESRD facilities to provide renal dialysis services. We did not propose a forecast error payment adjustment for CY 2023, and we are not finalizing such an adjustment for this final rule. As we have discussed in past rulemaking (85 FR 71434; 80 FR 69031) and in section II.B.1.b.(2) of this final rule, predictability in Medicare payments is important to enable ESRD facilities to budget and plan their operations. As we noted in section II.B.1.a.(3)(c) of this final rule, forecast error calculations are unpredictable, and can be both positive and negative. We note that over longer periods of time, the positive differences between the actual and forecasted market basket increase in prior years can offset negative differences; therefore, we do not believe it is necessary to implement a forecast error adjustment for the ESRD PPS based solely on a positive CY 2021 forecast error.

Final Rule Action: After consideration of the public comments received, we are finalizing a CY 2023 ESRD PPS base rate of $265.57. This amount reflects the CY 2023 wage index budget-neutrality adjustment factor of 0.999730, and the CY 2023 ESRD PPS productivity-adjusted market basket update of 3.0 percent.

e. Update to the Average per Treatment Offset Amount for Home Dialysis Machines

In the CY 2021 ESRD PPS final rule (85 FR 71427), we expanded eligibility for the TPNIES under § 413.236 to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. To establish the TPNIES basis of payment for these items, we finalized the additional steps that the Medicare Administrative Contractors (MACs) must follow to calculate a pre-adjusted per treatment amount, using the prices they establish under § 413.236(e) for a capital-related asset that is a home dialysis machine, as well as the methodology that CMS uses to calculate the average per treatment offset amount for home dialysis machines that is used in the MACs' calculation, to account for the cost of the home dialysis machine that is already in the ESRD PPS base rate. For purposes of this final rule, we will refer to this as the ''TPNIES offset amount.''

The methodology for calculating the TPNIES offset amount is set forth in § 413.236(f)(3). Section 413.236(f)(3)(v) states that effective January 1, 2022, CMS annually updates the amount determined in § 413.236(f)(3)(iv) by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor. The TPNIES for capital-related assets that are home dialysis machines is based on 65 percent of the MAC-determined pre-adjusted per treatment amount, reduced by the TPNIES offset amount, and is paid for 2 calendar years.

We proposed a CY 2023 TPNIES offset amount for capital-related assets that are home dialysis machines of $9.73, based on the proposed CY 2023 ESRDB market basket increase factor minus the productivity adjustment of 2.4 percent (2.8 percent minus 0.4 percentage point). We explained in the CY 2023 ESRD PPS proposed rule that applying the proposed update factor of 1.024 to the CY 2022 offset amount resulted in the proposed CY 2023 offset amount of $9.73 ($9.50 × 1.024 = $9.73). We proposed to update this calculation to use the most recent data available in the CY 2023 ESRD PPS final rule.

We received 5 comments on this proposal, including comments from an LDO, small dialysis organization, a home dialysis advocacy organization, a coalition of dialysis organizations, and a provider advocacy organization. The comments and our responses to the comments on the proposed update to the TPNIES offset amount are set forth below.

Comment: All of the commenters on this proposal expressed concern about the proposed application of the TPNIES offset amount for CY 2023. Two commenters expressed that the application of the TPNIES offset amount blunts the potential positive impact of the TPNIES. The LDO agreed with the application of the TPNIES offset amount but expressed that the current policy may diminish innovation and limit resources necessary for ESRD facilities to incorporate new and innovative equipment and supplies into their practices. The home dialysis advocacy organization expressed opposition to the application of the TPNIES offset amount but expressed appreciation for the proposed use of the market basket update factor to update the TPNIES offset adjustment amount.

Response: We appreciate the concerns that these commenters raised. As discussed in the CY 2021 ESRD PPS final rule (85 FR 71422 through 71423), we finalized an offset amount so that the TPNIES will cover the estimated marginal costs of new and innovative home dialysis machines. ESRD facilities using the new and innovative home dialysis machine receive a per treatment payment to cover some of the cost of the new machine per treatment minus a per treatment payment amount that we estimate to be included in the ESRD PPS base rate for current home dialysis machines that they already own. Because we have received questions about how the TPNIES offset amount is included in the calculation of payments under the ESRD PPS, we are clarifying that under the policy at § 413.236(f)(iii) that was established in the CY 2020 ESRD PPS final rule, the annually-adjusted offset amount is subtracted from the MAC-determined price to account for the cost of home dialysis machine that is already in the ESRD PPS base rate. We disagree with the commenters who stated that the TPNIES offset will lead to decreased resources or less innovation. Rather, the TPNIES offset amount prevents duplicate payment under the ESRD PPS for a service which is already included in the ESRD PPS base rate.

Final Rule Action: We are finalizing our proposal to calculate the CY 2023 TPNIES offset amount using the most recent data available. The CY 2022 TPNIES offset amount for capital-related equipment that are home dialysis machines used in the home is $9.50. As discussed previously in section II.B.1.a of this final rule, the final CY 2023 ESRDB market basket increase factor minus the productivity adjustment is 3.0 percent (3.1 percent minus 0.1 percent). Applying the update factor of 1.030 to the CY 2022 TPNIES offset amount results in a final CY 2023 TPNIES offset amount of $9.79 ($9.50 × 1.030).

f. Revision to the Oral-Only Drug Definition and Clarification Regarding the ESRD PPS Functional Category Descriptions

(1) Background

Section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. Section 1881(b)(14)(B) of the Act defines renal dialysis services, and subclause (iii) of such section states that these services include other drugs and biologicals [18] that are furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, and any oral equivalent form of such drug or biological.

When we implemented the ESRD PPS in 2011 (75 FR 49030), we interpreted this provision as including not only injectable drugs and biological products used for the treatment of ESRD (other than ESAs and any oral form of ESAs, which are included under clause (ii) of section 1881(b)(14)(B) of the Act), but also all oral drugs and biological products used for the treatment of ESRD and furnished under title XVIII of the Act. We also concluded that, to the extent oral-only drugs or biological products used for the treatment of ESRD do not fall within clause (iii) of section 1881(b)(14)(B) of the Act, such drugs or biological products would fall under clause (iv) of such section, and constitute other items and services used for the treatment of ESRD that are not described in clause (i) of section 1881(b)(14)(B) of the Act.

We finalized and promulgated the payment policies for oral-only renal dialysis service drugs or biological products in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49053). In that rule we defined renal dialysis services at § 413.171 as including other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was made separately prior to January 1, 2011 under Title XVIII of the Act, including drugs and biologicals with only an oral form. Although we included oral-only renal dialysis service drugs and biologicals in the definition of renal dialysis services in the CY 2011 ESRD PPS final rule (75 FR 49044), we also finalized a policy to delay payment for these drugs under the ESRD PPS until January 1, 2014. In the CY 2011 ESRD PPS proposed rule (74 FR 49929), we noted that the only oral-only drugs that we identified were phosphate binders and calcimimetics, specifically, cinacalcet hydrochloride, lanthanum carbonate, calcium acetate, sevelamer hydrochloride, and sevelamer carbonate. All of these drugs fall into the ESRD PPS functional category for bone and mineral metabolism. In the CY 2011 ESRD PPS final rule (75 FR 49043), we explained that there were certain advantages to delaying the implementation of payment for oral-only drugs and biological products under the ESRD PPS, including allowing ESRD facilities additional time to make operational changes and logistical arrangements to furnish oral-only renal dialysis service drugs and biological products to their patients. Accordingly, we codified the delay in payment for oral-only renal dialysis service drugs and biological products at § 413.174(f)(6), and provided that payment to an ESRD facility for renal dialysis service drugs and biological products with only an oral form would be incorporated into the PPS payment rates effective January 1, 2014. Since oral-only drugs are generally not a covered service under Medicare Part B, this delay of payment under the ESRD PPS also allowed coverage to continue under Medicare Part D.

On January 3, 2013, ATRA was enacted. Section 632(b) of ATRA precluded the Secretary from implementing the policy under § 413.174(f)(6) relating to oral-only ESRD-related drugs in the ESRD PPS prior to January 1, 2016. Accordingly, in the CY 2014 ESRD PPS final rule (78 FR 72185 through 72186), we delayed payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS until January 1, 2016. We implemented this delay by revising the effective date at § 413.174(f)(6) for providing payment for oral-only renal dialysis service drugs under the ESRD PPS from January 1, 2014 to January 1, 2016. In addition, we changed the date when oral-only renal dialysis service drugs and biological products would be eligible for outlier services under the outlier policy described in § 413.237(a)(1)(iv) from January 1, 2014 to January 1, 2016.

On April 1, 2014, PAMA was enacted. Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to preclude the Secretary from implementing the policy under § 413.174(f)(6) relating to oral-only renal dialysis service drugs and biological products prior to January 1, 2024. We implemented this delay in the CY 2015 ESRD PPS final rule (79 FR 66262) by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS at § 413.174(f)(6) from January 1, 2016 to January 1, 2024. We also changed the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2016 to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available.

On December 19, 2014, ABLE was enacted. Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025. Similar to the CY 2014 and CY 2015 ESRD PPS final rule changes, we implemented this delay in the CY 2016 ESRD PPS final rule (80 FR 469028) by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS at § 413.174(f)(6) from January 1, 2024, to January 1, 2025. We also changed the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2024 to January 1, 2025. We stated that we continue to believe that oral-only renal dialysis service drugs and biological products are an essential part of the ESRD PPS bundled payment and should be paid for under the ESRD PPS.

Section 217(c)(1) of PAMA required us to adopt a process for determining when oral-only drugs are no longer oral-only. In the CY 2016 ESRD PPS proposed rule (80 FR 37839), when considering a definition for the term ''oral-only drug,'' we noted that in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49039), we described oral-only drugs as those that have no injectable equivalent or other form of administration. In the CY 2016 ESRD PPS final rule (80 FR 69027), we finalized the definition of oral-only drug at § 413.234(a) to provide that an oral-only drug is a drug or biological with no injectable equivalent or other form of administration other than an oral form. We also finalized our process at § 413.234(d) for determining that an oral-only drug is no longer considered oral-only when a non-oral version of the

[18] As discussed in the CY 2019 ESRD PPS final rule (83 FR 56922), we began using the term ''biological products'' instead of ''biologicals'' under the ESRD PPS to be consistent with FDA nomenclature. We use the term ''biological products'' in this CY 2023 ESRD PPS proposed rule except where referencing specific language in the Act or regulations.

oral-only drug is approved by FDA. We stated that we will undertake rulemaking to include the oral and any non-oral version of the drug in the ESRD PPS bundled payment when it is no longer considered an oral-only drug under this regulation. In addition, we noted that we will pay for the existing oral-only drugs (which were, at that time, only phosphate binders and calcimimetics) using the TDAPA, as applicable. We stated that this will allow us to collect data reflecting current utilization of both the oral and injectable or intravenous forms of the drugs, as well as payment patterns and beneficiary co-pays, before we add these drugs to the ESRD PPS bundled payment. We also stated that for future oral-only drugs for which a non-oral form of administration comes on the market, we will apply our drug designation process as we will for all other new drugs.

In the CY 2016 ESRD PPS final rule (80 FR 69017), we also codified the term ESRD PPS functional category at § 413.234(a) as a distinct grouping of drugs and biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD. We explained that we codified this definition in regulation text to formalize the approach we adopted in CY 2011 because the drug designation process is dependent on the ESRD PPS functional categories (80 FR 69015). We provided a detailed discussion of how we accounted for renal dialysis drugs and biological products in the ESRD PPS base rate since the implementation of the ESRD PPS (80 FR 69013 through 69015). We discussed how we grouped renal dialysis drugs and biological products into functional categories based on their action (80 FR 37831). We explained that this was done for the purpose of adding new drugs and biological products with the same function into the functional categories and the ESRD PPS bundled payment as expeditiously as possible after the drug becomes commercially available to provide access for the ESRD Medicare population (80 FR 69014). Our approach of considering drugs and biological products as included in the ESRD PPS base rate if they fit within one of our ESRD PPS functional categories is reflected in the drug designation process set forth in our regulations at § 413.234.

In 2017, FDA approved an injectable calcimimetic. In accordance with the policy finalized in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027) described in the previous paragraphs, we issued a change request to implement payment under the ESRD PPS for both the oral and injectable forms of calcimimetics using the TDAPA.[19] We paid for calcimimetics using the TDAPA under the ESRD PPS for 3 years, CY 2018 through CY 2020, during which time CMS collected utilization data. In the CY 2021 ESRD PPS final rule (85 FR 71406 through 71410), we finalized a modification to the ESRD PPS base rate to account for the costs of calcimimetics following the methodology codified at § 413.234(f). Accordingly, effective January 1, 2021,[20] calcimimetics are no longer paid for using the TDAPA and instead are included in the ESRD PPS base rate. We also noted that effective January 1, 2021, calcimimetics are eligible for outlier payments as ESRD outlier services under § 413.237.[21]

As we explained in the CY 2023 ESRD PPS proposed rule (87 FR 38498), at the present time, phosphate binders are still considered oral-only drugs, and therefore under current law will be paid under Medicare Part D until January 1, 2025, as long as they remain oral-only drugs. Beginning January 1, 2025, in accordance with § 413.174(f)(6), payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form furnished to ESRD patients will be incorporated into the ESRD PPS and separate payment will no longer be provided.

Under our current policy (80 FR 69027), if an injectable equivalent or other form of administration of phosphate binders were to be approved by FDA prior to January 1, 2025, the phosphate binders would no longer be considered oral-only drugs and would no longer be paid outside the ESRD PPS. We would pay for the oral and any non-oral version of the drug using the TDAPA under the ESRD PPS for at least 2 years, during which time we would collect and analyze utilization data. If no other injectable equivalent (or other form of administration) of phosphate binders is approved by the FDA prior to January 1, 2025 then we would pay for these drugs using the TDAPA under the ESRD PPS for at least 2 years beginning January 1, 2025. CMS will then undertake rulemaking to modify the ESRD PPS base rate to account for the cost and utilization of the drug in the ESRD PPS bundled payment. As required by section 632(b)(1) of ATRA, as amended by section 217(a)(2) of PAMA, in establishing payment for oral-only drugs under the ESRD PPS, we will use the most recently available data.

(2) CMS Observations Regarding Decrease in Drug Utilization and Medicare Expenditures When Drugs Are Included in the ESRD PPS

As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38497), as we prepare for the incorporation of oral-only drugs into the ESRD PPS bundled payment beginning January 1, 2025, we have been studying trends in drug utilization and Medicare expenditures for renal dialysis drugs and biological products. We noted that our observations, presented below, provided further support for our longstanding view that oral-only renal dialysis service drugs and biological products are an essential part of the ESRD PPS bundled payment and should be paid for under the ESRD PPS.

With the transition of payment for calcimimetics from Medicare Part D to Medicare Part B, we observed two distinct patterns. First, when the calcimimetics were paid for using the TDAPA under the ESRD PPS beginning 2018, we observed a significant increase in the utilization of calcimimetics across patients of all races and ethnicities, with a more significant uptake by the African-American/Black minority population. As utilization increased, cost decreased. To demonstrate, before 2018, only brand-name oral calcimimetics were available, but in 2018, generic oral calcimimetics began to enter the market. We observed a greater than ten-fold decrease in the per milligram cost of Cinacalcet, the oral calcimimetic, from Quarter 1 2018, which was the beginning of the TDAPA period for calcimimetics, and Quarter 4 2020. We stated that we believed that the transition of payment for calcimimetics from Part D to Part B increased access for the population that lacked Part D coverage or had less generous coverage than the Part D standard benefit. Second, after we incorporated the calcimimetics into the ESRD PPS bundled payment beginning January 1, 2021, we noted a decrease in the calcimimetic utilization overall, with a pronounced decrease in the more expensive injectable calcimimetic. To mitigate the risk of potential access issues for minority populations, which include African-American/Black, Asian, Hispanic, and Other non-white populations, we stated that we believed it is important that any future oral-only

[19] Change Request 10065, Transmittal 1889, issued August 4, 2017, replaced by Transmittal 1999, issued January 10, 2018, implemented the TDAPA for calcimimetics effective January 1, 2018.

[20] Change Request 12011, Transmittal 10568, issued January 14, 2021.

[21] In the CY 2020 ESRD PPS final rule (84 FR 60803), CMS made a technical change to § 413.234(a) to revise the definitions of ''ESRD PPS functional category'' and ''Oral-only drug'' to use the term ''biological product'' instead of ''biological'' for greater consistency with FDA nomenclature.

drugs that fit into a current ESRD PPS functional category be included in the ESRD bundled payment through the processes previously finalized in our regulations at § 413.234 and described in this CY 2023 ESRD PPS final rule.

We stated in the proposed rule that we have noted a similar pattern in the change in utilization with other renal dialysis service drugs, such as vitamin D agents, which were separately paid prior to the establishment of the ESRD PPS and subsequently included in the ESRD PPS bundled payment. Prior to the implementation of ESRD PPS, certain renal dialysis drugs and biological products were separately paid according to the number of units of the drug administered; in other words, the more units of a drug or biological product administered, the higher the Medicare payment.[22] Between 2011 and 2013, the first 3 years of the new ESRD PPS, the utilization of formerly separately billable renal dialysis drugs and biological products included in the ESRD PPS bundled payment declined. With the inclusion of the formerly separately billable renal dialysis drugs and biological products in the ESRD PPS bundled payment, the ESRD PPS increased the incentive for ESRD facilities to be more efficient in providing these products.

We noted that CMS has observed that incorporation of formerly separately billable renal dialysis drugs and biological products into the ESRD PPS bundled payment is followed by a decrease in utilization of the drug. For example, by drug class, on a per treatment basis, between 2007 and 2013, the use of vitamin D agents (part of the bone and mineral metabolism ESRD PPS functional category) declined by 20 percent, with most of the decline occurring between 2010 and 2013. Under the ESRD PPS, drug utilization and ASP data suggest increased competition between the two principal vitamin D agents in the ESRD PPS bundled payment. Between 2010 and 2014, per treatment use of paricalcitol, the costlier vitamin D drug (according to Medicare ASP data) declined, while per treatment use of doxercalciferol, the less costly vitamin D drug, increased. Between 2010 and 2015, the ASP price per unit for both these products declined by 60 percent. We have observed a similar pattern in price decline as a result of competition with the oral calcimimetics between 2018 and 2021. The brand name oral cinacalcet (a calcimimetic) was paid under Medicare Part D drug before 2018, but the price of the oral drug dropped significantly once the injectable calcimimetic became available and the oral (both brand name and generics) and the injectable calcimimetic became eligible for payment using the TDAPA under the ESRD PPS.

We explained in the CY 2023 ESRD PPS proposed rule that we have been monitoring health outcomes since 2011 and have not observed any sustained increase in adverse outcomes related to incorporation of renal dialysis drugs or biological products into the ESRD PPS bundled payment, including adverse outcomes related to changes in utilization of different forms of calcimimetics, as noted in the previous paragraph. To date, we have monitored for hospitalizations, fractures, strokes, acute myocardial infarctions, heart failures, parathyroidectomies, and calciphylaxis. Utilization of calcimimetics remains higher among minority populations, which include African-American/Black, Asian, Hispanic, and Other non-white populations, and we have not observed any sustained adverse health outcomes due to this change in utilization. We noted that we continue to monitor these health outcomes on an ongoing basis.

(3) CMS Observations on Part D Spending for Dialysis Drugs

We noted in the CY 2023 ESRD PPS proposed rule that, while the use of formerly separately billable renal dialysis drugs included in the ESRD PPS bundled payment declined between 2011 and 2013, the use of dialysis drugs paid under Medicare Part D (as measured by Medicare spending) increased. Medicare Part D spending for oral-only drugs in 2016, which at that time only included calcimimetics and phosphate binders, grew to $2.3 billion, an increase of 22 percent per year compared with 2011. When calculated on a per treatment basis, Medicare Part D spending for dialysis drugs increased by 20 percent per year. In addition, between 2011 and 2016, total Medicare Part D spending for dialysis drugs grew more rapidly than total Medicare Part D spending for ESRD beneficiaries on dialysis (22 percent vs. 11 percent, respectively). In 2016, Medicare Part D spending for dialysis drugs constituted 60 percent of gross Medicare Part D spending for ESRD beneficiaries.

As we noted previously in the proposed rule and this section of the final rule, beginning on January 1, 2018, calcimimetics were paid for using the TDAPA under the ESRD PPS and beginning on January 1, 2021, were incorporated into the ESRD PPS bundled payment. Currently, phosphate binders are the only drugs that are paid for under Medicare Part D as oral-only drugs.

A number of studies, including studies by CMS, have examined trends in Medicare spending for phosphate binders. Between 2013 and 2014, Medicare Part D spending for phosphate binders increased by 24 percent to approximately $980 million. Medicare costs for phosphate binders for patients on dialysis and patients with chronic kidney disease enrolled in Medicare Part D exceeded $1.5 billion in 2015. Additionally, annual Medicare expenditures for phosphate binders increased by 118 percent (approximately $486 million) between 2008 and 2013, reflecting increasing numbers of patients on dialysis being prescribed phosphate binders and large increases in per-user phosphate binder costs. During these 6 years, total costs per user-year for phosphate binders increased 67 percent, in contrast to a 21 percent increase for all other Medicare Part D medications for patients receiving dialysis services.[23]

We noted that MedPAC has also studied Medicare spending under Part D for phosphate binders. According to MedPAC's report titled March 2021 Report to the Congress: Medicare Payment Policy,[24] between 2017 and 2018, spending for phosphate binders furnished to FFS beneficiaries on dialysis declined by 17 percent to $1.1 billion. This decline is linked to FDA's approval in 2017 for a generic version of Renvela® (sevelamer carbonate), a phosphate binder. By contrast, spending grew 12 percent per year for the five-year period 2012 through 2017. In 2018, Medicare Part D spending for phosphate binders accounted for 40 percent of all Medicare Part D spending for dialysis beneficiaries. The most recent CMS data through December 2021 indicates that total spending on phosphate binders is approximately $714 million. The average spending per treatment of phosphate binders in 2021 is approximately $20.09 among all adult ESRD beneficiaries, and $25.02 among all Part D eligible adult ESRD beneficiaries. This illustrates that Medicare Part D spending for the same category of drugs is more expensive for ESRD beneficiaries with Medicare Part D.

[22] Report to the Congress: Medicare Payment Policy, March 2017. p. 169. *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar17_medpac_ch6.pdf.*

[23] Am J Kidney Dis 2018 Feb;71(2):246–253. doi: 10.1053/j.ajkd.2017.09.007. Epub 2017 Nov 28. CMS's data also confirms this figure.

[24] *https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/.*

MedPAC has also noted the benefits of the future incorporation of phosphate binders into the ESRD PPS bundled payment as of January 1, 2025. As noted in MedPAC's report titled March 2022 Report to the Congress: Medicare Payment Policy,[25] this is expected to result in better drug therapy management for the ESRD beneficiary, and to improve their access to these medications. MedPAC stated that this is especially important since some beneficiaries lack Part D coverage, or have coverage less generous than the standard Part D benefit. MedPAC also noted that in addition to supporting equitable access for the ESRD beneficiaries, including phosphate binders in the ESRD PPS bundled payment might improve provider efficiency. MedPAC stated, and we have confirmed, that between 2018 and 2019, Medicare total spending increased for the phosphate binders that did not have generic competitors.

(4) The Oral-Only Drug Definition and ''Functional'' Equivalence Under the ESRD PPS

As noted previously in this section of the final rule, under § 413.234(a), we define an oral-only drug as ''A drug or biological product with no injectable equivalent or other form of administration other than an oral form.'' In addition, § 413.234(d) provides that an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by FDA. In the CY 2023 ESRD PPS proposed rule, we noted that there are various types of drug equivalences that are defined in regulation by FDA, including pharmaceutical equivalents, bioequivalence, and therapeutic equivalents.[26] However, we have not relied on these types of drug equivalences defined by FDA for purposes of the oral-only drug policy under the ESRD PPS.

Moreover, our regulations do not currently specify the meaning of the term ''equivalent'' in the definition of ''oral-only drug.'' [27] We stated that we believed that the history of the ESRD PPS and our longstanding drug designation process indicate that CMS must consider ''functional'' equivalence, which is not a term defined in FDA's regulations, to evaluate whether there is another form of administration other than an oral form and determine if a drug or biological product is an oral-only drug. We noted that for purposes of the ESRD PPS, we consider a drug or biological product to be functionally equivalent if it has the same end action effect as another renal dialysis drug or biological product. For example, when we first developed the Medicare ESRD PPS, we examined all renal dialysis drugs and biological products included in the prior composite rate payment system. Functional substitutes for those drugs or biological products were part of that evaluation. In the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053) we explained our process for identifying drugs and biological products used for the treatment of ESRD that would be included in the ESRD PPS base rate. We performed an extensive analysis of Medicare payments for Part B drugs and biological products billed on ESRD claims and evaluated each drug and biological product to identify its category by indication or mode of action. We stated that categorizing drugs and biological products on the basis of drug action allows us to determine which categories (and therefore, the drugs and biological products within the categories) would be considered used for the treatment of ESRD (75 FR 49047).

In the CY 2016 ESRD PPS final rule, we codified our longstanding drug designation process at § 413.234 and reiterated that injectable and intravenous drugs and biological products were grouped into ESRD PPS functional categories based on their action (80 FR 69014). This was done for the purpose of adding new drugs or biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs become commercially available so that beneficiaries have access to them. We further clarified that the ESRD PPS functional categories are not based on their mode of action, but rather end action effect (80 FR 69015 through 69017). Accordingly, and as noted previously in this section of this final rule, we finalized the definition of an ESRD PPS functional category in § 413.234(a) as a distinct grouping of drugs or biological products, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD (80 FR 69017 and 84 FR 60803).

Our guidance has also indicated that we consider functional equivalence when assessing whether particular drugs are renal dialysis services paid for under the ESRD PPS. The Medicare Benefit Policy Manual, Chapter 11, Section 20.3F states, ''Drugs that were used as a substitute for any of these drugs [that is, drugs that were considered composite rate drugs and not billed separately prior to the implementation of the ESRD PPS] or are used to accomplish the same effect are also covered under the composite rate.'' Given that we rely on functional equivalence in determining whether drugs are reflected in an ESRD PPS functional category and thus are renal dialysis services paid for under the ESRD PPS, we believe the same standard should apply when determining if a drug is an oral-only drug.

(5) Revision to the Definition of Oral-Only Drug

Based on our observations regarding renal dialysis drug utilization and spending and the upcoming changes related to payment for oral-only drugs under the ESRD PPS, in the CY 2023 ESRD PPS proposed rule, we proposed a change to the definition of oral-only drug at § 413.234(a). The current definition states that an oral-only drug is a drug or biological product with no injectable equivalent or other form of administration other than an oral form. We proposed a modification to the definition to specify that equivalence refers to functional equivalence, in line with our current drug designation process, which relies on the ESRD PPS functional categories. The proposed definition would state that an oral-only drug is a drug or biological product with no functional equivalent or other form of administration other than an oral form. We proposed that this change would take effect beginning January 1, 2025, to coincide with the incorporation of oral-only drugs into the ESRD PPS bundled payment under § 413.174(f)(6).

We proposed this change for several reasons. First, we noted that it would be consistent with the policies previously established for phosphate binders and calcimimetics. As discussed previously, in the CY 2016 ESRD PPS final rule, we finalized that when a non-oral form of administration of a phosphate binder or

[25] *https://www.medpac.gov/document/march-2022-report-to-the-congress-medicare-payment-policy/.*

[26] FDA has defined the terms ''pharmaceutical equivalents'', ''bioequivalence'', and ''therapeutic equivalents'' at 21 CFR 314.3(b). In FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the ''Orange Book''), therapeutic equivalence is used in the context of ''therapeutic equivalents'' as that term is defined in § 314.3(b) (*i.e.,* drug products containing the same active ingredient(s), among other requirements) and does not encompass a comparison of different therapeutic agents used for the same condition. *https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.*

[27] Neither ATRA, PAMA, nor ABLE includes a definition of ''equivalent'' for purposes of the oral-only drug determination. Additionally, CMS did not provide a definition for or elaborate on the meaning of ''equivalent'' for purposes of the oral-only drug determination in our prior rules.

calcimimetic is approved by FDA, we would go through rulemaking to include the oral and any non-oral form of administration of the drug in the ESRD PPS bundled payment. We explained that we would not take this approach for any subsequent drugs that are approved by FDA and fall within the bone and mineral metabolism functional category (or any other ESRD PPS functional categories). This is because the phosphate binders and calcimimetics were the only renal dialysis drugs for which we delayed payment under the ESRD PPS because we did not have utilization data (80 FR 69025). We stated in the proposed rule that we believed that a revision to the oral-only drug definition to clarify that a drug is not an oral-only drug if it has a functional equivalent is consistent with that policy; that is, only oral-only drugs that are calcimimetics and phosphate binders would be eligible for a potential base rate addition and we would not take this approach for any subsequent drugs that fall within any of the ESRD PPS functional categories (80 FR 69025). While Congress has delayed the incorporation of oral-only drugs into the ESRD PPS until January 1, 2025, and this delay still applies to the phosphate binders as oral-only drugs, we stated that we believed we could still take action at this time to ensure that our drug designation process clearly reflects the longstanding ESRD PPS functional category framework.

In addition, we explained in the proposed rule, this change would help ensure that we do not perpetuate any further access issues for renal dialysis services to disadvantaged ESRD beneficiaries through delayed incorporation into the ESRD PPS payment. As noted previously, throughout the years, a series of legislative actions delayed the inclusion of oral-only drugs into the ESRD PPS bundled payment, from 2014 to 2016, to 2024, to January 1, 2025. When we first implemented the payment system in 2011, we noted that there were certain advantages to delaying payment for oral-only drugs under the ESRD PPS and continuing to pay for them under Part D, such as giving ESRD facilities additional time to make operational changes. We stated that we believed that sufficient time has passed since 2011 and we have abundant data about historical patterns to incorporate all drugs and biological products that are renal dialysis services into the ESRD PPS bundled payment as soon as possible under current law.

We noted that the proposed modification would help ensure that new drugs and biological products that become available in the future and that are reflected in the ESRD PPS functional categories, are properly paid as part of the ESRD PPS. In other words, by specifying that an oral-only drug is one with no injectable ''functional'' equivalent, we would clearly define the scope of any new drugs or biological products that could be considered oral-only drugs in the future, and would therefore facilitate incorporation of these renal dialysis services into ESRD PPS. Any new oral renal dialysis drugs or biological products that are reflected in existing ESRD PPS functional categories and have functional equivalents in those categories would not meet the definition of an oral-only drug and thus could be included in the ESRD PPS bundled payment without delay, either immediately, or through the TDAPA eligibility, even if the functional equivalents are not ''chemical equivalents'' [28] (that is, products containing identical amounts of the same active drug ingredient). We noted that this would support beneficiary access to renal dialysis service drugs and would meet the intent of the ESRD PPS functional category framework, which is to be broad and to facilitate adding new drugs to the therapeutic armamentarium of the treating physician (83 FR 56941).

As we noted in the CY 2023 ESRD PPS proposed rule, over the past decade, CMS has been monitoring and analyzing data regarding beneficiary access to Medicare Part D drugs, Medicare expenditure increases for renal dialysis drugs paid under Medicare Part D, health equity implications of varying access to Medicare Part D drugs among patients with ESRD, and ESRD facility behavior regarding drug utilization. We have seen that incorporating Medicare Part D drugs into the ESRD PPS has had a significant positive effect of expanding access to such drugs for beneficiaries who do not have Medicare Part D coverage. As discussed earlier in this section of this final rule, the inclusion of Medicare Part D drugs into the ESRD PPS and the corresponding expansion of access to these drugs have significant health equity implications. For example, we have identified among these beneficiaries a significant uptake by the African-American/Black minority population for calcimimetics once we began paying for those drugs using the TDAPA under the ESRD PPS.

We stated that we believed the modification of the oral-only drug definition would facilitate the inclusion of oral renal dialysis drugs into the ESRD PPS bundled payment, as opposed to payment under Medicare Part D, and therefore would support health equity for beneficiaries with oral-only drugs in their plan of care who lack Medicare Part D coverage or have less generous than Medicare Part D standard benefit. From 2017 and 2021, between 10 to 20 percent of FFS beneficiaries on dialysis either had no Medicare Part D coverage or had coverage less generous than the Medicare Part D standard benefit. Timely inclusion of renal dialysis drugs and biological products into the ESRD PPS bundled payment would promote health equity for those beneficiaries who are not enrolled in Part D or who do not have access to these drugs through alternate insurance programs.

We noted that, when compared with all FFS beneficiaries, FFS beneficiaries receiving dialysis are disproportionately young, male, and African-American, have disabilities and low income as measured by dual status, and reside in an urban setting. We stated that we believed a clarification to help ensure that renal dialysis drugs and biological products are properly included in the ESRD PPS bundled payment would increase the likelihood of pharmaceutical compliance for this population of patients, promote health equity for patients that lack Medicare Part D coverage or have coverage less generous than the Part D standard benefit, and contribute to better clinical outcomes by leveling the playing field for all patients with ESRD. In addition, this requirement would support the goals of Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities through the Federal Government (86 FR 7009), which required Federal agencies to conduct an equity assessment and determine whether new policies, regulations, or guidance documents may be necessary to advance equity in agency actions and programs. In addition, advancing health equity is the first pillar of CMS's 2022 strategic plan (*https://www.cms.gov/cms-strategic-plan*), and this policy is consistent with that pillar of the agency's strategic plan.

In summary, as discussed in the CY 23 ESRD PPS proposed rule (87 FR 38500), we believed that a change to the definition of oral-only drug to specify ''functional'' equivalence would be consistent with the current policy for oral-only drugs and the ESRD PPS functional category framework, would help ensure that new renal dialysis

[28] Like functional equivalence, chemical equivalence is not a term defined in FDA's regulations. CMS is using the term chemical equivalents for the purpose of the ESRD PPS.

drugs and biological products are paid for under the ESRD PPS without delay, and would continue to support health care practitioners' decision-making to meet the clinical needs of their patients. Additionally, the proposed modification would promote health equity and support proper financial incentives for ESRD facilities, in keeping with our fiduciary responsibility to the Medicare Trust Funds. We solicited comments on this proposal.

We received public comments on our proposal to modify the definition of oral-only drug from MedPAC, a trade association, a drug manufacturer, a non-profit kidney organization, an LDO, a non-profit kidney care alliance, a national advocacy organization, a coalition of dialysis organizations, and a non-profit dialysis organization. The comments on our proposal and our responses are set forth below.

Comment: Overall, commenters expressed support for the proposed change to the definition of oral-only drug to specify that equivalence refers to functional equivalence. MedPAC expressed that this proposal would help maintain the integrity of the ESRD PPS bundled payment. An LDO stated that it agreed that clarifying that ''equivalence'' refers to ''functional equivalence'' better aligns with the current drug designation process. A non-profit dialysis organization commented that they think it is reasonable for CMS to refine the definition to specify that an oral-only drug or biological product need not be ''chemically identical'' to its intravenous counterpart. A non-profit kidney care alliance stated that it agreed with the proposed change to the definition, noting that it is reasonable to expect that a new drug or biological product would add value and not merely be a copycat product. Commenters generally supported CMS' effort to clarify the definition of an oral-only drug. However, a drug manufacturer expressed concern that CMS would apply the concept of functional equivalence across the entire ESRD PPS functional category and noted their concern that drugs for very different conditions could be treated as functional equivalents in a way that is not clinically appropriate and may, in fact, cause harm to the patient. A coalition of dialysis organizations recommended that CMS clearly state that the end action effect definition apply more narrowly within the ESRD PPS functional categories to the classes of products within the relevant functional category. Similarly, a drug manufacturer and non-profit kidney organization recommended that within the determination of functional equivalence, that is, end action effect, CMS should consider drug comparison at the drug class or subgroup level and not the functional category level. One commenter suggested this recommendation regarding drug class or subgroup would accomplish CMS' goal of refining the definition of drugs and biological products that qualify as oral only drugs while not setting an inappropriate precedent of comparing a single drug or biological product to an entire ESRD PPS functional category. A non-profit dialysis association noted that they do not believe that Congress, when it drew a distinction in statute related to oral-only drugs, intended to allow CMS to compare one product to an entire functional category of products.

Some commenters expressed concern that the functional equivalent categorization process sends a negative signal to manufacturers and stifles innovation. One commenter stated manufacturers have reported that there has been a significant decline in demand for certain types of drugs since the ESRD PPS bundled payment went into effect. One commenter recommended that CMS eliminate the ESRD PPS functional categories as a basis for payment policy through the drug designation process. Some commenters asked CMS to define functional categories by the ''FDA-[approved] indication(s),'' which they believe is a more objective way to ensure consistency in the categories.

Response: We appreciate the support from certain commenters regarding the proposed change to the definition of an oral-only drug to specify that equivalence means functional equivalence. We disagree with the commenters who suggested that functional equivalence for an oral-only drug be evaluated on mechanism of action and not end action effect, as that would be inconsistent with our longstanding policy. In the CY 2016 ESRD PPS final rule, we clarified that the ESRD PPS functional categories are not based on their mechanism of action, but rather their end action effect (80 FR 69015 through 69017). Accordingly, and as noted previously in this section of this final rule, we finalized the definition of an ESRD PPS functional category in § 413.234(a) as a distinct grouping of drugs or biological products, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD (80 FR 69017 and 84 FR 60803). We do not base the functional category determination by comparing the new drug or biological products to other drugs or biological products in the functional category. CMS reviews a new FDA-approved drug or biological product based on CMS' assessment of the end action effect and the description of the functional category. This review considers, but is not solely based on, the FDA-approved indication(s). The functional categories do not have classes and subclasses within the categories, and we do not think creating such a delineation or relying on mechanism of action is necessary or appropriate. CMS has been using the broader concept of end action effect in the context of ESRD PPS since the program's inception in 2011, so CMS is following longstanding precedent in this circumstance.

Regarding the suggestion that CMS should classify drugs by their FDA-approved indications rather than their end use function, CMS notes that functional substitutes for renal dialysis drugs and biological products were discussed when the ESRD PPS bundled payment was first constructed as a way to identify drugs that were appropriate to include in the ESRD PPS base rate. We used functional classification in ESRD payment prior to the establishment of the ESRD PPS in CY 2011. Specifically, regarding drugs that are included in the composite rate, in the CY 2011 ESRD PPS final rule, we specifically stated that drugs that are used as a substitute for any of these (composite rate) items, or are used to accomplish the same effect, are also covered in the composite rate (75 FR 49048). We also noted in the CY 2011 ESRD PPS final rule (75 FR 49048) that the composite rate includes the following: heparin, heparin antidotes, lidocaine, and local anesthetics, which are access management drugs; saline and mannitol, which are used for fluid management; Benadryl, an anti-pruritic drug; and antibiotics, which are anti-infectives. In the CY 2011 ESRD PPS final rule (75 FR 49049) one commenter noted that ESRD-related drugs used in the treatment of anemia and bone disease should be (75 FR 49058) included in the ESRD PPS bundled payment. CMS agreed and established the renal dialysis service ESRD drug categories included in the final ESRD PPS base rate, which included anemia management and bone and mineral metabolism (75 FR 49050). Categorizing drugs in this way permitted CMS to determine what categories of drugs are routinely used for the treatment of ESRD and should be included in the bundled payment. These categories simplified and expedited the process of adding new drugs to the bundled payment as they became available.

Regarding the concern that drugs for very different conditions could be treated as functional equivalents in a way that is not clinically appropriate and may, in fact, cause harm to the patient, we disagree. We believe that the functional category framework helps ensure that the ESRD PPS appropriately supports the unique needs of each ESRD patient. In the CY 2019 ESRD PPS final rule (83 FR 56928) we emphasized that the functional categories are deliberately broad in nature because, when a new drug becomes available, it is added to the therapeutic armamentarium of the treating physician (83 FR 56941). This allows the practitioner to tailor the pharmaceutical plan of care of the individual patient, considering their unique clinical and personal profile. In addition, as we noted in the CY 2023 ESRD PPS proposed rule (87 FR 38500), the functional category framework supports beneficiary access to renal dialysis service drugs and would meet the intent of the ESRD PPS functional category framework, which is to be broad and facilitate adding new drugs.

Finally, CMS supports innovation through many mechanisms under the ESRD PPS, including the use of the TDAPA for certain new renal dialysis drugs and biological products. Regarding the suggestion that CMS eliminate the functional categories as the basis for payment, we believe this would undermine the ESRD PPS bundled payment. The use of functional categories and functional equivalence, in the context of the ESRD PPS, supported the goals of the MIPPA, including the incorporation of the composite rate services into the ESRD PPS bundled payment (75 FR 49036), which already included drugs and their substitutes used to accomplish the same effect (75 FR 49048).

Comment: Two commenters requested more information on the process CMS would use to determine functional equivalence, factors CMS would consider in making functional equivalence decisions, the transparency that would be provided for interested parties as these decisions are made, and the mechanisms for engaging with CMS as part of this process. A trade association requested that we provide specific details on which office in CMS would make the functional equivalence decision, who runs the office, and their qualifications.

Response: We appreciate and understand the requests for more transparency. The standard for determining functional equivalence is in the definitions of an oral-only drug and ESRD functional PPS category as set forth in § 413.234(a). In the CY 2023 ESRD PPS proposed rule, CMS outlined the history of the oral-only drugs and biological products and the history of the ESRD PPS functional categories, going back to the CY 2011 ESRD PPS rulemaking (87 FR 38499 through 38503). The determination of whether a new drug or biological product is included in an ESRD PPS functional category is an element of the drug designation process. More information about the drug designation process can be found in the Medicare Benefit Policy Manual, Pub. 100–2, Chapter 11, Section 20.3.1.[29] As noted in the CY 2016 ESRD PPS final rule (80 FR 69018 through 69019), to determine whether a product is a new injectable or intravenous drug or biological product, whether the new injectable or intravenous drug or biological product is a renal dialysis service, and whether the new injectable or intravenous drug or biological product fits into an existing functional category, CMS will review the data and information in the new product's FDA approved physician labeling, review the new product's information presented for obtaining a HCPCS code, and conduct an internal medical review following the announcement of the new product's FDA approval and HCPCS decision.

CMS experts, including medical officers, our contractor, along with their clinicians, work collaboratively on the structure of the ESRD PPS functional categories, including renal dialysis service drugs and biological products that may be suitable and appropriate for inclusion in the ESRD PPS bundled payment. The drug designation process is connected to the TDAPA application process, which is described at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.* Specifically, we determine whether the new drug is a renal dialysis service, whether it is within an existing functional category, and whether the drug is eligible for TDAPA. For certain drugs, the TDAPA eligibility process involves CMS looking at New Drug Application classifications made by the FDA (84 FR 60657 through 60668). TDAPA eligibility determinations are released to the public via the CMS Change Request process.

Comment: A trade association, an LDO, a coalition of dialysis organizations, and a pharmaceutical company recommended CMS adopt an objective clinical standard to serve as the basis for functional equivalence when comparing drugs or biological products by relying upon FDA-approved indications for those drugs and biological products, which they believe is a more objective way to ensure consistency in the categories. They recommended that CMS rely on the expertise and role of FDA to make functional equivalence determinations.

Response: FDA is responsible for approving drugs and biological products based on safety and efficacy. CMS's functional category determination relies, in part, on FDA's expertise, as CMS considers FDA's marketing approval of a drug or biological product and the information contained in the drug or biological product's FDA-approved labeling as part of the basis for the functional category determination. In addition, § 413.234(a) states that a new renal dialysis drug or biological product is an injectable, intravenous, oral, or other form or route of administration drug or biological product that is used to treat or manage a condition(s) associated with ESRD. It must be approved by FDA on or after January 1, 2020, under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, have an HCPCS application submitted in accordance with the official Level II HCPCS coding procedures, and designated by CMS as a renal dialysis service under *§ 413.171.* Oral-only drugs are excluded until January 1, 2025. There are also additional factors considered in the determination for TDAPA eligibility. It is CMS's role, not the role of FDA, to make determinations about the ESRD PPS payment policy. We believe that the history of the ESRD PPS and our longstanding drug designation process indicate it is proper for us to consider ''functional'' equivalence to evaluate whether there is another form of administration other than an oral form and determine if a drug or biological product is an oral-only drug. This history and CMS' reliance on functional equivalence when assessing drugs and biological products as oral-only drugs and the placement of drugs and biological products in ESRD PPS functional categories is described in length in this section of this final rule.

Comment: We also received several comments related to issues that we either did not discuss in the CY 2023 ESRD PPS proposed rule or that we discussed for the purpose of background or context, but for which we did not propose changes. Some commenters suggested oral-only drugs, specifically phosphate binders, should be separately payable indefinitely and should be permanently excluded from the ESRD

[29] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf.*

PPS bundled payment. Some commenters were concerned that adding drugs to the ESRD PPS bundled payment may reduce utilization and patients would lose access to oral-only drugs that would impact their care. Some drug manufacturers suggested that oral-only drugs should continue to be accessed and paid for under Medicare Part D. One commenter focused their comments on CMS paying for oral-only drugs that are dispensed versus those that are consumed in the billing period. The commenter also asked CMS to address what it views as the lack of access to renal dialysis service drugs in the Medicare Advantage program.

Response: With regard to carving out some oral-only drugs, such as phosphate binders, from the ESRD PPS bundled payment and paying separately for them, we emphasize it was always CMS's intention to pay for oral-only drugs as part of the ESRD PPS bundled payment (75 FR 49038 through 49039). Regarding access to renal dialysis service drugs by Medicare beneficiaries, our data has shown that more Medicare patients, especially minorities, who are receiving dialysis have better access to drugs and biological products when those drugs and biological products are part of the ESRD PPS bundled payment. Regarding the comment about access to renal dialysis services in the Medicare Advantage program, we expect that Medicare ESRD beneficiaries would have access to the same renal dialysis services covered under Parts A and B when they are enrolled in the Medicare Advantage program.[30]

We have previously addressed the request for a change in billing guidance for ESRD facilities to report amount dispensed versus the amount consumed in the CY 2018 ESRD PPS final rule (82 FR 50753). Although we are not specifically addressing comments that are out-of-scope of the CY 2023 ESRD PPS proposed rule or topics for which we did not propose changes, we thank the commenters for their input and may consider the recommendations in future rulemaking.

Final Rule Action: After consideration of the comments received and for the reasons outlined in the proposed rule and earlier in this section of the final rule, we are finalizing our proposal to include the word ''functional'' in the definition of oral-only drug at § 413.234(a). To apply this change effective January 1, 2025 as proposed, we are finalizing a technical modification to the amendatory language to update the regulation text at § 413.234(a). Accordingly, we are updating the definition of oral-only drug at § 413.234(a) (effective January 1, 2025) to read as follows: ''*Oral-only drug.* A drug or biological product with no injectable functional equivalent or other form of administration other than an oral form.''

(6) Revisions To Clarify the ESRD PPS Functional Category Descriptions

In the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053), we discussed the extensive analysis of Medicare payments that we performed to identify drugs and biological products that are used for the treatment of ESRD and therefore meet the definition of renal dialysis services (defined at section 1881(b)(14)(B) of the Act and 42 CFR 413.171) that would be included in the ESRD PPS base rate. We analyzed Medicare Part B drugs and biological products billed on ESRD claims and evaluated each drug and biological product to identify its category by indication or mode of action. We also explained that categorizing drugs and biological products on the basis of drug action would allow us to determine which categories (and therefore, the drugs and biological products within the categories) would be considered used for the treatment of ESRD (75 FR 49047).

Using this approach, we established categories of drugs and biological products that are not considered for the treatment of ESRD, categories of drugs and biological products that are always considered for the treatment of ESRD, and categories of drugs and biological products that *may* be used for the treatment of ESRD but are also commonly used to treat other conditions (75 FR 49049 through 49051). Those drugs and biological products that were identified as not used for the treatment of ESRD were not considered renal dialysis services and were not included in computing the ESRD PPS base rate. The categories of drugs and biologicals that were always considered used for the treatment of ESRD were identified as access management, anemia management, anti-infectives (specifically vancomycin and daptomycin used to treat access site infections), bone and mineral metabolism, and cellular management (75 FR 49050). In the CY 2015 ESRD PPS final rule, we removed anti-infectives from the list of categories of drugs and biological products that are included in the ESRD PPS base rate and not separately payable (79 FR 66149 through 66150). The categories of drugs that were considered always used for the treatment of ESRD have otherwise remained unchanged since we finalized them in the CY 2011 ESRD PPS final rule. The current categories of drugs that are included in the ESRD PPS base rate and that may be used for the treatment of ESRD but are also commonly used to treat other conditions are antiemetics, anti-infectives, antipruritics, anxiolytics, drugs used for excess fluid management, drugs used for fluid and electrolyte management including volume expanders, and pain management (analgesics) (79 FR 66150).

Although commenters requested that we list the specific ESRD-only drugs in the CY 2011 ESRD PPS final rule rather than specifying drugs and biological products used for the treatment of ESRD, we chose to identify drugs and biological products by functional category. We did not finalize a drug-specific list because we did not want to inadvertently exclude drugs that may be substitutes for drugs identified. We stated that using categories of drugs allows CMS to update the bundled ESRD PPS base rate accordingly as new drugs and biological products become available (75 FR 49050). Because there are many drugs and biological products that have multiple uses, and because new drugs and biological products are being developed, we stated that we did not believe that a drug-specific list will be beneficial (75 FR 49050).

However, we provided a list of the specific Part B drugs and biological products (75 FR 49205 through 49209) and the former Part D drugs that were included in the bundled ESRD PPS base rate (75 FR 49210). We emphasized that drugs or biological products furnished for the purpose of access management, anemia management, vascular access or peritonitis, cellular management and bone and mineral metabolism will be considered a renal dialysis service

[30] Except for the instances specified in 42 CFR 422.318 (for entitlement that begins or ends during a hospital stay) and 42 CFR 422.320 (with respect to hospice care), an Medicare Advantage organization offering an MA plan must provide enrollees in that plan with all Part A and Part B original Medicare services [see Section 1852(a)(1)(A) of the Act and 42 CFR 422.100(c)(1)], including covered services under Original Medicare related to treatment of ESRD if the enrollee is entitled to benefits under both parts, and Part B services if the enrollee is a grandfathered ''Part B only'' enrollee. The Medicare Advantage Organization fulfills its obligation of providing original Medicare benefits by furnishing the benefits directly, through arrangements, or by paying for the benefits on behalf of enrollees. As noted in 42 CFR 422.112(a), an MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. Therefore, Medicare Advantage enrollees with ESRD may need to receive dialysis services from in-network providers to avoid full financial liability of the cost of the service.

under the ESRD PPS and will not be eligible for separate payment. In addition, we noted that any drug or biological product used as a substitute for a drug or biological product that was included in the bundled ESRD PPS base rate would also be a renal dialysis service and would not be eligible for separate payment (75 FR 49050).

In the CY 2016 ESRD PPS final rule (80 FR 69024), we finalized the drug designation process in our regulations at § 413.234 as being dependent upon the ESRD PPS functional categories, consistent with our policy since the implementation of the ESRD PPS in 2011. We discussed the history of the ESRD PPS functional category approach and noted that we grouped the injectable and intravenous drugs and biological products into ESRD PPS functional categories for the purpose of adding new drugs or biological products with the same functions to the bundled ESRD PPS base rate as expeditiously as possible. We also stated that in previous regulations we referred to these categories as drug categories; however, we believe the term functional categories is more precise and better reflects how we have used the categories. We explained that CMS has designated several new drugs and biological products as renal dialysis services because they fit within the ESRD PPS functional categories, consistent with the process noted in CY 2011 ESRD PPS final rule.

As described more fully in the CY 2016 ESRD PPS final rule (80 FR 69023 through 69024), CMS established a TDAPA policy in our regulation at § 413.234 that is based on a determination as to whether or not a drug fits into an existing ESRD PPS functional category. We defined an ESRD PPS functional category in our regulation at § 413.234(a) as a distinct grouping of drugs or biological products, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

In addition, in the CY 2016 ESRD PPS final rule (80 FR 69017), we explained that commenters suggested changes to our descriptions of some of the ESRD PPS functional categories in the preamble of the CY 2016 ESRD PPS proposed rule to more precisely define the drugs that will fit into the categories. In particular, the commenters suggested changes to the anti-infective, pain management, and anxiolytic ESRD PPS functional categories to better describe how each of the categories relate to the treatment of ESRD in accordance with the statute. The commenters suggested that we remove language from the description of the antiemetic functional category to eliminate drugs used to treat nausea caused by the use of oral-only drugs because these drugs are paid outside the ESRD PPS bundled payment and are covered under a separate benefit category.

In response to these suggestions, in the CY 2016 ESRD PPS final rule, we moved the anti-infective functional group from the list of drugs always used for the treatment of ESRD to the list of drugs that may be used for the treatment of ESRD (80 FR 69017). We also adopted the commenters' recommendations regarding narrowing the functional categories to describe how the category relates to the treatment of ESRD. We explained that many of the commenters' recommendations were consistent with how we believe the categories should be defined and help to ensure that the drugs that fall into them are those that are essential for the delivery of maintenance dialysis. We presented the final ESRD PPS functional categories, as revised with suggestions from commenters, in Table 8B in the CY 2016 ESRD PPS final rule (80 FR 69018). In that CY 2016 ESRD PPS final rule table, we listed each ESRD PPS functional category and rationale for association, meaning the reason we included drugs in each category, with examples of drugs in certain categories. Table 8B also separated the functional categories into those that describe drugs always considered used for the treatment of ESRD and those that described drugs that may be used for treatment of ESRD.

In the CY 2019 ESRD PPS final rule (83 FR 56928) we discussed the current ESRD PPS functional categories as part of our final policy to expand the TDAPA to all new renal dialysis drugs and biological products without modifying the base rate for drugs in existing functional categories. We emphasized that the functional categories are deliberately broad in nature because, when a new drug becomes available, it is added to the therapeutic armamentarium of the treating physician (83 FR 56941).

In 2021, a new antipruritic drug was granted marketing authorization by FDA. The new antipruritic drug was approved for a single indication, chronic kidney disease associated pruritus. The new antipruritic drug was approved for the ESRD PPS TDAPA in December 2021 and will receive the TDAPA from April 1, 2022 until March 31, 2024. The Change Request (CR) 12583 that established the TDAPA for KORSUVA™ (difelikefalin) was issued on March 15, 2022.[31] As stated in that CR, the drug qualifies for the TDAPA as a drug or biological product used to treat or manage a condition for which there is an existing ESRD PPS functional category, specifically, the antipruritic category. Because the new drug already fits within the antipruritic ESRD PPS functional category, the drug will receive the TDAPA for 2 years (§ 413.234(b)). After the TDAPA period, the drug will be considered included in the ESRD PPS bundled payment and there will be no modification to the base rate (§ 413.234(c)(1)(i)).

In the CY 2023 ESRD PPS proposed rule (87 FR 38502–38503), we explained that carefully reviewed the descriptions for the existing ESRD PPS functional categories and proposed certain clarifications to ensure our descriptions are as clear as possible for potential TDAPA applicants and the public. We noted that these modifications to the descriptions would be consistent with our current policies for the ESRD PPS functional categories and would not be changes to the categories themselves. As required by the definition in § 413.234(a), the drugs and biological products in the ESRD PPS functional categories are grouped by end action effect, and as we have stated in the past, the functional categories are deliberately broad by design to provide practitioners an array of drugs to use that meet the specific needs of the ESRD patient (83 FR 56941). In offering category descriptions, which we have also identified as rationales for association (80 FR 69015, 69016, and 69018), we noted it has not been our intention to strictly define or limit drugs in any functional category but rather to broadly describe the renal dialysis drugs and biological products that are currently available and fall into the categories. We proposed to make the following clarifications:

- Indicate that certain ESRD PPS functional categories may include, but are not limited to, drugs that have multiple clinical indications. For example, drugs and biological products in the anxiolytic functional category could have multiple clinical indications, and we proposed to amend the description to reflect this understanding.
- Add the term ''biological products'' to the descriptions of several ESRD PPS functional categories, which currently refer only to ''drugs''.
- Update the examples provided in some category descriptions to describe the end action effect of drugs or

[31] *https://www.cms.gov/files/document/r11295CP.pdf.*

biological products included in that functional category.

As published in the CY 2023 ESRD PPS proposed rule (87 FR 38503), the clarifications to the descriptions of the ESRD PPS functional categories are shown in italics in Table 12 of this final rule.

TABLE 12: Clarifications to ESRD PPS Functional Category Descriptions

Functional Category	*Description and Examples*
Access Management	Drugs/*biological products* used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management	Drugs/*biological products* used to stimulate red blood cell production and/or treat or prevent anemia. *Examples of drugs/biological products in this category include ESAs and iron.*
Bone and Mineral Metabolism	Drugs/*biological products* used to prevent/treat bone disease secondary to dialysis. *Examples of drugs/biological products in t*his category include phosphate binders and calcimimetics.
Cellular Management	Drugs/*biological products* used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.
Antiemetic	*Drugs/biological products* used to prevent or treat nausea and vomiting secondary to dialysis. Excludes antiemetics used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	*Drugs/biological products u*sed to treat infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs/*biological products* in this *category are included for their action to* treat itching *secondary* to dialysis *but may have* multiple clinical indications.
Anxiolytic	Drugs/*biological products* in this *category* are included for the treatment of restless leg syndrome *secondary* to dialysis *but may* have multiple *clinical indications*.
Excess Fluid Management	Drugs/*biological products/*fluids used to treat fluid excess *or fluid* overload.
Fluid and Electrolyte Management Including Volume Expanders	Intravenous drugs/*biological products/*fluids used to treat fluid and electrolyte needs.
Pain Management	Drugs/*biological products* used to treat graft site pain and to treat pain medication overdose.

We solicited comments on this proposal and received public comments from four organizations: MedPAC, a physicians' professional association, a drug manufacturer, and a coalition of dialysis organizations. The comments and our responses are set forth below.

Comment: MedPAC supported the proposed revisions to the descriptions of the ESRD PPS functional categories. The Commission noted that an important goal of the ESRD PPS is to give ESRD facilities an incentive to provide ESRD-related items and services as efficiently as possible. They stated that this goal is best achieved by relying on the ESRD bundled payment to the greatest extent possible when determining payment amounts. Additionally, they expressed that including all items and services with a similar function in the ESRD PPS bundled payment fosters competition for ESRD-related items and services and generates incentives for dialysis providers to constrain their costs.

Response: We agree with MedPAC's assessment and thank them for their support of our proposal.

Comment: Two of the commenters suggested CMS should not proceed with its proposed clarifications to the ESRD PPS functional category descriptions, as more details are necessary to explain the full intent of these changes. One of these commenters suggested the proposed clarifications were ''substantive changes'' to the ESRD PPS functional category, thus needing more clarification on CMS's intent.

Response: Just as CMS did in the CY 2016 ESRD PPS final rule (80 FR 69017), we are taking the opportunity in this rule to make clarifying modifications to our descriptions of some of the ESRD PPS functional categories to more precisely describe the drugs and biological products that will fit into the categories. In the CY 2023 ESRD PPS proposed rule, we explained that these proposed changes would help ensure our descriptions are as clear as possible for potential TDAPA applicants and the public (87 FR 38502). Additionally, we explained that in offering category descriptions, which we have also identified as rationales for association (80 FR 69015, 69016, and 69018), it has not been our intention to strictly define or limit drugs in any functional category but rather to broadly describe the renal dialysis drugs and biological products that are currently available and fall into the categories. In addition, we have stated that the intent of the ESRD PPS functional category framework is to be broad and to facilitate adding new drugs to the therapeutic armamentarium of the treating physician (83 FR 56941). We believe these clarifications are consistent with these goals and will help ensure that potential TDAPA applicants and the public have a clear picture of the drugs and biological products that will fit into each category.

Comment: One commenter noted multiple examples of functional categories including products for multiple indications. They suggested there is no clinical basis to group drugs or biological products that are for the treatment of different clinical indications into broader categories, such as the ''functional categories.'' They stated that in assigning these drugs and biological products to the same functional category, CMS has created a ''nexus'' between these drugs that does not exist to the clinician or the patient.

Response: With regard to the functional categories including products with multiple indications, it has not been our intent to exclude a drug from a functional category because it has multiple indications. Rather, the functional category structure helps to ensure the ESRD patient has broad access to all renal dialysis service drugs, which is a distinct benefit to the patient. In addition, the structure of the functional categories helps to ensure the treating physician has a broad array of drugs to meet the specific, individual needs of each ESRD patient, including differing pharmaceutical profiles, co-morbidities, contra-indications with other drugs the patient may be taking, and personal patient preference. To the extent the functional categories create a nexus between the drugs and biological products in the categories, this nexus is for payment purposes under the ESRD PPS and we believe it is beneficial for patients and their clinicians.

CMS initially placed drugs and biological products in the functional categories to group the drugs and biological products by end action when used for the treatment of ESRD and thus ensure they are included in the ESRD PPS base rate and not separately payable (79 FR 66149 through 66150). The functional categories have been critical to the drug designation process and the inclusion of new drugs and biological products into the base rate. As stated previously in this section of this rule, in the CY 2016 ESRD PPS final rule (80 FR 69017), we defined the term ESRD PPS functional category at § 413.234(a) as a distinct grouping of drugs and biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD. We discuss at length the use of ''end action effect'' in determining functional categories. Although clinical indications are part of the information CMS uses in making a functional category decision for new drugs and biological products, it is not the sole basis.

Comment: Physician members of the coalition of dialysis organizations commented on our proposed addition of the phrase ''secondary to dialysis'' to the antipruritic and bone mineral metabolism ESRD PPS functional category descriptions. They stated that these products are not secondary to dialysis, which is a procedure and not a patient condition. These commenters claimed that these products are secondary to kidney disease, and they suggested that CMS adopt more clinically appropriate language. Another commenter stated they do not understand CMS's intent in using the phrase ''secondary to dialysis'' in the antipruritic and anxiolytic functional categories. This commenter noted that their clinicians do not recognize ''secondary to dialysis'' as a clinical term. They further questioned CMS' intent in changing the language from ''related to dialysis'' to ''secondary to dialysis.'' The coalition of dialysis organizations stated that it assumes that CMS intends for these phrases to have different meanings, but cannot discern what that difference may be. They requested clarification on the intent of the change and stated they will not support any changes intended to expand the scope of the functional categories.

Response: As we explained in the CY 2023 ESRD PPS proposed rule (87 FR 38502), it has not been our intention to strictly define or limit drugs in any functional category, but rather to broadly describe the renal dialysis drugs and biological products that are currently available and fall into the categories. Our intent in proposing the clarifications to these functional category descriptions was not to expand the scope of the functional categories, but rather to more clearly describe them. CMS has previously used the phrase ''secondary to dialysis'' in some of the descriptions of past rules. For example, the phrase ''secondary to dialysis'' was used in Table 8A presenting the ESRD PPS functional categories in the CY 2016 ESRD PPS proposed rule (80 FR 37832) and final rule (80 FR 69015 through 69016). In both rules, the phrase was used in the rationale for association for the same three categories that we proposed to use it in now, that is, antiemetic, antipruritic, and anxiolytic. In the CY 2019 ESRD PPS proposed rule (83 FR 34310) and final rule (83 FR 56928), we replaced the phrase ''secondary to dialysis'' with ''related to dialysis'' in those three functional categories. That modification did not provide the clarity we had anticipated, and some interested parties incorrectly interpreted this language as changing the scope of these functional categories. Therefore, we proposed to revert back to our original language, ''secondary to dialysis,'' in the description of these three categories in the context of other proposed modifications to the functional category descriptions. The provision of renal dialysis services is central to the ESRD PPS, and all renal dialysis service drugs and biological products are ''secondary to dialysis.'' Therefore, we believe the phrase ''secondary to dialysis'' is a term that appropriately reflects that the drugs and biological products in these categories are included for the treatment of ESRD-related conditions in a dialysis unit, either during or between dialysis treatments. Finally, as we did not propose to clarify the description of the bone and mineral metabolism category in the CY 2023 ESRD PPS proposed rule, the phrase ''secondary to dialysis'' in that functional category description remains unchanged.

Comment: Regarding the bone and mineral metabolism functional category, one commenter expressed confusion as to whether the proposed addition of ''Examples of drugs/biological products'' is intended merely to clarify that phosphate binders and calcimimetics are included in the bone and mineral metabolism functional category or if CMS intends this new language to be a mechanism to expand

the scope of the bone and mineral metabolism functional category. The commenter stated that it does not support language that expands the scope of the bone and mineral metabolism functional category.

Response: We stated in the proposed rule that we are taking the opportunity to review the descriptions for the existing ESRD PPS functional categories and propose certain clarifications to ensure our descriptions are as clear as possible for potential TDAPA applicants and the public (87 FR 38502). These clarifications are meant to address some questions raised by applicants that indicated to us that our wording could leave room for interpretation on issues where we felt our policy intent was clear. In particular, we wanted to clarify that biological products are also included in the categories, examples are not exhaustive lists, and drugs and biological products with single indications are not excluded from any functional categories that include drugs and biological products with multiple indications.

Comment: For the antipruritic functional category, one commenter noted that given the recent approval of KORSUVA™, it is important for CMS to affirm that we are not proposing any retroactive changes to the antipruritic functional category.

Response: CMS affirmed the disposition of antipruritic drug KORSUVA™ (difelikefalin) in both the CY 2023 ESRD PPS proposed rule (87 FR 38502) and again in this section of the final rule. In addition, CR 12583 stated that the drug qualifies for the TDAPA as a drug or biological product used to treat or manage a condition for which there is an existing ESRD PPS functional category, specifically, the antipruritic category. Because the new drug already fits within the antipruritic ESRD PPS functional category, the drug will receive the TDAPA for 2 years (§ 413.234(b)). After the TDAPA period, the drug will be considered included in the ESRD PPS bundled payment and there will be no modification to the base rate (§ 413.234(c)(1)(i)). The new antipruritic drug was approved for the ESRD PPS TDAPA in December 2021 and will receive the TDAPA from April 1, 2022 until March 31, 2024, as noted in CR 12583.

Final Rule Action: After considering the comments and for the reasons discussed earlier in this section of this final rule, we are finalizing the changes to the descriptions of the ESRD PPS functional categories as proposed, as noted in the following Table 13. These changes will be effective January 1, 2023.

TABLE 13: Final ESRD PPS Functional Category Descriptions

Functional Category	Description and Examples
Access Management	Drugs/biological products used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management	Drugs/biological products used to stimulate red blood cell production and/or treat or prevent anemia. Examples of drugs/biological products in this category include ESAs and iron.
Bone and Mineral Metabolism	Drugs/biological products used to prevent/treat bone disease secondary to dialysis. Examples of drugs/biological products in this category include phosphate binders and calcimimetics.
Cellular Management	Drugs/biological products used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.
Antiemetic	Drugs/biological products used to prevent or treat nausea and vomiting secondary to dialysis. Excludes antiemetics used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	Drugs/biological products used to treat infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs/biological products in this category are included for their action to treat itching secondary to dialysis but may have multiple clinical indications.
Anxiolytic	Drugs/biological products in this category are included for the treatment of restless leg syndrome secondary to dialysis but may have multiple clinical indications.
Excess Fluid Management	Drugs/biological products/fluids used to treat fluid excess or fluid overload.
Fluid and Electrolyte Management Including Volume Expanders	Intravenous drugs/biological products/fluids used to treat fluid and electrolyte needs.
Pain Management	Drugs/biological products used to treat graft site pain and to treat pain medication overdose.

C. Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for CY 2023 Payment

1. Background

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), CMS established the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS, under the authority of section 1881(b)(14)(D)(iv) of the Act, to support ESRD facility use and beneficiary access to these new technologies. We established this add-on payment adjustment to help address the unique circumstances experienced by ESRD facilities when incorporating new and innovative equipment and supplies into their businesses and to support ESRD facilities transitioning or testing these products during the period when they are new to market. We added § 413.236 to establish the eligibility criteria and payment policies for the TPNIES.

In the CY 2020 ESRD PPS final rule (84 FR 60650), we established in § 413.236(b) that for dates of service occurring on or after January 1, 2020, we would provide the TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning granted marketing authorization by the Food and Drug Administration (FDA) on or after January 1, 2020; (3) is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take effect; (4) has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular CY; (5) is innovative, meaning it meets the substantial clinical improvement criteria specified in the Inpatient Prospective Payment System (IPPS) regulations at § 412.87(b)(1) and related guidance; and (6) is not a

capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

Regarding the innovation requirement in § 413.236(b)(5), in the CY 2020 ESRD PPS final rule (84 FR 60690), we stated that we would use the following criteria to evaluate substantial clinical improvement for purposes of the TPNIES under the ESRD PPS based on the IPPS substantial clinical improvement criteria in § 412.87(b)(1) and related guidance:

A new technology represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. First, CMS considers the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. Second, a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:

- The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or
- The new renal dialysis equipment or supply 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 renal dialysis service to make a diagnosis affects the management of the patient; or
- The use of the new renal dialysis equipment or supply significantly improves clinical outcomes relative to renal dialysis services previously available as demonstrated by one or more of the following: (1) a reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; (2) a decreased rate of at least one subsequent diagnostic or therapeutic intervention; (3) a decreased number of future hospitalizations or physician visits; (4) a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; (5) an improvement in one or more activities of daily living; an improved quality of life; or (6) a demonstrated greater medication adherence or compliance; or,
- The totality of the circumstances otherwise demonstrates that the new renal dialysis equipment or supply substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Third, evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services 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.

Fourth, the medical condition diagnosed or treated by the new renal dialysis equipment or supply may have a low prevalence among Medicare beneficiaries.

Fifth, the new renal dialysis equipment or supply 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 renal dialysis equipment or supply.

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we also established a process modeled after IPPS's process of determining if a new medical service or technology meets the substantial clinical improvement criteria specified in § 412.87(b)(1). As we discussed in the CY 2020 ESRD PPS final rule (84 FR 60682), we believe it is appropriate to facilitate access to new and innovative equipment and supplies through add-on payment adjustments similar to the IPPS New Technology Add-On Payment and to provide stakeholders with standard criteria for both inpatient and ESRD facility settings. In § 413.236(c), we established a process for our announcement of TPNIES determinations and a deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. We would consider whether a new renal dialysis equipment or supply meets the eligibility criteria specified in § 413.236(b) and summarize the applications received in the annual ESRD PPS proposed rules. Then, after consideration of public comments, we would announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS in the ESRD PPS final rule. In the CY 2020 ESRD PPS final rule, we also specified certain deadlines for the application requirements. We noted that we would only consider a complete application received by February 1 prior to the particular CY. In addition, we required that FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular CY. We also stated in the CY 2020 ESRD PPS final rule (84 FR 60690 through 60691) that we would establish a workgroup of CMS medical and other staff to review the materials submitted as part of the TPNIES application, public comments, FDA marketing authorization, and HCPCS application information and assess the extent to which the product provides substantial clinical improvement over current technologies.

In the CY 2020 ESRD PPS final rule, we established § 413.236(d) to provide a payment adjustment for a new and innovative renal dialysis equipment or supply. We stated that the TPNIES is paid for two calendar years. Following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will become an eligible outlier service as provided in § 413.237.

Regarding the basis of payment for the TPNIES, in the CY 2020 ESRD PPS final rule, we finalized at § 413.236(e) that the TPNIES is based on 65 percent of the price established by the MACs, using the information from the invoice and other specified sources of information.

In the CY 2021 ESRD PPS final rule (85 FR 71410 through 71464), we made several changes to the TPNIES eligibility criteria at § 413.236. First, we revised the definition of new at § 413.236(b)(2) as within 3 years beginning on the date of the FDA marketing authorization. Second, we changed the deadline for TPNIES applicants' HCPCS Level II code application submission from September 1 of the particular CY to the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the CY. In addition, a copy of the applicable FDA marketing authorization must be

submitted to CMS by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website in order for the equipment or supply to be eligible for the TPNIES the following year. Third, we revised § 413.236(b)(5) to remove a reference to related guidance on the substantial clinical improvement criteria, as the guidance had already been codified.

Finally, in the CY 2021 ESRD PPS final rule, we expanded the TPNIES policy to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. We explained that capital-related assets are defined in the Provider Reimbursement Manual (chapter 1, section 104.1) as assets that a provider has an economic interest in through ownership (regardless of the manner in which they were acquired). We noted that examples of capital-related assets for ESRD facilities are dialysis machines and water purification systems. We explained that, although we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38354) that we did not believe capital-related assets should be eligible for additional payment through the TPNIES because the cost of these items is captured in cost reports, they depreciate over time, and are generally used for multiple patients, there were a number of other factors we considered that led us to consider expanding eligibility for these technologies in the CY 2021 ESRD PPS rulemaking. We explained that, following publication of the CY 2020 ESRD PPS final rule, we continued to study the issue of payment for capital-related assets under the ESRD PPS, taking into account information from a wide variety of stakeholders and recent developments and initiatives regarding kidney care. For example, we considered various HHS home dialysis initiatives, Executive Orders to transform kidney care, and how the risk of COVID–19 for particularly vulnerable ESRD beneficiaries could be mitigated by encouraging home dialysis.

After closely considering these issues, we proposed a revision to § 413.236(b)(6) in the CY 2021 ESRD PPS proposed rule to provide an exception to the general exclusion for capital-related assets from eligibility for the TPNIES for capital-related assets that are home dialysis machines when used in the home for a single patient and that meet the other eligibility criteria in § 413.235(b), and finalized the exception as proposed in the CY 2021 ESRD PPS final rule. We finalized the same determination process for TPNIES applications for capital-related assets that are home dialysis machines as for all other TPNIES applications; that we will consider whether the new home dialysis machine meets the eligibility criteria specified in § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. In accordance with § 413.236(c), we will only consider, for additional payment using the TPNIES for a particular CY, an application for a capital-related asset that is a home dialysis machine received by February 1 prior to the particular CY. If the application is not received by February 1, the application will be denied and the applicant is able to reapply within 3 years beginning on the date of FDA marketing authorization to be considered for the TPNIES, in accordance with § 413.236(b)(2).

In the CY 2021 ESRD PPS final rule, at § 413.236(f), we finalized a pricing methodology for capital-related assets that are home dialysis machines when used in the home for a single patient, which requires the MACs to calculate the annual allowance and the preadjusted per treatment amount. The pre-adjusted per treatment amount is reduced by an estimated average per treatment offset amount to account for the costs already paid through the ESRD PPS base rate.[32] We finalized that this amount would be updated on an annual basis so that it is consistent with how the ESRD PPS base rate is updated.

We revised § 413.236(d) to reflect that we would pay 65 percent of the pre-adjusted per treatment amount minus the offset for capital-related assets that are home dialysis machines when used in the home for a single patient.

We revised § 413.236(d)(2) to reflect that following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237, except a capital-related asset that is a home dialysis machine will not be an eligible outlier service as provided in § 413.237.

In summary, under the current eligibility requirements in § 413.236(b), CMS provides for a TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning within 3 years beginning on the date of the FDA marketing authorization; (3) is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take effect; (4) has a complete HCPCS Level II code application submitted in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the CY; (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1); and (6) is not a capital-related asset, except for capital-related assets that are home dialysis machines.

We received three applications for the TPNIES for CY 2023. A discussion of these applications is presented below.

a. CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System)

CloudCath submitted an application for the TPNIES for the CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System) for CY 2023. According to the applicant, the CloudCath System is a tabletop passive drainage system that detects and monitors solid particles in dialysate effluent during peritoneal dialysis (PD) [33] treatments. Solid particles in dialysate effluent, manifesting itself as cloudy dialysate, may indicate that the patient has peritonitis, an inflammation of the peritoneum in the abdominal wall, usually due to a bacterial or fungal infection.[34] PD therapy is a common cause of peritonitis.[35] If left untreated, the condition can be life threatening.[36] We note that CloudCath previously submitted an application for the TPNIES for the CloudCath System for CY 2022, as summarized in the CY 2022 ESRD PPS proposed rule (86 FR 36343 through 36347), but withdrew that application prior to the issuance of the CY 2022 ESRD PPS final rule (86 FR 61889). As indicated in the CY 2022 ESRD PPS final rule (86 FR 61889), the applicant withdrew its application from consideration after the issuance of the CY 2022 ESRD PPS proposed rule because it did not receive FDA marketing authorization by July 6, 2021,

[32] The CY 2021 TPNIES offset amount was $9.32. The CY 2022 TPNIES offset amount is $9.50. CMS is finalizing a CY 2023 TPNIES offset amount of $9.79, as discussed in section II.B.1.(e) of this final rule.

[33] Peritoneal Dialysis: Waste products pass from the patient's body through the peritoneal membrane into the peritoneal (abdominal) cavity where the bath solution (dialysate) is introduced and removed periodically. Medicare Benefit Policy Manual Chapter 11—End Stage Renal Disease (ESRD) (Rev. 257, 03–01–19).

[34] Mayo Clinic Staff, ''Peritonitis,'' June 18, 2020, available at: *https://www.mayoclinic.org/diseases-conditions/peritonitis/symptoms-causes/syc-20376247.*

[35] *Ibid.*

[36] *Ibid.*

which was the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services. Under § 413.236(c), an applicant for the TPNIES must receive FDA marketing authorization for its new equipment or supply by that deadline prior to the particular calendar year. Therefore, as we stated in the CY 2022 ESRD PPS final rule, the CloudCath System was not eligible for consideration for the TPNIES for CY 2022.

PD-related peritonitis is a major complication and challenge to the long-term success and adherence of patients on PD therapy.[37] The applicant stated that only about 12 percent of eligible patients are on PD therapy.[38] The applicant claimed that the risk of PD-related peritonitis, and the challenges to detect it, are the main reasons for these figures. The guidelines for diagnosis of PD-related peritonitis, as outlined by the International Society for Peritoneal Dialysis (ISPD), recommend that peritonitis be diagnosed when at least two of the following criteria are present: (1) the patient experiences clinical features consistent with peritonitis (abdominal pain and/or cloudy dialysate effluent); (2) the patient's dialysate effluent has a whole blood count (WBC)

$$> 100 \text{ cells/}\mu\text{L or} > 0.1 \times 10/\text{L}$$

with polymorphonuclear (PMN) cells >50 percent; and (3) positive dialysis effluent culture is identified.[39] Additionally, the guidelines recommend that PD patients presenting with cloudy effluent be presumed to have peritonitis and treated as such until the diagnosis can be confirmed or excluded.[40] Per the guidelines, this means that for patients undergoing PD treatments at home, it is recommended that they self-monitor for symptoms of peritonitis, cloudy dialysate and/or abdominal pain, and seek medical attention for additional testing and treatment upon experiencing any or both of these symptoms.

According to the applicant, despite the fact that peritonitis is highly prevalent, symptom monitoring is insensitive and non-specific, which can contribute to late presentation for medical attention and treatment. The applicant stated that under the current standard of care, PD patients face the following challenges in detecting peritonitis. First, the applicant stated that patients' fluid observation has low compliance rates as it relies on patients' close examination of their own dialysate effluent during PD treatments, which often occur while patients are asleep. Second, the applicant noted that it can be difficult for patients to visually detect peritonitis in dialysate effluent using a ''newspaper test'' for cloudiness, and can be even more difficult to see when the fluid is drained into a toilet, where it is diluted by water. The applicant stated that, as a result of these challenges, patients with ESRD suffer unsatisfactorily high mortality and morbidity from peritonitis, as well as high rates of PD modality loss, meaning they must discontinue PD and begin a different type of dialysis treatment. Per the applicant, the CloudCath System addresses these challenges by detecting changes in dialysate effluent at much lower levels of particle concentrations than the amount needed to accumulate for visual detection by patients.

Per the applicant, the CloudCath System consists of three components: (1) drain set, (2) sensor, and (3) patient monitoring software. As explained in the application, the CloudCath System's drain set connects to a compatible PD cycler's drain line to enable draining and monitoring of dialysate effluent before routing the fluid to the drainage receptacle. Per the CloudCath System User Guide, included in the application, the CloudCath System is compatible with the following PD cyclers: Baxter Healthcare Home Choice PRO™, Baxter Healthcare AMIA™ Automated PD System, and Fresenius Liberty® Select Cycler. Per the applicant, once the CloudCath System is attached to a compatible cycler, the dialysate effluent runs through the drain set, through the CloudCath System's optical sensor. The applicant explained that the CloudCath System's optical sensor detects and monitors changing concentrations of solid particles in the dialysate effluent during each dialysis cycle and reports the concentrations in a turbidity score. Per the applicant, the CloudCath System will indicate whether dialysate effluent has normal turbidity and will notify the patient and/or health care professional if the dialysate effluent turbidity has exceeded the notification threshold set by the patient's dialysis provider. The applicant stated that the optical sensor's hardware and software components allow for data trending over time and remote monitoring by a health care professional.

(1) Renal Dialysis Service Criterion (§ 413.236(b)(1))

Regarding the first TPNIES eligibility criterion in § 413.236(b)(1), that the item has been designated by CMS as a renal dialysis service under § 413.171, monitoring for peritonitis is a service furnished to individuals for the treatment of ESRD that is essential for the delivery of maintenance dialysis. We received no public comments on whether the CloudCath System meets this criterion. We consider the CloudCath System to be a renal dialysis service under § 413.171.

(2) Newness Criterion (§ 413.236(b)(2))

With respect to the second TPNIES eligibility criterion in § 413.236(b)(2), that the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant stated that the CloudCath System received FDA marketing authorization on February 9, 2022. We received no public comments on whether the CloudCath System meets this criterion. Based on the information provided by the applicant, we agree that the CloudCath System meets the newness criterion.

(3) Commercial Availability Criterion (§ 413.236(b)(3))

Regarding the third TPNIES eligibility criterion in § 413.236(b)(3), that the item is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment will take effect, the applicant stated in its application that the CloudCath System was not currently commercially available but noted that it expected the CloudCath System would be commercially available immediately after receiving FDA marketing authorization. In the CY 2023 ESRD PPS proposed rule (87 FR 38506), we stated that we did not have information as to whether the product became currently commercially available following the FDA marketing authorization on February 9, 2022. We solicited comment on the CloudCath System's commercial availability.

Comment: We received a comment from the applicant indicating that the CloudCath System has been commercially available to the U.S. population since July 2022. The applicant also provided a link to the

[37] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[38] Briggs, et al., ''Early Detection of Peritonitis in Patients Undergoing Peritoneal Dialysis: A Device and Cloud-Based Algorithmic Solution,'' unpublished report.

[39] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[40] *Ibid.*

CloudCath System's marketing materials.[41]

Response: Based on the information provided by the applicant, we agree that the CloudCath System meets the commercial availability criterion.

(4) HCPCS Level II Application Criterion (§ 413.236(b)(4))

Regarding the fourth TPNIES eligibility criterion in § 413.236(b)(4) requiring that the applicant submit a complete HCPCS Level II code application by the HCPCS Level II application deadline of July 5, 2022, the applicant stated that it submitted a complete HCPCS Level II code application prior to the July 5, 2022 deadline. CMS received a HCPCS Level II application by the deadline and therefore, we agree the applicant has met the HCPCS Level II application criterion.

(5) Innovation Criteria (§§ 413.236(b)(5) and 412.87(b)(1))

(a) Substantial Clinical Improvement Claims and Sources

With regard to the fifth TPNIES eligibility criterion under § 413.236(b)(5), that the item is innovative, meaning it meets the substantial clinical improvement criteria specified in § 412.87(b)(1), the applicant made two claims. First, the applicant stated that the CloudCath System offers substantial clinical improvement over technologies currently available for the Medicare patient population by offering the ability to monitor changes in turbidity of peritoneal dialysate effluent through continuous remote monitoring in patients with ESRD receiving PD therapy earlier than the current standard of care. Per the applicant, by allowing the clinical standard of care to be initiated earlier, the use of the CloudCath System changes the management of peritonitis patients by enabling clinicians to both diagnose peritonitis and initiate antibiotic treatment earlier. Second, the applicant stated that the CloudCath System offers substantial clinical improvement over existing technologies because the device's remote monitoring capabilities provides patients with oversight and increased confidence that should peritonitis occur, it will be detected more reliably than visual detection and earlier than the current standard of care, allowing for earlier diagnosis and treatment management. The applicant claimed that by alleviating the fear associated with peritonitis and providing this additional support and confidence to patients, the CloudCath System can enable patients to either switch to or remain on home-PD, ultimately improving quality of life.

The applicant submitted two studies on the technology in support of its substantial clinical improvement claims. First, the applicant included a preliminary, unpublished report by Briggs, et al. of a proof of principle observational study that tested the ability of the CloudCath System and its dialysate effluent monitoring algorithm to detect indicators of peritonitis.[42] The study consisted of 70 PD patients outside of the U.S. who had been on PD for a long interval of time (>10 days), and thus were at an increased risk of developing peritonitis. Out of the 64 PD patients whose data were included in the study, over 40 PD patients were receiving intermittent PD,[43] which is not commonly used in the U.S. The remainder of the study participants were receiving Continuous Ambulatory Peritoneal Dialysis (CAPD).[44] The report states that in the U.S., PD is generally performed in a modality called Continuous Cycling Peritoneal Dialysis (CCPD),[45] in which a cycler automatically administers multiple dialysis exchange cycles, typically while patients sleep. Samples were collected from patients' PD effluent drainage bags and measured in the CloudCath System against a proprietary Turbidity Score threshold value and also tested for reference laboratory measurements according to ISPD guidelines for WBC count and differential

(> 100 cells/ꝛL, > 50 percent PMN).[46] Regarding the Turbidity Score threshold value, the study set a score to determine if the effluent sample in the CloudCath System was infected or not; samples greater than or equal to the Turbidity Score threshold value would be classified as infected, and samples less than the Turbidity Score threshold value would be classified as non-infected. The crude sensitivity and specificity of the CloudCath System was 96.2 percent and 91.2 percent, respectively. A majority of false positives (44 of 77 samples) occurred among patients already receiving antibiotic treatment for peritonitis, and another 20 false positive reports occurred because the patient had elevated turbidity due to a cause other than peritonitis. The investigators subsequently removed samples from patients already receiving treatment for peritonitis, setting the sensitivity for detecting peritonitis using the CloudCath System at 99 percent and the specificity at 97.6 percent.

The second study the applicant submitted is the Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH).[47] The applicant stated that it initiated this ongoing single-arm, open-label, multi-center study to demonstrate that the CloudCath System is able to detect changes in turbidity associated with peritonitis in PD patients prior to laboratory diagnosis of peritonitis with a high degree of specificity and sensitivity. The target enrollment is 186 participants over 18 years of age using CCPD as their PD modality, with at least 2 exchanges per night.[48] Patients with

[41] CloudCath, Remote Monitoring Platform for Catheter-Based Treatments. Available at: *https://www.cloudcath.com.* Accessed on September 8, 2022.

[42] Briggs, et al., ''Early Detection of Peritonitis in Patients Undergoing Peritoneal Dialysis: A Device and Cloud-Based Algorithmic Solution,'' unpublished report.

[43] Intermittent Peritoneal Dialysis (IPD)—Waste products pass from the patient's body through the peritoneal membrane into the peritoneal cavity where the dialysate is introduced and removed periodically by machine. Peritoneal dialysis generally is required for approximately 30 hours a week, either as three 10-hour sessions or less frequent, but longer, sessions. Medicare Benefit Policy Manual Chapter 11—End Stage Renal Disease (ESRD) (Rev. 257, 03–01–19).

[44] Continuous Ambulatory Peritoneal Dialysis (CAPD)—In CAPD, the patient's peritoneal membrane is used as a dialyzer. The patient connects a 2-liter plastic bag of dialysate to a surgically implanted indwelling catheter that allows the dialysate to pour into the beneficiary's peritoneal cavity. Every 4 to 6 hours the patient drains the fluid out into the same bag and replaces the empty bag with a new bag of fresh dialysate. This is done several times a day. Medicare Benefit Policy Manual Chapter 11—End Stage Renal Disease (ESRD) (Rev. 257, 03–01–19).

[45] Continuous Cycling Peritoneal Dialysis (CCPD)—CCPD is a treatment modality that combines the advantages of the long dwell, continuous steady-state dialysis of CAPD, with the advantages of automation inherent in intermittent peritoneal dialysis. The solution exchanges are performed at nighttime and are performed automatically with a peritoneal dialysis cycler. Generally, there are three nocturnal exchanges occurring at intervals of 2½ to 3 hours. Upon awakening, the patient disconnects from the cycler and leaves the last 2-liter fill inside the peritoneum to continue the daytime long dwell dialysis. Medicare Benefit Policy Manual Chapter 11—End Stage Renal Disease (ESRD) (Rev. 257, 03–01–19).

[46] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[47] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report (NCT04515498), Jan 27, 2020.

[48] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to

Continued

active infection and/or cancer are excluded from the trial.[49] The primary endpoint is time of peritonitis detection by the CloudCath System (defined as two consecutive Turbidity Scores >7.0) as compared to laboratory evidence of peritonitis (defined as WBC count >100 cells/μL or > 0.1×10^9/L with percentage of PMN >50 percent).[50] While the study is ongoing, the applicant included the study protocol and the first preliminary results with its application.[51] According to the applicant, the first preliminary results demonstrate that as of December 29, 2020, 132 participants were enrolled in the CATCH Study at 13 sites.[52]

Enrolled participants underwent an average of 4.5 dialysate exchanges per night.[53] The preliminary results indicated that, as of December 29, 2020, there have been 7 peritonitis events that met the ISPD peritoneal fluid cell counts and differentials standard.[54] According to the applicant, 5 of the 7 peritonitis events described in the CATCH study occurred after initial use of the CloudCath System, and all 5 of the peritonitis events were also detected by the CloudCath System.[55] In the 5 events, the CloudCath System detected peritonitis 44 to 368 hours prior to the time of detection from a clinical laboratory.[56] The CloudCath System also detected peritonitis 27 to 344 hours prior to participants presenting to the hospital or clinic with signs or symptoms of peritonitis.[57] The applicant stated that these results support the claim that the CloudCath System would enable diagnosis of peritonitis earlier than the current standard of care through turbidity monitoring. According to the applicant, in the remaining 2 peritonitis events, participants experienced peritonitis prior to initial use of the CloudCath System, however, the CloudCath System detected peritonitis upon initial use.

In addition to the studies on the technology, the applicant submitted an article by Muthucumarana, et. al. on the impact of time-to-treatment on clinical outcomes of PD-related peritonitis.[58] The article included data from the Presentation and the Time of Initial Administration of Antibiotics With Outcomes of Peritonitis (PROMPT) Study, a prospective multicenter study from 2012 to 2014 that observed symptom-to-contact time, contact-to-treatment time, defined as the time from health care presentation to initial antibiotic, and symptom-to-treatment time in Australian PD patients. One hundred sixteen patients participated in the survey.[59] Out of the sample size of 116 survey participants, there were 159 episodes of PD-related peritonitis. Of these, 38 patient episodes met the primary outcome of PD failure (defined as catheter removal or death) at 30 days.[60] The median symptom-to-treatment time was 9.0 hours in all patients, 13.6 hours in the PD-fail group, and 8.0 hours in the PD-cure group.[61] The study found that the risk of PD-failure increased by 5.5 percent for each hour of delay of administration of antibiotics once patients presented to a health care provider.[62] However, neither symptom-to-contact nor symptom-to-treatment was associated with PD-failure in non-adjusted analyses, and the time from presentation to a health care provider to treatment was only associated with PD-failure outcomes in multivariable-adjusted analyses in a subset of patients who presented to hospital-based facilities. In addition to the Muthucumarana et al. article, the applicant cited to other studies that have found that antibiotic treatment should begin as soon as possible to effectively treat infections other than peritonitis.[63] [64] [65] Per the applicant, these articles on time-to-treatment demonstrate that the CloudCath System's ability to detect effluent changes substantially earlier improves the standard of care, enabling PD-related peritonitis diagnosis and antibiotic treatment earlier while decreasing the likelihood of PD-failure due to PD-related peritonitis.

The applicant also submitted letters of support from a nephrologist at an academic institution and the following ESRD patient advocacy groups: the American Kidney Fund, the American Association of Kidney Patients, and the International Society of Nephrology. The nephrologist's letter of support endorsed the CloudCath System's ability to detect peritonitis and enable clinicians to begin to treat the infection earlier, preventing hospitalizations and complications such as the abandonment of home dialysis. The nephrologist's letter also stated that the CloudCath System helps address the challenge of peritonitis as the main reason for abandonment of PD for HD, and will encourage a greater number of patients to select PD as their dialysis modality of choice. The letters from the American Association of Kidney Patients and the International Society of Nephrology encouraged CMS to consider the CloudCath System's TPNIES application, explaining that the technology would have several benefits to patients, for example, by reducing peritonitis-related hospitalizations, increasing adherence to PD, and encouraging higher utilization of PD as a viable alternative to in-center HD. The American Kidney Fund's letter emphasized that peritonitis is a significant concern for PD patients[66] and requested CMS support of all efforts that ensure patients with ESRD undergoing PD treatments can quickly detect and treat infections.

As noted previously in this section of the final rule, the applicant previously submitted a TPNIES application for CY 2022, but withdrew its application. Compared to the CY 2022 application, the applicant updated the number of patients and sites that were enrolled in the CATCH study. In its CY 2022 application, the applicant reported that as of December 29, 2020, 132 patients were enrolled in the CATCH study at 15 sites. In its CY 2023 application, the applicant provided updated enrollment figures and stated that as of May 5, 2021, 185 patients were enrolled in the CATCH study at 15 sites.

Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Study Protocol (CC–P–001), June 24, 2020.

[49] *Ibid.*

[50] *Ibid.*

[51] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report (NCT04515498), Jan 27, 2020.

[52] *Ibid.*

[53] *Ibid.*

[54] *Ibid.*

[55] *Ibid.*

[56] *Ibid.*

[57] *Ibid.*

[58] Muthucumarana, et al., ''The Relationship Between Presentation and the Time of Initial Administration of Antibiotics With Outcomes of Peritonitis in Peritoneal Dialysis Patients: The PROMPT Study.,'' Kidney Int Rep. 2016 Jun 11;1(2):65–72. doi: 10.1016/j.ekir.2016.05.003. PMID: 29142915; PMCID: PMC5678844.

[59] *Ibid.*

[60] *Ibid.*

[61] *Ibid.*

[62] *Ibid.*

[63] Gacouin, A. et al., ''Severe pneumonia due to Legionella pneumophila: prognostic factors, impact of delayed appropriate antimicrobial therapy,'' Intensive Care Medicine 28, 686–691 (2002), *https://doi.org/10.1007/s00134-002-1304-8.*

[64] Houck, PM. et al., ''Timing of antibiotic administration and outcomes for Medicare patients hospitalized with community-acquired pneumonia,'' Arch Intern Med. 2004 Mar 22;164(6):637–44. doi: 10.1001/archinte.164.6.637. PMID: 15037492.

[65] Lodise TP, et al., ''Outcomes analysis of delayed antibiotic treatment for hospital-acquired Staphylococcus aureus bacteremia,'' Clin Infect Dis. 2003 Jun 1;36(11):1418–23. doi: 10.1086/375057. Epub 2003 May 20. PMID: 12766837.

[66] Mehrotra, Rajnish et al., ''The Current State of Peritoneal Dialysis,'' Journal of the American Society of Nephrology 27: 3238–3252, 2016. doi: 10.1681/ASN.2016010112, available at: *https://jasn.asnjournals.org/content/jnephrol/27/11/3238.full.pdf?with-ds=yes.*

In response to CMS' preliminary assessment of CloudCath's substantial clinical improvement claims in the CY 2022 ESRD PPS proposed rule, the applicant provided additional information to clarify how the CloudCath System fits into the current standard of care and how use of the CloudCath System affects the management of the patient. The applicant stated that the monitoring of changes in turbidity enabled by the CloudCath System does not require clinicians to deviate from their current diagnosis or treatment sequence, since sign and symptom monitoring is an already accepted trigger for subsequent clinical steps and patient management. However, per the applicant, the detection of turbidity does allow clinicians to evaluate patients earlier in this clinical pathway for diagnosis of peritonitis and antibiotic/antimicrobial treatment in accordance with the ISPD guidelines. The applicant further stated that earlier detection of turbidity would not impact appropriate diagnosis and treatment with respect to false positives and that, while a small number of patients in the Briggs et al. study showed a change in turbidity that ultimately resulted in a false positive for infection, these patients would not have received inappropriate use of antimicrobial therapy compared to the standard of care per ISPD guidelines. The applicant further stated that even though the CloudCath System may in some instances detect change in turbidity in patients without infection, these patients would still be clinically evaluated for peritonitis diagnosis and eligibility for antimicrobial treatment by a clinician as per the existing standard of care with the change in turbidity. Therefore, the applicant stated, the CloudCath System does not result in increased provision of unnecessary antimicrobial therapy, nor deviate from the ISPD guidelines in terms of antimicrobial treatment pattern.

(b) CMS Assessment of Substantial Clinical Improvement Claims and Sources

As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38509 through 38510), after review of the information provided by the applicant regarding the CloudCath System, we noted the following concerns with regard to the substantial clinical improvement criteria under § 413.236(b)(5) and § 412.87(b)(1).

Because the applicant claims to offer the ability to diagnose a medical condition, PD-related peritonitis, earlier in a patient population than allowed by currently available methods, we stated that the applicant must also include evidence that use of the new technology to make a diagnosis affects the management of the patient, as required under the substantial clinical improvement criteria at § 412.87(b)(1)(ii)(B). Specifically, § 412.87(b)(1)(ii)(B) states that a determination that a technology represents substantial clinical improvement over existing technology means: 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.

As noted previously in the CY 2022 ESRD PPS proposed rule (86 FR 36346 through 36347), it was not clear to us whether the studies submitted demonstrate or examine the impacts of using the technology on patients with ESRD such that we can determine whether it represents an advance that substantially improves the treatment of Medicare beneficiaries compared to renal dialysis services previously available. We noted that the studies submitted serve as ''proof of concept,'' as they are testing whether the CloudCath System detects turbidity in dialysate effluent that may indicate PD-related peritonitis, and whether they do so earlier than patient observation and a cell count test. However, the studies are limited in that they do not observe how the CloudCath System, in measuring the turbidity in dialysate effluent and doing so earlier than traditional self-monitoring, affects the management of the patient as required under the substantial clinical improvement criteria at § 412.87(b)(1)(ii)(B). For example, as part of the CATCH Study, investigators deactivated the notification capability of the CloudCath System for the duration of the study, so that neither the participants nor the investigators would be aware of the device measurements.[67] Therefore, as currently designed, the CATCH study may not examine patient and clinician behavior, including the medical management of the patient, after the CloudCath System detected the solid particles in the dialysate effluent. The Briggs et al. study also did not examine how use of the CloudCath System impacted management of the patient. The investigators in that study stated that none of the data from the device was used for clinical decision making, which indicates to us that the study did not test how or if the CloudCath System offered the ability to diagnose a medical condition and how use of the CloudCath System to make a diagnosis affected the management of the patient.[68] Because the studies submitted did not observe how patients and clinicians use the CloudCath System's monitoring to make decisions regarding patient management, we stated that it was unclear how they support a finding that early detection of PD-related peritonitis by the CloudCath System meets the substantial clinical improvement criteria at § 412.87(b)(1)(ii)(B).

Similarly, while the applicant submitted evidence to show that time-to-treatment plays a role in preventing PD failure in patients with ESRD with PD-related peritonitis,[69] we stated that we had not received information regarding how the CloudCath System would affect management of the patient by reducing time-to-treatment for patients with ESRD receiving PD therapy. We also noted that the applicant referenced studies that support beginning antibacterial therapy for infections other than PD-related peritonitis, like pneumonia, and therefore, do not directly demonstrate the importance of time-to-treatment for PD-related peritonitis.

As we noted in both the CY 2022 ESRD PPS proposed rule (86 FR 36346), and the CY 2023 ESRD PPS proposed rule (87 FR 38509) it was also not clear to us whether the CloudCath System would affect medical management of the patient because use of the technology may potentially detect turbidity changes in dialysate effluent so early, that, in some cases, health care providers may still decide to wait for confirmation via patient symptoms, cell count, or positive culture as stated in the ISPD guidelines on diagnosis.[70] It is unclear

[67] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report, NCT04515498, Jan 27, 2020.

[68] Briggs, et. al., ''Early Detection of Peritonitis in Patients Undergoing Peritoneal Dialysis: A Device and Cloud-Based Algorithmic Solution,'' unpublished report.

[69] Muthucumarana, et. al., ''The Relationship Between Presentation and the Time of Initial Administration of Antibiotics With Outcomes of Peritonitis in Peritoneal Dialysis Patients: The PROMPT Study.,'' Kidney Int Rep. 2016 Jun 11;1(2):65–72. doi: 10.1016/j.ekir.2016.05.003. PMID: 29142915; PMCID: PMC5678844.

[70] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and

Continued

whether clinicians would begin treatment for peritonitis without observing patient symptoms, cloudy dialysate, or confirming cell count via fluid test or how turbidity information would be incorporated into clinical practice among physicians who may empirically treat asymptomatic patients with antibiotics while awaiting cell count and culture results to confirm a peritonitis diagnosis.

We noted that the applicant stated that the first preliminary results of the CATCH study demonstrated that the CloudCath System detected PD-related peritonitis 33 to 367 hours prior to the time of detection from a clinical laboratory, and it also detected PD-related peritonitis 27 to 344 hours prior to participants presenting to a healthcare facility with symptoms of PD-related peritonitis.[71] [72] However, we noted that no evidence was submitted to show that clinicians would begin to treat suspected peritonitis if the CloudCath System alerted the patient and clinician of possible PD-related peritonitis that was too early to detect via any of the ISPD guidelines.[73] In other words, we had not received evidence to demonstrate that the CloudCath System would affect medical management of the patient by replacing one of the ISPD guidelines for diagnosis.[74] As two criteria are necessary for diagnosis of peritonitis (per ISPD guidelines noted by the applicant), it is unclear why the CloudCath System detection alone in the control arm (absent clinical manifestations such as symptomatic patients or cloudy effluent) is comparable as a diagnosis of peritonitis to patients with clinical manifestations plus laboratory evidence of peritonitis. In other words, we questioned whether a more appropriate comparison to demonstrate a time difference would be time to laboratory-confirmed peritonitis in both study arms, or time to antibiotic initiation following the CloudCath System notification versus antibiotic initiation following standard of care patient monitoring.

Further, we noted that we were concerned by the applicant's statements in response to the concerns we noted in the CY 2022 ESRD PPS proposed rule that the monitoring of changes in turbidity enabled by the CloudCath System does not require clinicians to deviate from their current diagnosis or treatment sequence. As stated previously, our regulations under § 412.87(b)(1)(ii)(B) require evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient. We requested information that demonstrates that the CloudCath System affects the management of the patient, including by impacting clinicians' diagnosis or treatment sequence.

While the applicant updated the CY 2023 application to include more patient and site enrollment, CMS noted concerns that the CATCH trial is not designed to indicate potential changes in clinical practice in a way that would be helpful for substantial clinical improvement assessment. We stated in the CY 2023 ESRD PPS proposed rule that we welcomed additional information regarding whether use of CloudCath has demonstrated lower hospitalization rates, an increase in PD use, or decrease in peritoneal dialysis modality loss, or improved mortality for our analysis. We stated that any data on clinician and patient behavior while using the CloudCath System, for example by enabling CloudCath notifications or alarms in the CATCH Study, would be informative in our assessment.

Finally, regarding the applicant's claim that the CloudCath System's remote monitoring capabilities help to assure patients that peritonitis could be detected and treated earlier, and that by alleviating the fear of peritonitis, the CloudCath System enables patients to either switch to or remain on home-PD, ultimately improving quality of life, we expressed concern there may be insufficient evidence to demonstrate that the CloudCath System improves patients' quality of life. The applicant referenced literature regarding health-related quality of life in home dialysis patients as well as information regarding the challenges of managing PD patients remotely.[75] [76] [77] However, we noted that we did not receive any data demonstrating improved quality of life or PD retention with the use of the CloudCath System, and stated that we would be interested in additional evidence to support this claim.

We solicited public comments on whether the CloudCath System meets the substantial clinical improvement criteria for the TPNIES.

We received multiple comments on the substantial clinical improvement claims made in the TPNIES application for the CloudCath System, ranging from commenters with concerns about the applicant's claims to comments in support of the application, including those from the applicant, patients, clinicians, ESRD facilities and professional organizations. The comments on the substantial clinical improvement claims, and our responses to the comments, are set forth below.

Comment: We received a comment from the applicant in support of its application. The applicant included an updated analysis in support of its claim that the CloudCath™ System offers the ability to detect peritonitis earlier by more closely monitoring changes in turbidity of peritoneal dialysate effluent and provided responses to CMS concerns identified in the CY 2023 ESRD PPS proposed rule. We also received comments in support of the TPNIES approval from patients, clinicians, ESRD facilities, and professional organizations.

With respect to the applicant's first claim, that the CloudCath System offers substantial clinical improvement by offering the ability to detect peritonitis earlier by more closely monitoring changes in turbidity of peritoneal dialysate effluent, the applicant submitted an updated analysis of the CATCH study. Per the applicant, as of March 10, 2021, 12 individual participants experienced 14 peritonitis events meeting ISPD criteria. The applicant stated that the CloudCath System detected changes in all 14 peritonitis events of which 12 occurred after the initial use of the CloudCath System. The applicant further stated that two of the events occurred prior to the initial use of the CloudCath System and the CloudCath System detected changes in turbidity upon initial use. Per the applicant, of the 12 peritonitis events that occurred after the initial use, the CloudCath System detected the peritonitis events within a median of 108.42 hours prior to the time that

Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[71] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report (NCT04515498), Jan 27, 2020.

[72] *Ibid.*

[73] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[74] *Ibid.*

[75] Bonenkamp AA, van Eck van der Sluijs et al. Kidney Medicine, Health-Related Quality of Life in Home Dialysis Patients Compared to In-Center Hemodialysis Patients: A Systematic Review and Meta-analysis. Vol.2(2) P139–154.

[76] 25 Ronco C, Crepaldi C, Rosner MH (eds): Remote Patient Management in Peritoneal Dialysis. Contrib Nephrol. Basel, Karger, 2019, vol 197, pp I–VI.

[77] Hansson JH, Finkelstein FO. Kidney Med. 2020 Sep 1;2(5):529–531.

clinical laboratory results became available and detected changes in turbidity within a median of 97.04 hours prior to the time that the patient presented to medical providers for peritonitis-related symptoms under current standard of care.

In response to CMS' concern that the studies submitted by the applicant do not observe how the CloudCath System affects the management of the patient, the applicant stated that since the CloudCath System enables clinicians to initiate, order and receive WBC count and differential laboratory results days earlier, and subsequently initiate appropriate treatment days earlier than the current standard of care, this delta in diagnosis and treatment initiation time represents a significant positive change in patient management.

The applicant described a clinician work flow asserting that it would occur following a notification from the CloudCath System. Per the applicant, upon receiving a notification from the CloudCath System, a clinician should order a rapid WBC count and differential and that results would typically be available in 2 to 4 hours. The applicant stated that this would be considered the standard diagnostic workup for patients suspected of peritonitis before starting antimicrobial treatment. The applicant further clarified that the CloudCath System is not intended to be used as a replacement to bypass the need for laboratory diagnostics. The applicant further noted that if the results from the WBC count and differential return WBC >100/μL with >50% polymorphonuclear leukocytes (PMN,) clinicians would have confidence to proceed with initiating antimicrobial treatment. As such, the applicant stated that the use of the CloudCath System would not result in any more unnecessary antimicrobial use than would occur with the current standard of care guidelines to initiate antibiotic treatment solely based on the presentation of cloudy effluent.

The applicant also surveyed 18 physicians who confirmed via a consensus affidavit the anticipated workflow described by the applicant; the conclusion that the use of the CloudCath System would not result in increased unnecessary antimicrobial treatment; and that the use of the CloudCath System is expected to result in a positive change in patient management.

We received several supporting comments from clinicians and a trade association regarding use of the CloudCath System as a monitoring system. Several physician commenters shared their experience with the CloudCath System, stating that the notification from the CloudCath System would allow them to achieve an earlier diagnosis by verifying the CloudCath System's results with results of peritoneal fluid cell counts and differentials before initiating antimicrobial treatment. A trade association stated that because of the severity of patient risk from peritonitis, current clinical guidelines provide physicians with flexibility to prescribe antibiotic treatment without advance receipt of a positive antibody cell culture, if other signs and symptoms are present. A physician commenter stated that an elevated turbidity score from the CloudCath System would help clinicians make empiric antimicrobial treatment decisions as early as possible while results of peritoneal fluid cell counts and differentials are pending. This same commenter noted that the practice would not increase antibiotic use as it falls in line with the way that other suspected infections are treated like bacteremia and urinary tract infections according to current sepsis guidelines.

With regard to the concern about whether use of the CloudCath System has demonstrated improved clinical outcomes, including lower hospitalization rates, an increase in the use of PD, a decrease in PD modality loss, or improved mortality, the applicant claimed that studies have shown the benefits of home dialysis compared to in-center HD, such as survival, quality of life, decreased transportation costs, increased patient autonomy and clinical benefits such as enhanced blood pressure and phosphorus control. The applicant cited a study by Uchiyama et al. highlighting the ability of remote patient monitoring in patients undergoing automated PD to reduce cost, disease burden, clinical resources, hospitalizations, technique failures as well as improved treatment adherence and blood pressure control.[78] The applicant stated that prioritizing PD is beneficial for patients, providers and payers in light of the findings that more frequent dialysis in the home setting is associated with improved clinical outcomes, such as improvement in blood pressure control with fewer antihypertensive medications, volume management, left ventricular hypertrophy, phosphate control, and fewer hospital days and hospitalizations.[79] [80] [81] [82] The consensus affidavit supported the claim that the CloudCath System is expected to result in a significant clinical improvement in outcomes related to patient survival and sustained use of the PD modality.

With regard to the concern that there may be insufficient evidence to demonstrate that the CloudCath System improves patients' quality of life, the applicant stated that at-home PD has been shown to improve health-related quality of life because it can be administered in the comfort of the patient's own home, commonly when they are sleeping rather than during the day such as in the case of in-center HD. The applicant further claimed that for many patients, this improves their quality of life by allowing them to remain in the workforce.

Several commenters expressed appreciation for the CloudCath System's remote continuous monitoring feature. Individuals identifying as patients and clinicians stated that knowing that there is a system providing continuous monitoring support would give patients and the clinical team more confidence in patient oversight for PD than the current standard of care. Patient commenters stated that their healthcare providers would have the ability to react to peritonitis and other complications faster with the notification from the CloudCath System than if they were to monitor signs and symptoms by themselves.

Response: We thank the applicant and other commenters for their input and have taken this information into consideration in our determination of whether the CloudCath System meets the TPNIES eligibility criteria at § 413.236(b)(5) and § 412.87(b)(1). We have responded in further detail to comments discussing the significant clinical improvement claims for the CloudCath System at the end of this section of the final rule.

Comment: A commenter, a dialysis product and service provider, stated that the evidence presented in the TPNIES

[78] Uchiyama, Kiyotaka et al. Effects of a remote patient monitoring system for patients on automated peritoneal dialysis: a randomized crossover controlled trial. International urology and nephrology, 1–9. 1 Apr. 2022, doi:10.1007/s11255–022–03178–5.

[79] Walker, Rachael C et al. Home hemodialysis: a comprehensive review of patient-centered and economic considerations. ClinicoEconomics and outcomes research: CEOR vol. 9 149–161. 16 Feb. 2017, doi:10.2147/CEOR.S69340.

[80] Yu, Xueqing et al. Shared Decision-Making for a Dialysis Modality. Kidney international reports vol. 7,1 15–27. 30 Oct. 2021, doi:10.1016/j.ekir.2021.10.019.

[81] Cozzolino, Mario et al. COVID–19 pandemic era: is it time to promote home dialysis and peritoneal dialysis?. Clinical kidney journal vol. 14, Suppl 1 i6–i13. 2 Feb. 2021, doi:10.1093/ckj/sfab023.

[82] Lockridge, Robert Jr et al. A Systematic Approach To Promoting Home Hemodialysis during End Stage Kidney Disease. Kidney360 vol. 1,9 993–1001. 8 Jul. 2020, doi:10.34067/KID.0003132020.

application for the CloudCath System does not meet the substantial clinical improvement criterion. In referring to the evidence provided by the applicant, including the Briggs et al. study [83] and the CATCH study,[84] the commenter stated that the applicant had not presented evidence showing how use of the CloudCath System to detect peritonitis affects the management of the patient, as is required by the substantial clinical improvement criterion. For example, the commenter stated that in the CATCH study, neither the investigators nor subjects were aware of the CloudCath System's measurements and no clinical decision making was based upon readings from the CloudCath System. The commenter further stated that in the Briggs et. al. study, the authors comment that none of the data from the device was used for clinical decision-making, which indicates that the study did not test how or if the CloudCath System offered the ability to diagnose a medical condition more rapidly and how use of the CloudCath System to make a diagnosis affected the management of the patient.

The commenter also expressed concern regarding the Briggs et al. study, in which a large number of samples were false positives including already being on antibiotics for peritonitis as well as causes other than peritonitis. The commenter further stated that such a high false positive rate and the need to exclude patients already receiving treatment for peritonitis, who might have a resistant infection, could lead to inappropriate prescribing of antibiotics, increasing the risk of secondary infections or fungal infections.

The commenter also expressed concerns with the applicant's claims that patients with a false positive for infection would not have received inappropriate use of antimicrobial therapy compared to the standard of care per ISPD guidelines. The commenter noted that if this were the case with the CloudCath System, then earlier intervention with antimicrobial therapy would never occur if the patient had not yet met at least 2 of the ISPD diagnostic criteria. As such, the commenter concluded that CloudCath does not have sufficient evidence that it offers substantial clinical improvement to the current standard of care.

The commenter stated that there is no evidence that use of the CloudCath System would decrease future hospitalizations or physician visits or lead to a more rapid beneficial resolution of the disease process. The commenter stated that the Muthucumarana et al. study [85] submitted by the applicant was not related to the CloudCath System and no data or evidence was provided that demonstrated that the CloudCath System would reduce time to treatment in patients.

Response: We appreciate the commenters' input regarding whether the CloudCath System meets the TPNIES innovation criterion at § 413.236(b)(5) and substantial clinical improvement criteria at § 412.87(b)(1).

We acknowledge that the updates to the CATCH study submitted by the applicant provide additional evidence that the CloudCath System identifies nearly every case where peritonitis was ultimately diagnosed. While these additional cases did not include clinical vignettes, the patient presentations from earlier cases were reassuring that identified cases represent true instances of peritonitis. The finding that changes in turbidity were identified by the CloudCath System within a median of 97.04 hours prior to the time that the patient presented to medical providers for peritonitis-related symptoms suggests that the CloudCath System has the potential to produce an earlier diagnosis of peritonitis. We agree that early diagnosis is important because, as referenced by the applicant in the PROMPT study, each hour of delay in treating peritonitis is associated with 7% increased risk of PD failure and patient death. We also agree that the prevention of severe infection could lead to improved health outcomes and, for some patients, the ability to remain on peritoneal dialysis for longer.

We understand from input provided by clinician commenters that clinicians might use the CloudCath System in place of clinical signs and symptoms of peritonitis when assessing for possible peritonitis and that many clinicians would not initiate antibiotics until peritonitis is confirmed through a cell count and differential of peritoneal fluid. CMS agrees that the use of the CloudCath System in this way would limit the potential for unnecessary antibiotic treatments due to false positive readings, although unnecessary laboratory testing with cell counts in otherwise asymptomatic patients might still result from high false positive rates. The applicant asserts, without study data, that the use of the CloudCath System would not result in any more unnecessary antimicrobial use than would occur with the current standard of care ISPD guidelines to initiate antibiotic treatment.

We appreciate comments pertaining to patient experiences and the way in which monitoring via the CloudCath System may reassure patients and providers. We also acknowledge the information about the ways in which peritoneal dialysis improves quality of life, reduces the use of health care resources, improves health outcomes, and offers patients with autonomy, but note the absence of data demonstrating that the CloudCath System helps patients to continue using peritoneal dialysis.

CMS is supportive of new and innovative supplies and equipment for renal dialysis services. However, we remain concerned that there is no evidence, as required under the substantial clinical improvement criteria at § 412.87(b)(1)(ii)(B), that using the CloudCath System affects the management of the patient in a way that improves the diagnosis and treatment of peritonitis. Current evidence is mainly based off proof of principle studies. Despite new updates to the CATCH study, we note that, similar to previously reported findings, the updates do not include evidence that peritonitis was actually diagnosed or acted on sooner by clinicians. Importantly, the findings do not include information about whether the detection of peritonitis by the CloudCath System led to improvements in key health outcomes required for demonstrating substantial clinical improvement. Any additional data provided is still limited by the overall study design.

The applicant has not provided clear evidence that using the CloudCath System affects the management of the patient by reducing time-to-treatment. With the CloudCath System alarm turned off, the studies did not evaluate patient or clinician behavior resulting from information generated by the CloudCath System. In the Briggs et al. study, CloudCath data was not used for clinical decision making. Similarly, in the CATCH study, neither participants nor investigators were aware of the CloudCath System's measurements. There are no studies addressing outcomes such as hospitalizations,

[83] Briggs, et al., ''Early Detection of Peritonitis in Patients Undergoing Peritoneal Dialysis: A Device and Cloud-Based Algorithmic Solution,'' unpublished report.

[84] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report, NCT04515498, Jan 27, 2020.

[85] Muthucumarana, et al., ''The Relationship Between Presentation and the Time of Initial Administration of Antibiotics With Outcomes of Peritonitis in Peritoneal Dialysis Patients: The PROMPT Study.,'' Kidney Int Rep. 2016 Jun 11;1(2):65–72. doi: 10.1016/j.ekir.2016.05.003. PMID: 29142915; PMCID: PMC5678844.

resolution of disease process, or healthcare use. While the PROMPT study refers to the dangers of a delay in treating peritonitis, it did not evaluate the CloudCath System.

We acknowledge that the applicant, clinician affidavit, and other commenters provided input on how the CloudCath System *could be used* in a clinical setting. While clinician commenters offered input about the way in which clinicians might manage a patient following a CloudCath System notification, commenters provided multiple conflicting reports of how clinicians would use the technology. Comments from clinicians indicate a varied response: some may treat a patient empirically based on turbidity findings, while others may wait for rapid cell counts if available.

In light of the first response (treating empirically based on turbidity), possible harm from the presence of false positives remains a serious concern. The applicant's submitted evidence does not convincingly refute the concern of possible false positives from the CloudCath System. Thus, clinicians who choose to prescribe antibiotics without waiting for confirmatory diagnostic tests such as a cell count have the potential for overprescribing antibiotics. Using the technology to make decisions about empiric treatment, might be especially likely to occur when patients cannot come to the dialysis unit for a peritoneal fluid collection or when laboratory results are not expedited.

We remain concerned that if there is a high false positive rate, the device may inequitably result in certain vulnerable populations disproportionately receiving inappropriate antibiotics. In particular, beneficiaries living in underserved areas may not have access to a rapid cell count or quick turnaround of other confirmatory tests and could be particularly vulnerable to the potential harm of treating false positives. Clinicians in underserved areas may not have access to rapid cell counts and patients in these areas may be less likely to access rapid cell counts except through an Emergency Department. As such, more information about false positivity would be beneficial to better understand the ramifications of practice changes, and whether clinical benefits from more rapid detection outweigh costs from false positives. We note that demonstration of a low false positive rate could offset concerns for inappropriate antibiotic use, especially in underserved areas where rapid cell counts may not be available. As such, a low false positive rate is more likely to improve health equity.

We acknowledge that many clinician commenters stated that they would not initiate empiric antibiotics without confirmatory testing. However, for these situations, the applicant did not present evidence that the CloudCath System would result in a quicker diagnosis or treatment of peritonitis. It is also unclear how much sooner patients would present to a healthcare provider in response to a positive CloudCath System reading when compared to traditional signs and symptoms of peritonitis. Evidence of clinician behavior, meaning data that captures the way in which the CloudCath System's notifications affect the management of the patient in the clinical setting, would help to address these uncertainties.

Finally, we appreciate the patient letters describing the risks and anxieties of venturing out on home dialysis, mostly without the clinician oversight or accessibility that would be available to patients dialyzing in-center. While there is potential for the CloudCath System to improve quality of life by providing an added level of assurances, the applicant has not provided supporting evidence to demonstrate improvements in quality of life, which per § 412.87(b)(1)(ii)(C)(6), is one way that a new technology can demonstrate substantial clinical improvement.

After carefully reviewing the application, the information submitted by the applicant addressing our concerns raised in the CY 2023 ESRD PPS proposed rule, as well as the many comments submitted by the public, we have determined that the CloudCath System has not shown that it represents an advance that substantially improves, relative to renal dialysis services previously available, the treatment of Medicare beneficiaries. Therefore, we conclude that the CloudCath System does not meet the TPNIES innovation criteria under § 413.236(b)(5) and § 412.87(b)(1).

(6) Capital-Related Assets Criterion (§ 413.236(b)(6))

Regarding the sixth TPNIES eligibility criterion in § 413.236(b)(6), limiting capital-related assets from being eligible for the TPNIES, except those that are home dialysis machines, the applicant stated that the CloudCath System is not a capital-related asset. We noted in the CY 2023 ESRD PPS proposed rule that the CloudCath System does not meet the definition of a capital-related asset under § 413.236(a)(2), because it is not an asset that the ESRD facility has an economic interest in through ownership and is subject to depreciation [86] and we received no public comments on this criterion.

Final Rule Action: After a consideration of all the public comments received, we have determined that the evidence and public comments submitted are not sufficient to demonstrate that the CloudCath System meets all eligibility criteria to qualify for the TPNIES for CY 2023. As a result, the CloudCath System will not be paid for using the TPNIES per § 413.236(d).

We note that in the CY 2021 ESRD PPS final rule (85 FR 71412), CMS indicated that entities would have 3 years beginning on the date of FDA marketing authorization in which to submit their applications for the TPNIES. Based on the CloudCath System's FDA marketing authorization date of February 9, 2022, the applicant is eligible to apply for the TPNIES for CY 2024, CY 2025, or CY 2026, and CMS will review any new information provided for the particular CY rulemaking cycle.

b. SunWrap™ System

Sun Scientific, Inc. submitted an application for the TPNIES for the SunWrap™ System for CY 2023. According to the applicant, the technology is comprised of a compression sleeve with a transparent air bladder and hand pump designed to provide static pneumatic compression to the forearm and/or upper arm following dialysis needle removal from the arteriovenous (AV) fistula access. The applicant explained that following HD, gauze is placed over the puncture sites as the needles are removed, and then the SunWrap™ System is placed around the arm with the transparent bladder positioned over the gauze-covered access site. Per the applicant, the SunWrap™ System is then inflated, compressing the site to stop bleeding. Per the applicant, the SunWrap™ System provides a sufficient source of pressure to compress the AV intervention puncture site and has adjustable compression at 20–30 mmHg and 30–40 mmHg. The applicant also stated that the inflation portion of the wrap is composed of completely transparent film, allowing for visualization of the puncture site(s) and ensuring that the hemostasis can be monitored. The applicant stated that the SunWrap™ System is easy to apply, safe, non-invasive, requires minimal

[86] See also CMS Provider Reimbursement Manual, Chapter 1, Section 104.1. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.*

training of only one tutorial, and has been proven to meet patient satisfaction and safety requirements after multiple trials.

The applicant also submitted a SunWrap™ System brochure noting that the product is indicated for post-HD treatment needle puncture management for hemostasis of needle site and that it is contraindicated for use directly on an open wound. The applicant submitted the following listing of the SunWrap™ System's line of products: Upper Arm—Right Small, Upper Arm—Right Large, Forearm Right, Upper Arm—Left Small, Upper Arm—Left Large, Forearm Left, and MINI—Single Site.

The applicant stated that the SunWrap™ System is meant to replace the current method of compression for bleeding control, which relies on the patient or skilled caregiver manually applying pressure to the puncture site for up to 15 minutes following HD. Per the applicant, inadequate or incorrect application of compression can result in discomfort, excessive bleeding, hematoma, fistula damage, and potentially even death. The applicant stated that use of the SunWrap™ System allows for more consistent application of compression, frees up the hands of the patient or skilled caregiver, and allows for simultaneous visual management of the needle site.

(1) Renal Dialysis Service Criterion (§ 413.236(b)(1))

Regarding the first TPNIES eligibility criterion in § 413.236(b)(1), that the item has been designated by CMS as a renal dialysis service under § 413.171, compression to the HD access site following dialysis needle removal is a service that is furnished to individuals for the treatment of ESRD and essential for the delivery of maintenance dialysis. We received no public comments on whether the SunWrap™ System meets this criterion. We consider the SunWrap™ System to be a renal dialysis service under § 413.171.

(2) Newness Criterion (§ 413.236(b)(2))

With respect to the second TPNIES eligibility criterion in § 413.236(b)(2), that the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant did not submit an FDA marketing authorization date but instead, indicated that the SunWrap™ System is considered FDA Class I Exempt. We note that under FDA regulatory scheme, Class I exempt status is determined by FDA, which maintains on its website the listing of devices exempt from the premarket notification (510(k)) requirements. As described on the FDA website, Class I devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. Examples include enema kits and elastic bandages.[87]

As we discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38511), the applicant submitted the following information pertaining to Sun Scientific, Inc.'s registration and product classification: (1) a document labeled *Class I Exempt Documentation* and (2) listing, registration, and Firm Establishment Identifier (FEI) numbers for *SunWrap.* While the *Class I Exempt Documentation* lacked identifying product information such as the SunWrap™ System's product name(s) and date of the Class I Exempt status determination, we located supplemental information online. Sun-Scientific, Inc. is identified on the FDA website with Registration Number: 3008773774, FEI Number: 3008773774, and Owner/Operator Number: 10034866.[88] Twelve devices were identified with this Owner/Operator Number, but only the following two devices include the regulation number (880.5075) included in the application: Dressing, Compression—Aerowrap; SunWrap and Dressing, Compression—SunWrap.[89]

After a review of the information provided by the applicant, in the proposed rule, we noted the following concerns with regard to the newness criterion under § 413.236(b)(2). Consistent with § 413.236(c), we stated that CMS would announce its final determination regarding whether the SunWrap™ System meets the newness criterion and other eligibility criteria for the TPNIES in the CY 2023 ESRD PPS final rule.

First, the applicant included a product brochure and product selection listing of 7 SunWrap™ System products and did not clearly indicate which of the 7 products are the subject of the CY 2023 TPNIES application. In addition, it is not clear whether the listing and registration numbers provided apply to all 7 products. We requested that the applicant clarify these points.

Second, while the applicant stated that the Sun Wrap™ System is considered FDA Class I Exempt, as indicated in § 413.236(b)(2), to be eligible for the TPNIES, the applicant must apply within three years of the FDA marketing authorization date. While our primary concern is the lack of FDA marketing authorization, we also noted that the applicant did not clearly indicate the date of Class I Exempt status. Therefore, it is unclear whether the SunWrap™ System's Class I Exempt status is within the three-year window.

We noted that manufacturers of devices that fall into a category of exempted Class I devices are not required to submit to FDA a premarket notification and obtain FDA clearance before marketing the device in the U.S. However, the manufacturer is required to register its establishment and list its device with FDA.[90] Devices that receive FDA marketing authorization have met regulatory standards that provide a reasonable assurance of safety and efficacy for the devices. For exempt devices, FDA has determined that a premarket notification is not required to provide a reasonable assurance of safety and effectiveness for the devices. However, exempt devices still must comply with certain regulatory controls (known as ''general controls'') to provide a reasonable assurance of safety and effectiveness for such devices. Our intent in requiring applicants to receive FDA marketing authorization was to exclude devices that lack FDA marketing authorization. However, we welcomed public comment on these issues.

Comment: One commenter agreed with CMS regarding the lack of clarity as to which of the 7, in the family of the SunWrap™ System products, are the subject of the CY 2023 TPNIES application and with regard to the lack of a date that the product received Class 1 Exempt status. The commenter also stated that the newness criterion delineates FDA marketing authorization as a requirement to apply for the TPNIES and that for CMS to extend the eligibility criterion beyond technologies with FDA marketing authorization (that

[87] Food & Drug Administration. Learn if a Medical Device Has Been Cleared by FDA for Marketing. Available at: *https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing.* Accessed on March 23, 2022.

[88] U.S. Food & Drug Administration. Establishment Registration & Device Listing. Sun-Scientific Inc. Available at: *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=124922.* Accessed on March 29, 2022.

[89] U.S. Food & Drug Administration. Establishment Registration & Device Listing. Sun-Scientific Inc. Available at: *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&showList=1&establishmentName=&regNum=&StateName=&CountryName=&OwnerOperatorNumber=10034866&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=EstablishmentName20%25ASC&RegistrationNumber=3008773774.* Accessed on March 29, 2022.

[90] Food & Drug Administration. Learn if a Medical Device Has Been Cleared by FDA for Marketing. Available at: *https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing.* Accessed on March 23, 2022.

is, Class I Exempt status) would require future rulemaking. The commenter stated that CMS should clarify in future rulemaking whether devices that are considered FDA Class I Exempt are eligible for the TPNIES.

Response: We thank the commenter for their comments regarding the newness criterion. We did not receive additional information from the applicant pertaining to our newness concerns. Therefore, it remains unclear as to which of the SunWrap™ System products are the subject of the TPNIES application. We also note that as indicated in the CY 2023 ESRD PPS proposed rule, devices that receive FDA marketing authorization have met regulatory standards that provide a reasonable assurance of safety and efficacy for the devices. We maintain that our intent in requiring applicants to receive FDA marketing authorization was to exclude devices that lack FDA marketing authorization (87 FR 38511). Therefore, in the absence of evidence that the technology is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the SunWrap™ System does not meet the TPNIES newness criterion under § 413.236(b)(2).

(3) Commercial Availability Criterion (§ 413.236(b)(3))

Regarding the third TPNIES eligibility criterion in § 413.236(b)(3), that the item is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, the applicant stated that the SunWrap™ System is currently commercially available. While we received no public comments on this criterion, and we continue to have questions about which of the 7 products are the subject of the TPNIES application, the SunWrap™ System appears to meet the commercial availability criterion.

(4) HCPCS Level II Application Criterion (§ 413.236(b)(4))

Regarding the fourth TPNIES eligibility criterion in § 413.236(b)(4) requiring that the applicant submit a complete HCPCS Level II code application by the HCPCS Level II application deadline of July 5, 2022, the applicant stated that it submitted that application on January 31, 2022. We received no public comment on whether the SunWrap™ System meets this criterion, however CMS received a HCPCS Level II application by the deadline. Therefore, we agree the applicant has met the HCPCS Level II application criterion.

(5) Innovation Criteria (§§ 413.236(b)(5) and 412.87(b)(1))

(a) Substantial Clinical Improvement Claims and Sources

With regard to the fifth TPNIES eligibility criterion under § 413.236(b)(5), that the item is innovative, meaning it meets the substantial clinical improvement criteria specified in § 412.87(b)(1), as discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38511 through 38513), the applicant stated that the use of the SunWrap™ System significantly improves clinical outcomes relative to the current standard of care, which it identified as reliance on the patient or a skilled caregiver manually applying pressure to the puncture site for up to 15 minutes following HD.

The applicant presented the following six substantial clinical improvement claims: (1) a reduction in at least one clinically significant adverse event; (2) a decreased rate of at least one subsequent diagnostic or therapeutic intervention; (3) a decreased number of future hospitalizations or physician visits; (4) a more rapid beneficial resolution of the disease process treatment; (5) an improvement in one or more activities of daily living; and (6) an improved quality of life.

Regarding the first claim, a reduction in at least one clinically significant adverse event, the applicant stated that the SunWrap™ System potentially reduces the incidence of hematoma, fistula stenosis/thrombosis, and Fatal Vascular Access Hemorrhage (FVAH).

Regarding the second claim, a decreased rate of at least one subsequent diagnostic or therapeutic intervention, the applicant stated that the SunWrap™ System potentially reduces the incidence of ER visits, estimated at $10,000 per visit, ultrasound assessment, or interventions for stenosis or thrombosis. The applicant also stated that the SunWrap™ System potentially reduces the incidence of hospital admissions that are estimated at $15,000 or more per admission. The applicant further stated that incident cases of ESRD are reaching nearly 21,000 annually, and that vascular access complications account for 16 to 25 percent of hospital admissions.[91]

Regarding the third claim, a decreased number of future hospitalizations or physician visits, the applicant stated that the SunWrap™ System reduces ER visits due to bleeding and the potential for subsequent admission, saving approximately $10,000 per visit.[92] The applicant also stated that the SunWrap™ System reduces the need for revascularization due to stenosis/thrombosis.[93]

Regarding the fourth claim, a more rapid beneficial resolution of the disease process treatment, the applicant stated that the SunWrap™ System reduces the need for nurses to be tied up with manual compression therapy, maximizing their efforts around dialysis treatment. The applicant also stated that the SunWrap™ System adds a layer of assurance as patients transfer to home therapy, as compression is not reliant on patient or caregiver ability to provide compression consistent with care that occurs in the clinics. Per the applicant, the SunWrap™ System provides consistent compression to needle sites post-dialysis with the ability to visualize sites through a transparent window potentially reducing the incidence of unrecognized bleeding.

Regarding the fifth claim, an improvement in one or more activities of daily living, the applicant stated that the SunWrap™ System could increase comfort levels of patients in the home setting and could help reduce fatigue-related compression interruption, and allow some normal activity while ensuring post-dialysis compression is provided, resulting in potential for improved patient satisfaction.

Regarding the sixth claim, improved quality of life, the applicant stated that the SunWrap™ System allows the patient to become more autonomous and that the ability to have their hands free while stopping bleeding post-HD is beneficial. The applicant also stated that the potential reduction in fistula complications could improve quality of life on a broader scale.

The applicant did not provide direct links to the supporting materials for each of the six claims, but rather referred more broadly to several sources of information as evidence of demonstrating substantial clinical improvement, including a U.S. Centers for Disease Control and Prevention fact sheet on Chronic Kidney Disease (CKD),[94] case studies on fatal

[91] Simon, E. (2016). The dialysis patient: managing fistula complications in the emergency department. EMDocs. Available at: *http://www.emdocs.net/dialysis-patient-managing-fistula-complications-emergency-department/*. Accessed on March 17, 2022.

[92] Simon, E. (2016). The dialysis patient: managing fistula complications in the emergency department. EMDocs. Available at: *http://www.emdocs.net/dialysis-patient-managing-fistula-complications-emergency-department/*. Accessed on March 17, 2022.

[93] Ibid.

[94] Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2021. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and

Continued

hemorrhage from HD vascular access sites,[95] and a case study of managing fistula complications in the Emergency Department.[96] The applicant stated that there are 786,000 annual ESRD patients, 71 percent are on dialysis and 29 percent have kidney transplants.[97] Referring to Gage, et al, the applicant stated that 75 percent of AV fistulae and AV grafts required one or more interventions; stenosis and thrombosis were the most common complications diagnosed and treated (41 percent and 16 percent respectively); and that potential needle-related complications accounted for 6 percent of this data set.[98] The applicant also stated that a review of standard and early cannulation graft literature reveals that HD complications are similar across the graft types. The applicant further noted that in retrospective review articles, infection, hematoma, pseudoaneurysm, and bleeding occur at rates of up to 26 percent, 24 percent, 15 percent, and 14 percent, respectively.

The applicant also included a summary of what it described as evidence from an unpublished pilot study involving 54 patients in two vascular access laboratory sites, 23 and 31 patients from each site, respectively who required intervention on their AV fistula or graft access site.[99] The applicant provided background information stating that patients require AV fistula or graft interventions for various reasons such as maintenance angioplasty, fistulogram, or thrombectomy. Per the applicant, the physician normally uses sutures to close the puncture site and after the procedure, the patients are monitored in the recovery room for a few hours before the sutures are removed or patients revisit the clinic for suture removal. The applicant stated that this suturing technique is frequently used because it is quick, straightforward, and has been the common practice. The applicant further indicated that suture removal poses a risk of infection. The applicant stated that during the study, the SunWrap™ System was applied for wound closure in place of suturing with an inflation pressure at 20–40 mmHg and hold-time at 20 to 30 minutes for most of the patients because most patients were punctured with a large note sheath size of 6–8 F. The applicant also stated that in ESRD facilities, the needle size is relatively smaller and less inflation pressure and shorter hold-times are needed to achieve hemostasis. As such, the applicant stated that the SunWrap™ System could be safely applied in the ESRD facility setting without extensive training.

The applicant noted two reported cases of immediate post-operative bleeding; one reported case (fistula) of thrombosis at 48 to 72 hours post-operatively; and three reported cases (two fistula and one graft) of thrombosis 30 days post-operatively. The applicant stated that there were no reported cases of post-operative bleeding, infection, and pseudoaneurysm at 48 to 72 hours.

Per the applicant, the two cases of immediate post-operative bleeding were directly due to the SunWrap™ System. Per the applicant, the first case occurred during training in the initial phase of the study and there was no repetitive event after modification of the technique and timing of the application of the SunWrap™ System. We noted in the CY 2023 ESRD PPS proposed rule that the applicant did not specify the way in which the technique or timing of applying the SunWrap™ System were modified. The applicant stated that the second case was due to two distant puncture sites that exceeded the coverage for the SunWrap™ System. Per the applicant, in patients with two puncture sites that measure more than 7.5 cm apart or if there is immediate bleeding, suturing is the treatment of choice.

The applicant stated that the thrombosis cases identified (one case at 48 to 72 hours post-operatively and three cases 30-days post-operatively) were not directly due to the SunWrap™ System. Per the applicant, the patients did not have any complications while on the SunWrap™ System and left the clinic safely after thorough monitoring in the recovery room. The applicant further stated that the patients underwent dialysis after the removal of the SunWrap™ System and stated that the dialysis may have been the major contributing factor for the thrombosis.

(b) CMS Assessment of Substantial Clinical Improvement Claims and Sources

After a review of the information provided by the applicant, in the CY 2023 ESRD PPS proposed rule, we noted the following concerns with regard to the substantial clinical improvement criteria under § 413.236(b)(5) and § 412.87(b)(1).

The applicant stated that the SunWrap™ System has the potential to represent substantial clinical improvement. However, it is not clear whether or how the evidence submitted by the applicant supports the applicant's 6 substantial clinical improvement claims. We stated that it will be helpful for our evaluation if the applicant will directly link each claim to the relevant supporting information. The applicant provided summary points of a non-published, single pilot study of 54 patients treated with the SunWrap™ System at two vascular access laboratory sites. While the applicant provided a bullet-point summary of the study setting, complications, and a brief discussion of study data, the applicant did not provide details pertaining to study type, timeframe, patient demographics and endpoints. We noted that this study appears to involve patients treated with the SunWrap™ System for the purpose of controlling bleeding following interventional procedures involving an AV fistula or graft and does not involve use of the SunWrap™ System following HD treatment in the ESRD facility setting. We questioned the extent to which this data would be generalizable to the ESRD facility setting and stated that we would be interested in any data pertaining to the use the SunWrap™ System for the purpose of controlling bleeding in the ESRD facility setting; specifically, at the needle puncture sites following HD.

We also noted that the applicant stated that the SunWrap™ System provides static pneumatic compression to the forearm and/or upper arm with a gauze bandage, following dialysis needle removal from the AV fistula access. We requested clarification as to whether the SunWrap™ System's indication for use is limited to patients with AV fistula access sites or if it is also indicated for use among patients with AV graft access sites.

Prevention; 2021. Available at: *https://www.cdc.gov/kidneydisease/pdf/Chronic-Kidney-Disease-in-the-US-2021-h.pdf*. Accessed on March 17, 2022.

[95] Jose, M., Marshall, M., Read, G., Lioufas, N., Ling, J., Snelling, P., Polkinghorne, K. (2017). Fatal dialysis vascular access hemorrhage. Am J Kidney Dis., 70(4), 570–575. Available at: *https://www.sciencedirect.com/science/article/pii/S0272638617307497*. Accessed on March 17, 2022.

[96] Simon, E. (2016). The dialysis patient: managing fistula complications in the emergency department. EMDocs. Available at: *http://www.emdocs.net/dialysis-patient-managing-fistula-complications-emergency-department/*. Accessed on March 17, 2022.

[97] Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2021. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2021. Available at: *https://www.cdc.gov/kidneydisease/pdf/Chronic-Kidney-Disease-in-the-US-2021-h.pdf*. Accessed on March 17, 2022.

[98] Gage SM, Reichert H. Determining the incidence of needle-related complications in hemodialysis access: We need a better system. J Vasc Access. 2021 Jul;22(4):521–532. doi: 10.1177/1129729820946917. Epub 2020 Aug 18. PMID: 32811335. Available at: *https://pubmed.ncbi.nlm.nih.gov/32811335/Accessed* on March 17, 2022.

[99] Summary points included in the application identified as: Sun-Wrap A Novel device for arteriovenous (AV) access hemostasis, Presented by Steven H.S. Tan, M.D. & Sundaram Ravikumar, M.D., FACS.

The applicant identified 6 cases of post-operative complications within the pilot study, stating that two were directly due to the SunWrap™ System and that the 4 remaining cases were unrelated to the SunWrap™ System, but did not offer data to substantiate this statement. In addition, the applicant stated that the SunWrap™ System has met patient satisfaction and safety requirements after multiple trials, but did not provide specific information in support of this statement within the application. We stated that we would appreciate additional information regarding these trials, as well as any additional data demonstrating that the SunWrap™ System represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. For example, we stated that it would be useful to consider data comparing the SunWrap™ System's outcomes to outcomes of patients treated by manual compression at the puncture site following HD.

The applicant referred to the SunWrap™ Mini, stating that it targets single puncture sites and may be useful for achieving hemostasis for puncture sites which are more than 7.5 cm apart, may be easier to use in ESRD facilities, and is currently in its initial phase of study. As noted previously in this section of the final rule, the applicant provided a listing of 7 SunWrap™ System products. We requested clarification as to which of the 7 SunWrap™ System products were included in the primary pilot study of 54 patients. We welcomed public comment on these issues.

Comment: We received several public comments regarding the substantial clinical improvement claims made in the TPNIES application for the SunWrap™ System. While one commenter offered general support of all technologies being considered for CY 2023 TPNIES, including the SunWrap™ System, the remaining commenters expressed concerns.

A few commenters stated that direct clinical evidence was not provided to support the applicant's claims of substantial clinical improvement. One commenter emphasized that each claim of substantial clinical improvement should be directly linked to supporting evidence.

With respect to CMS' concern regarding the absence of data pertaining to the use of the SunWrap™ System in the ESRD facility setting, commenters agreed that specific data pertaining to the use the SunWrap™ System for the purpose of controlling bleeding at the needle puncture sites following HD in the ESRD facility setting would be needed to establish substantial clinical improvement. One commenter questioned whether the unpublished single pilot study would support the technology's intended use as a renal dialysis service given that it does not involve the use of the SunWrap™ System following HD treatment in the ESRD facility setting.

One commenter stated that human holding of the needle site is the standard of care and allows variable pressure post needle removal, and that the SunWrap™ System does not allow for this variable adjustment. One commenter stated that patients who attempted to use the device post dialysis, experienced excessive bleeding. Another commenter stated the two cases of post-operative bleeding and four cases of thrombosis resulted in a complication rate of 11.1 percent compared to a more typical rate of 1.7 percent, and expressed concern that the SunWrap™ System potentially predisposes patients to greater risk of thrombosis after its use.

Response: We appreciate the input provided by the commenters and agree that there is a lack of evidence that the SunWrap™ System controls bleeding at the needle puncture sites following HD in the ESRD facility setting. We also agree with the comments expressing uncertainty as to whether the use of the SunWrap™ System predisposes patients to greater risk of thrombosis after its use. Because we did not receive a public comment from the applicant addressing our concerns set forth in the CY 2023 ESRD PPS proposed rule (87 FR 38513), those concerns also remain. First, it is not clear whether the technology is indicated for use limited to patients with AV fistula access sites or if it is also indicated for use among patients with AV graft access sites. Second, it is unclear which of the 7 SunWrap™ System products were included in the primary pilot study. Finally, we did not receive evidence that the SunWrap™ System met patient satisfaction and safety requirements after multiple trials nor did we receive data comparing the SunWrap™ System's outcomes to outcomes of patients treated by manual compression at the puncture site following HD. Therefore, we conclude that the SunWrap™ System does not meet the TPNIES innovation criteria under § 413.236(b)(5) and § 412.87(b)(1).

(6) Capital-Related Assets Criterion (§ 413.236(b)(6))

Regarding the sixth TPNIES eligibility criterion in § 413.236(b)(6), limiting capital-related assets from being eligible for the TPNIES, except those that are home dialysis machines, the applicant did not address this criterion within its application. We received no public comments on this criterion. However, because the SunWrap™ System is not an asset that the ESRD facility has an economic interest in through ownership and is subject to depreciation, it is not a capital-related asset.[100]

Final Rule Action: After a consideration of all the public comments received, we have determined that the evidence and public comments submitted are not sufficient to demonstrate that the SunWrap™ System meets all eligibility criteria to qualify for the TPNIES for CY 2023. As a result, the SunWrap™ System will not be paid for using the TPNIES per § 413.236(d).

c. THERANOVA 400 Dialyzer/ THERANOVA 500 Dialyzer (THERANOVA)

Baxter Healthcare Corporation (Baxter) submitted an application for the TPNIES for the THERANOVA 400 Dialyzer/THERANOVA 500 Dialyzer, collectively referred to as ''THERANOVA,'' for CY 2023. According to the applicant, THERANOVA is a new class of single-use dialyzer, featuring an innovative three-layer membrane structure that enables more comprehensive removal of certain harmful proteins known as large middle molecules (LMMs), while selectively maintaining essential proteins in the blood during HD, compared to conventional low-flux and high-flux dialyzers. The applicant noted that the '400' and '500' denote differences in surface area. The applicant stated that THERANOVA is used with standard HD machines, like most other high-flux dialyzers, but has unique membrane properties that allow for enhanced removal of LMM uremic toxins contributing to disease burden (cardiovascular disease, development of inflammation, and other comorbidities) while retaining appropriate levels of beneficial molecules such as albumin, coagulation factors, and immunoglobulins. As we noted in the CY 2023 ESRD PPS proposed rule, Baxter previously submitted an application for the TPNIES for THERANOVA for CY 2021, as discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42167 through 42177) and the

[100] 42 CFR 413.236(a)(2); CMS Provider Reimbursement Manual, Chapter 1, Section 104.1. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.*

CY 2021 ESRD PPS final rule (85 FR 71444 through 71457).[101]

The applicant stated that THERANOVA is intended to treat kidney failure by expanded hemodialysis (HDx). The applicant noted that previous dialyzers were only able to remove toxins up to 25 kilodaltons (kDa), while HDx, enabled by the THERANOVA dialyzer, can remove molecules from 25 kDa to approximately 45 kDa. The applicant explained that patients with CKD have increasing difficulty removing these solutes as their kidneys fail. The applicant further explained that these non-protein bound uremic solutes can be divided into three main categories: (1) small molecules (SMs), <0.5 kDa, with effective removal by diffusion, (2) small and medium middle molecules (SMMMs), 0.5 − <25 kDa, with limited removal by diffusion, and (3) large middle molecules (LMMs), 25 − 60 kDa, which requires higher permeability membranes for effective and efficient removal.[102] The applicant noted that evidence to date demonstrates a strong link between LMMs and the development of different outcome-related morbidities, and that uremia related to the retention of SMMMs/LMMs is associated with inflammation and cardiovascular events.[103] [104] [105] The applicant stated that THERANOVA's innovative hollow fiber, medium cut-off (MCO) membrane shows a permeability profile close to that of the natural kidney and expands the range of uremic toxin removal beyond what is achieved with current membranes during regular HD.

The applicant stated that the design of THERANOVA allows for use on any HD machine, both in-center and home, made by Baxter or another manufacturer, by merely changing the dialyzer. The applicant stated that the membrane is compatible with standard fluid quality and does not require any additional fluid quality control measure.[106]

(1) Renal Dialysis Service Criterion (§ 413.236(b)(1))

With respect to the first TPNIES eligibility criterion under § 413.236(b)(1), whether the item has been designated by CMS as a renal dialysis service under § 413.171, maintenance dialysis treatments and all associated services, including historically defined dialysis-related drugs, laboratory tests, equipment, supplies, and staff time, were included in the composite rate for renal dialysis services as of December 31, 2010 (75 FR 49036). While we received no public comments on whether THERANOVA meets this criterion, a dialyzer would be considered a supply essential for the delivery of maintenance dialysis and, therefore, we will consider THERANOVA to be a renal dialysis service under § 413.171.

(2) Newness Criterion (§ 413.236(b)(2))

With respect to the second TPNIES eligibility criterion under § 413.236(b)(2), whether the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant stated that the THERANOVA received FDA marketing authorization for home use on August 28, 2020. We received no public comments on whether the THERANOVA meets the newness criterion. Based on information provided by the applicant, we agree that THERANOVA meets the newness criterion.

(3) Commercial Availability Criterion (§ 413.236(b)(3))

With respect to the third TPNIES eligibility criterion under § 413.236(b)(3), whether the item is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, the applicant stated that THERANOVA is commercially available in the U.S. We received no public comments on whether the THERANOVA meets this criterion. Based on the information provided by the applicant, THERANOVA meets the commercial availability criterion.

(4) HCPCS Level II Application Criterion (§ 413.236(b)(4))

With respect to the fourth TPNIES eligibility criterion under § 413.236(b)(4), whether the applicant submitted a HCPCS Level II code application by the July 5, 2022 deadline, the applicant stated a HCPCS application was submitted on June 27, 2020. The applicant also indicated that it submitted a HCPCS Level II application for THERANOVA by the July 5, 2022, deadline. We received no other public comments on whether THERANOVA meets this criterion, however, we received a HCPCS Level II application by the deadline. Therefore, we agree the applicant has met the HCPCS Level II application criterion.

(5) Innovation Criteria (§§ 413.236(b)(5) and 412.87(b)(1))

(a) Substantial Clinical Improvement Claims and Sources

With respect to the fifth TPNIES eligibility criterion under § 413.236(b)(5), that the item is innovative, meaning it meets the substantial clinical improvement criteria specified in § 412.87(b)(1), the applicant stated that THERANOVA significantly improves clinical outcomes relative to the current standard of care for dialysis membranes. As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38513 through 38520), the applicant presented the following substantial clinical improvement claims: (1) decrease in the number of future hospitalization by up to 45 percent; (2) improved recovery time by up to 2 hours; (3) improved quality of life (QoL) as indicated by reduced pruritus, improvement in two Kidney Disease Quality of Life (KDQoL) survey domains, and improved London Evaluation of Illness (LEVIL) scores; (4) reduced restless leg syndrome by 10 percent or more; and (5) reduced rate of subsequent therapeutic interventions such as reduced need for and use of erythropoietin stimulating agents (ESAs), iron, and insulin. The applicant supported these claims with seven published papers, one paper accepted for publication, and one poster. Several of the studies were secondary analyses of the same trial data.

With respect to the claim that THERANOVA decreases the number of future hospitalizations, the applicant noted that emergent need for hospitalization can be a serious and life-threatening event, especially for medically-fragile populations, and that hospitalization is a frequent and costly occurrence for the ESRD population. The applicant stated that an estimated 792,643 HD patient hospitalizations occur every year,[107] with roughly 40

[101] As noted in the CY 2021 ESRD PPS final rule, we did not find the submitted evidence and public comments sufficient in meeting the substantial clinical improvement ''totality of the circumstances'' criterion at § 412.87(b)(1)(i). Therefore, we determined that THERANOVA did not qualify for the TPNIES at that time (85 FR 71457).

[102] Baxter. Theranova 400/500 Instructions For Use. N50 648 rev 003, 2017–05–29.

[103] Yilmaz MI, Carrero JJ, Axelsson J, Lindholm B, Stenvinkel P: Low-grade inflammation in chronic kidney disease patients before the start of renal replacement therapy: sources and consequences. Clin Nephrol 68:1–9,2007.

[104] Stenvinkel P. Can treating persistent inflammation limit protein energy wasting? Semin Dial. 2013;26(1):16–19. doi:10.1111/sdi.12020.

[105] Akchurin OM, Kaskel Fl. *Update on inflammation in chronic kidney disease.* Blood Purif 2015; 39:84–92.

[106] Alvarez L, et al. Intradialytic Symptoms and Recovery Time in Patients on Thrice-Weekly In-Center Hemodialysis: A Cross-sectional Online Survey, Kidney Med. 2020;2(2)125–130.

[107] The applicant's information on the number of hospitalizations is based on a Moran Company

percent of new dialysis patients averaging nearly two hospitalizations per year.[108] The applicant also stated that ESRD patients often have health impairments associated with their condition and other comorbidities that put them at greater risk for hospitalization, and at greater risk for adverse outcomes once hospitalized. The applicant stated that, for example, a recent study found that hospitalized ESRD patients on maintenance dialysis had higher odds of mortality after cardiopulmonary resuscitation (odds ratio, 1.24; 95 percent CI, 1.11 to 1.3; p <0.001), compared to the general patient population.[109] The applicant explained that the frequency and severity of hospitalizations in the ESRD patient population adds urgency to adopting innovative technologies that can help prevent hospitalization and associated morbidity and mortality.

To support its claim that the use of THERANOVA decreases the number of future hospitalizations, the applicant referred to a poster by Tran et al. (2021), which was an abstract of a secondary analysis of a prospective, open-label, randomized controlled trial [110] of 172 patients (86 THERANOVA; 85 high-flux HD (HF–HD), with 1 patient not treated). As a post hoc analysis of a randomized controlled trial, the applicant stated that the objective of the study was to evaluate the association of HDx with the THERANOVA dialyzer with hospitalization rates, as compared to conventional HD. The applicant stated that patients were randomized and treated with either Theranova 400 or a conventional high-flux dialyzer in 21 U.S. study centers. The applicant noted that hospitalization was defined by the occurrence of any serious adverse event containing a hospitalization admission date, hospitalization rate was defined by treatment as total number of hospitalizations divided by total person-years of follow-up, and hospital length of stay was defined as number of days between admission and discharge. The applicant stated that this study found that the rate of hospitalizations for patients using THERANOVA was statistically significantly lower—45 percent—than those using HF–HD (IRR = 0.55; p = 0.0495).[111]

The applicant also referred to a multi-center, observational retrospective, cohort study by Molano-Triviño et al. (2022) that used propensity score matching assignment methods for 1,098 patients (534 HF–HD; 564 HDx with THERANOVA). The applicant stated that the objective of the study was to evaluate clinical effectiveness of THERANOVA versus HF–HD dialyzers, in terms of hospitalization rate and duration, cardiovascular event rate and survival in a HD cohort in Colombia. The applicant stated that adult HD patients (>90 days in HD) at Baxter Renal Care Services Colombia were included between September 1, 2017 to November 30, 2017, with follow-up until 2 years. The applicant noted that inverse probability of treatment weighting on the propensity score was used to balance comparison groups on indicators of baseline socio-demographic and clinical characteristics, and that the investigators compared rates and duration of hospitalization and cardiovascular events using a negative binomial regression to estimate weighted incidence rate ratios (IRRs). The applicant stated that this study found a statistically significant lower hospitalization rate in the THERANOVA group, compared to the HF–HD group (IRR HDx with THERANOVA/HF–HD: 0.82, 95 percent CI 0.69 to 0.98; p = 0.03), without differences in hospitalization duration or survival.[112]

The applicant also referred to two other papers to further support reductions in hospitalization and medication utilization. According to the applicant, Sanabria et al. (2021) was a multi-center, observational prospective cohort study of 81 patients (Year 1, HF–HD; Year 2, HDx with THERANOVA). In this study across 3 clinics, the applicant noted that 175 patients with ESRD on chronic HD were originally recruited, and 23 did not meet the eligibility criteria. The applicant stated that patients received HF–HD for at least 1 year and then switched to HDx and were followed up for 1 year. The applicant stated that patients were excluded if they discontinued therapy, changed provider, underwent kidney transplant, recovered kidney function, or changed to PD, another dialyzer, or another renal clinic. The applicant noted that only 81 patients were eligible for analysis because 71 patients were lost to follow-up. The applicant stated that the study results demonstrated that the rate of hospitalizations per patient-year was lower twelve months after switching to HDx, from 0.77 (95 percent CI: 0.60–0.98, 61 events) to 0.71 (95 percent CI: 0.55–0.92, 57 events), p = 0.6987. The applicant also reported that the study results demonstrated significantly reduced hospital day rate per patient-year, from 5.94 days in the year prior to switching compared with 4.41 days after switching (p = 0.0001).[113]

The applicant also cited Ariza et al. (2021), which the applicant noted analyzed the same study sample of 81 patients as Sanabria et al. (2021),[114] discussed previously in this section, with the stated objective of examining new evidence linking HDx using THERANOVA with hospitalizations, hospital days, medication use, costs, and patient utility. The applicant stated that this retrospective study utilized data from the Renal Care Services medical records database in Colombia from 2017 to 2019. The applicant noted that the study data included years on dialysis, hospitalizations, medication use, and QoL measured by the KDQoL survey at the start of HDx, and 1 year after HDx. The applicant stated that generalized linear models were run comparing patients before and after switching to HDx. The applicant stated that the study results demonstrated that HDx was also significantly associated with lower hospital days per year (5.94 on HD vs. 4.41 on HDx), although not with the number of hospitalizations. The applicant stated that the results showed that HDx was statistically significantly associated with reduced hospitalization days.[115]

analysis of the following sourced figure: 'Average hospitalization rate' of hemodialysis patients captured from the United States Renal Data System (USRDS), 2020 Annual Data Report (ADR), End Stage Renal Disease, Chapter 4: Hospitalization, Figure 4.1a Adjusted hospitalization rates in prevalent Medicare beneficiaries with ESRD by treatment modality, 2009–2018.

[108] Nissenson AR, Improving Outcomes for ESRD Patients: Shifting the Quality Paradigm. CJASN Feb 2014, 9 (2) 430–434; DOI: 10.2215/CJN.05980613 *https://doi.org/10.2215/CJN.05980613.*

[109] Saeed F, Adil MM, Malik AA, Schold JD, Holley JL, Outcomes of In-Hospital Cardiopulmonary Resuscitation in Maintenance Dialysis Patients. JASN Dec 2015, 26 (12) 3093–3101; DOI: 10.1681/ASN.2014080766 *https://doi.org/10.1681/ASN.2014080766.*

[110] Weiner D, et al. Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Controlled Trial, CJASN15: 1310–1319, 2020. doi: 10.2215/CJN.01210120.

[111] Tran H, Falzon L, Bernardo A, Beck W, Blackowicz M. Reduction in all-cause Hospitalization Events Seen in a Randomized Controlled Trial Comparing Expanded Hemodialysis vs High-Flux Dialysis. Annual Dialysis Conference. Abstract #1070. Published 2021 Jan 28.

[112] Molano AP, Hutchison CA, Sanchez R, Rivera AS, Buitrago G, Dazzarola MP, Munevar M, Guerrero M, Vesga JI, Sanabria M, Medium Cut-Off Versus High-Flux Hemodialysis Membranes and Clinical Outcomes: A Cohort Study Using Inverse Probability Treatment Weighting, Kidney Medicine (2022), doi: *https://doi.org/10.1016/j.xkme.2022.100431.*

[113] Sanabria RM, Hutchison CA, Vesga JI, Ariza JG, Sanchez R, Suarez AM. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron 2021;145:179–187. doi: 10.1159/000513328.

[114] Ibid.

[115] Ariza, JG, Walton, SM, Suarez, AM, Sanabria, M, Vesga, JI. An initial evaluation of expanded

Continued

With respect to the claim that THERANOVA is associated with improved recovery time by up to 2 hours, the applicant stated that the treatment intensity and recovery time for patients on HD is a significant burden. The applicant explained that patients might receive in-center HD 3 days a week for 3 to 5 hour sessions, or home HD. The applicant noted that following treatment, there is often a prolonged period before a patient recovers to pre-treatment function and energy levels, with many patients reporting that they feel tired and in need of rest or sleep. The applicant cited an estimate that 40 to 80 percent of patients receiving chronic HD face post-dialysis fatigue.[116] The applicant also noted that patients who were highly fatigued had a significantly higher risk of adverse cardiovascular events (hazard ratio: 2.17; p <0.01).[117] The applicant referred to the Dialysis Outcomes and Practice Patterns Study (DOPPS), which analyzed over 6,000 HD patients from 12 countries in Europe, Japan, Canada, and the U.S. The applicant noted that 25 percent of patients required more than 6 hours of recovery time, and that patient-reported recovery time was positively associated with rates of first hospitalization (adjusted hazard ratio [AHR] per additional hour of recovery time [RT], 1.03; 95 percent CI, 1.02–1.04) and all-cause mortality (AHR, 1.05; 95 percent CI, 1.03–1.07).[118] The applicant stated that improving recovery time is not only critical to averting hospitalization and increased risk of mortality, but also ensures that ESRD patients have meaningful QoL improvements.

To support its claim of improved recovery time, the applicant referred to a single-center, single-arm, observational, retrospective, cohort study by Bolton et al. (2021) of 58 patients with HF–HD at baseline who switched to THERANOVA. The applicant stated that a dialysis unit performed regular assessments of patient-reported symptom burden, using the POS–S Renal Symptom questionnaire and the ''Recovery time from last dialysis session'' question as part of routine patient focused care. The applicant noted that of the 90 people who initially agreed to provide patient reported outcome measures (PROMs) data, the number of participants providing data at 3, 6, 9, and 12 months were 80, 72, 68, and 59 respectively. The applicant concluded that a sustained clinically relevant reduction in post-dialysis recovery time was observed following the therapy switch. The applicant stated that the study results demonstrated that the percentage of patients reporting a recovery time greater than 360 minutes decreased from 36 percent at baseline to 26 percent, 14 percent, 14 percent, and 9 percent at 3, 6, 9, and 12 months, respectively. The applicant noted that additionally, there was a statistically significant improvement in median recovery time from a baseline of 210 minutes (IQR 7.5–600) to 60 minutes after 6 months (0–210; p = 0.002), 60 minutes after 9 months (0–225; p <0.001), and 105 minutes after 12 months (0–180; p = 0.001).[119]

With respect to the claim that THERANOVA is associated with improved QoL, as indicated by reduced pruritus, improvement in two KDQoL survey domains, and improved London Evaluation of Illness (LEVIL) scores, the applicant described the background and significance of each indicator. The applicant noted that that pruritus can be uncomfortable and significantly interfere with ESRD patients' daily living activities. The applicant stated that pruritus that is severe or chronic can prevent ESRD patients from sleeping normally,[120] and that in addition to causing sleep loss, pruritus can also cause anxiety and depression.[121] The applicant also noted that prolonged scratching of itchy skin also leads to skin injury, scarring, and infection.[122]

The applicant also explained that one of the most commonly used tools to assess kidney disease QoL in the U.S. is the KDQoL[123] patient survey, which assesses patients' physical and mental well-being, the burden of kidney disease, treatment-associated symptoms and problems, and the effects of kidney disease on daily life. The applicant noted that the survey assesses a patient's ability to accomplish desired tasks, levels of depression and anxiety, the ability to participate in social activities, and some daily life activities.

The applicant also referenced the LEVIL survey, which measures patient-reported outcomes and evaluates well-being, energy level, sleep quality, bodily pain, appetite, and shortness of breath. Per the applicant, the survey is validated, and scores are correlated with acute hospital admissions, abnormal fluid status, and vascular access events.[124]

To support its claim of improved pruritus and improvement in two KDQoL survey domains, the applicant referred to a prospective, open-label, randomized control trial by Lim, Park, et al. (2020). This study randomized patients to either Theranova 400 or a high-flux dialyzer. Forty-nine HD patients (24 using THERANOVA; 25 using a high-flux dialyzer) completed the study. Per the applicant, QoL was assessed at baseline and after 12 weeks of treatment using the KDQoL Short Form-36, and pruritus was assessed using a questionnaire and visual analog scale. The applicant stated that the study concluded that laboratory markers, including serum albumin, did not differ between the two groups after 12 weeks, though removals of kappa and lambda free light chains were greater for THERANOVA than high-flux dialyzer. The applicant noted that the results showed that the THERANOVA group had lower mean scores for morning pruritus distribution (1.29 ± 0.46 vs. 1.64 ± 0.64, p = 0.034) and frequency of scratching during sleep (0.25 ± 0.53 vs. 1.00 ± 1.47, p = 0.023), compared to the high-flux group. The applicant also stated that in the same study, the THERANOVA group also had statistically significant higher scores (indicating better QoL) in KDQoL domains for physical functioning (75.2 ± 20.8 vs. 59.8 ± 30.1, p = 0.042) and physical role (61.5 ± 37.6 vs. 39.0 ± 39.6, p = 0.047), compared to the high-flux group.[125]

hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia. Ther Apher Dial. 2021; 25: 621– 627. *https://doi.org/10.1111/1744-9987.13620.*

[116] Bossola M, et al. Fatigue is associated with increased risk of mortality in patients on chronic hemodialysis. Nephron 2015; 130:113–118.

[117] Koyama H, Fukuda S, Shoji T, Inaba M, Tsujimoto Y, Tabata T, Okuno S, Yamakawa T, Okada S, Okamura M, Kuratsune H, Fujii H, Hirayama Y, Watanabe Y, Nishizawa Y, Fatigue Is a Predictor for Cardiovascular Outcomes in Patients Undergoing Hemodialysis CJASN Apr 2010, 5 (4) 659–666; DOI: 10.2215/CJN.08151109.

[118] Rayner HC, et al. Recovery time, quality of life, and mortality in hemodialysis patients: The Dialysis Outcomes and Practice Patterns Study (DOPPS). Am J Kidney Dis 2014; 64:86–94.

[119] Bolton S, Gair R, Nilsson LG, Matthews M, Stewart L, McCullagh N. Clinical Assessment of Dialysis Recovery Time and Symptom Burden: Impact of Switching Hemodialysis Therapy Mode. Patient Relat Outcome Meas.2021;12:315–321 *https://doi.org/10.2147/PROM.S325016.*

[120] Mayo Clinic, Itchy skin (pruritus), available at *https://www.mayoclinic.org/diseases-conditions/itchy-skin/symptoms-causes/syc-20355006.*

[121] Ibid.

[122] Ibid.

[123] RAND Corporation, Kidney Disease Quality of Life Instrument (KDQOL), available at *https://www.rand.org/health-care/surveys_tools/kdqol.html.*

[124] Pittman Z, et al. Collection of daily patient reported outcomes is feasible and demonstrates differential patient experience in chronic kidney disease. Hemodialysis International, 2017; 21:265–273.

[125] Lim JH, Park Y, Yook JM, et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. Sci Rep. 2020;10(1):7780. Published 2020 May 8. doi:10.1038/s41598–020–64622-z.

To support its claim of improved QoL scores, the applicant referred to a study by Penny et al. (2021). According to the applicant, this was a single-center interventional pilot study with 28 patients established on maintenance HD. The single-arm study consisted of 2-week observation (baseline at conventional HF–HD) followed by 12 weeks of HDx. The study also had an extension phase; where patients had a 2-week baseline period, followed by 24 weeks of HDx, and then an 8-week washout period in which patients returned to HF–HD to assess the presence of any carryover effect. The applicant stated that health-related quality of life (HRQoL) was assessed using the dynamic PROM instrument, LEVIL, twice weekly. The applicant noted that 22 patients completed all study procedures to contribute to the full 12-week analysis. The applicant stated that the study results demonstrated that 73 percent of participants who had low overall health-related QoL at baseline with HF–HD (mean, 51.5 ± 10.2; range, 36.1–69.3) had a statistically significant improvement at 8 weeks after switching to HDx (mean, 64.6 ± 16.2; p = 0.001) and at 12 weeks (67.2 ± 16.9; p = 0.001). The applicant stated that the study also found that all participants had a statistically significant improvement in 'feeling washed out/drained' from baseline with HF–HD (mean, 40.3 ± 20.5; range, 8.7–67.4) to HDx at 8 weeks (59.9 ± 22.8; p = 0.001) and at 12 weeks (64.7 ± 19.6; p <0.001). The applicant noted that likewise, 73 percent of study participants assessed on their 'feeling of general well-being' had a statistically significant improvement from baseline with HF–HD (mean, 43 ± 14.1; range, 19.7–69.5) to HDx at 8 weeks (65.2 ± 21.9; p <0.001) and at 12 weeks (66.3 ± 17.7; p = 0.002). Additionally, the applicant stated that 73 percent of study participants who experienced poor 'sleep quality' had a statistically significant improvement from baseline with HF–HD (37.2 ± 20.1; range, 7.2–66.2) after 4 weeks with HDx (mean, 52.8 ± 26.7; p = 0.01), and continually improved at 8 weeks (57 ± 22.2; p = 0.002) and 12 weeks (61.7 ± 24.5; p <0.001).[126]

With respect to the claim that THERANOVA is associated with reducing restless leg syndrome (RLS) by 10 percent or more, the applicant stated that RLS is another common and debilitating side effect of long-term dialysis. The applicant noted that an estimated 6.6 percent to 62 percent of patients on long-term dialysis therapy suffer from RLS,[127] with one study suggesting 20 to 25 percent of ESRD patients demonstrated overt (moderate to severe) RLS.[128] The applicant stated that extreme discomfort of RLS worsens during periods of physical inactivity and at night,[129] contributing to sleep loss and sleep deprivation in ESRD patients, and that loss of sleep carries over into the day for many patients, leaving them feeling lethargic and preventing them from fully engaging in daily activities. The applicant also noted that a study found that RLS among HD patients is associated with a significant increase in new cardiovascular events, that these events increased with the severity of RLS, and that HD patients with RLS had a higher risk of mortality than their non-RLS peers.[130] The applicant also described an additional study that found RLS was associated with significantly higher risk of developing cardiovascular events, strokes, and all-cause mortality among ESRD patients.[131] The applicant explained that RLS is treated with many medications such as dopamine antagonists, benzodiazepines, anti-epileptics, iron dextran, Vitamin C, and intradialytic aerobic exercise—all of which produce side effects and only provide limited improvement in RLS symptoms.[132] The applicant stated that medical interventions for RLS in dialysis populations have not been particularly effective, are costly, and may contribute to polypharmacy and adverse drug reactions in a population already at risk.[133]

To support its claim that THERANOVA is associated with reducing RLS, the applicant referred to a multi-center, observational prospective cohort study by Alarcon et al. (2021) which assessed 992 individuals with HF–HD at baseline, who switched to THERANOVA and were observed over a 12-month period. The applicant explained that changes in KDQoL 36-Item Short Form Survey domains, Dialysis Symptom Index (DSI), and RLS 12 months after switching to THERANOVA were compared with the patient baseline responses on high-flux dialyzers. Per the applicant, the study found a significant decrease in the proportion of patients diagnosed with RLS from 22.1 percent at baseline to 12.5 percent at 6 months, and 10 percent at 12 months (p <0.0001). Additionally, the applicant stated that a post hoc comparison showed statistically significant differences between each pair of repeated observations (baseline vs. 6 months: p <0.0001; baseline vs. 12 months: p <0.0001; 6 vs. 12 months: p = 0.003).[134]

With respect to the claim that THERANOVA reduces the rate of subsequent therapeutic interventions, such as the use of ESAs, iron, and insulin, the applicant stated that almost all dialysis patients and those with CKD experience anemia as a side effect of their treatment, which contributes negative clinical outcomes such as weakness, irregular heartbeat, shortness of breath, dizziness and lightheadedness, chest pain, and headaches.[135] The applicant stated that anemia significantly impairs QoL for dialysis patients and requires additional treatment, and that ESAs are a widely used treatment that mitigates anemia by enabling the body to produce more red blood cells. The applicant stated that reductions in ESA treatment can preserve or enhance patient QoL and can generate savings to the Medicare program.

With regard to iron supplementation, the applicant noted that iron supplements are another important treatment for patients with renal failure and anemia. The applicant explained that iron deficiency occurs more frequently among patients with ESRD because of an increase in external losses of iron, a decreased ability to store iron in the body, and potential deficits in

[126] Penny J, Jarosz P, Salerno F, Lemoine S, McIntyre CW. Impact of Expanded Hemodialysis Using Medium Cut-off Dialyzer on Quality of Life: Application of Dynamic Patient-Reported Outcome Measurement Tool. Kidney Medicine. Published 2021, Jul. 29. *https://doi.org/10.1016/j.xkme.2021.05.010.*

[127] Kavanagh D, et al. Restless legs syndrome in patients on dialysis Am J Kidney Dis. 2004 May;43(5):763–71.

[128] Winkelman JW, Chertow GM, Lazarus JM. Restless legs syndrome in end-stage renal disease. Am J Kidney.

[129] Kavanagh D, et al. Restless legs syndrome in patients on dialysis Am J Kidney Dis. 2004 May;43(5):763–71.

[130] La Manna G, et al. Restless legs syndrome enhances cardiovascular risk and mortality in patients with end-stage kidney disease undergoing long-term haemodialysis treatment. Nephrol Dial Transplant.2011;26(6):1976–83.

[131] Lin CH, et al. Restless legs syndrome is associated with cardio/cerebrovascular events and mortality in end-stage renal disease. Eur J Neurol. 2015;22(1):142–9.

[132] Gopaluni S, Sherif M, Ahmadouk NA. Interventions for chronic kidney disease-associated restless legs syndrome. Cochrane Database Syst Rev 2016; 11: CD010690.

[133] Gopaluni S, Sherif M, Ahmadouk NA. Interventions for chronic kidney disease-associated restless legs syndrome. Cochrane Database Syst Rev 2016; 11: CD010690.

[134] Alarcon JC, Bunch A, Ardila F, et al. Impact of Medium Cut-Off Dialyzers on Patient-Reported Outcomes: COREXH Registry. Blood Purification. 2021; 50(1):110–118. DOI: 10.1159/000508803. PMID: 33176299.

[135] Mayo Clinic's overview of anemia, available at *https://www.mayoclinic.org/diseases-conditions/anemia/symptoms-causes/syc-20351360.*

intestinal iron absorption.[136] The applicant stated that reductions in iron treatment can preserve or enhance patient QoL and can generate savings to the Medicare program.[137]

Finally, with regard to insulin use, the applicant stated that diabetes is a common comorbidity in ESRD patients,[138] and many ESRD patients require additional insulin administration. The applicant stated that through reductions in insulin use, Medicare could realize cost savings of $3,949 annually per diabetes patient.[139]

To support its claim of reduced rate of subsequent therapeutic interventions such as reduced need for and use of ESAs, iron, and insulin, the applicant referred to three sources. The first source, Lim, Jeon, et al. (2020), was a secondary analysis of a prospective, open-label, randomized controlled trial by Lim, Park, et al. (2020).[140] Lim, Park, et al. (2020) was previously described. According to the applicant, the primary outcome of the secondary analysis was the change in erythropoietin resistance index (ERI; U/kg/wk/g/dL) between baseline and 12 weeks. The applicant stated that the study found statistically significant decreases in ESA dose, weight-adjusted ESA dose, and erythropoiesis resistance index for THERANOVA patients, compared to the high-flux dialyzer group at 12 weeks ($p < 0.05$). The applicant also stated that there was a statistically significant higher serum iron level in the THERANOVA group at 12 weeks (iron [μg/dL]: 72.1 ± 25.4 vs. 55.9 ± 25.0), ($p = 0.029$), indicating an improvement in iron metabolism as a potential clinical marker for the reduced need of iron supplementation.[141]

The applicant also referred to the Sanabria et al. (2021) study, previously described, of 81 patients (Year 1, HF–HD; Year 2, HDx with THERANOVA). The applicant stated the study concluded that there was a statistically significant reduction in the mean dose of ESA after switching from HF–HD to HDx with THERANOVA ($p = 0.0361$).[142] The applicant also stated that the study found a statistically significant reduction in the mean dose of intravenous iron from 73.46 mg/month with HF–HD to 66.36 mg/month with HDx with THERANOVA ($p = 0.003$).[143]

Finally, the applicant referred to the Ariza et al. (2021) study, described previously in this section of the final rule. The applicant stated that study authors found a statistically significant reduction in the dosage per patient per year of ESA in international units from 181,318 with HF–HD (95 percent CI: 151,647–210,988) to 168,124 with HDx with THERANOVA (95 percent CI: 138,452–197,794; $p < 0.01$) as well as a statistically significant reduction in dosage per patient per year of iron in milligrams from 959 with HF–HD (95% CI: 760–1158) to 759 with HDx (95 percent CI: 560–958; $p < 0.01$).[144] The applicant also stated that the study found a statistically significant reduction in dosage per patient per year of insulin in international units from 5383 with HF–HD (95 percent CI: 3274–7490) to 3434 with HDx with THERANOVA (95 percent CI: 1327–5543; $p < 0.01$).[145]

The applicant also referred to CMS' final determination and public comments regarding its CY 2021 TPNIES application, as summarized in the CY 2021 ESRD PPS final rule (85 FR 71453 through 71458). The applicant stated that stakeholders largely provided favorable comments and supported TPNIES approval for THERANOVA. The applicant noted that in particular, physicians who used THERANOVA and had direct patient experience with the product strongly supported the application.[146] The applicant also noted that some stakeholders, however, expressed concerns about THERANOVA's CY 2021 TPNIES application. Specifically, the applicant stated that commenters noted that the supporting studies had small sample sizes that did not represent the U.S. patient population, and that the duration of the studies was too short. The applicant also stated that some stakeholders expressed a belief that HDx with THERANOVA may result in decreased albumin levels, potentially causing harm to patients. The applicant stated that with the updated and additional information provided in its CY 2023 application, the applicant has addressed these concerns.

The applicant stated that all substantial clinical improvement claims included in its CY 2023 application are now supported by at least one study that has undergone full peer review and has been published, or accepted for publication and is being prepared for publishing. The applicant explained that the application's supporting studies feature statistically significant findings and have a range of appropriate sample sizes, such as Molano-Triviño et al., n = 1,098,[147] and Alarcon et al., n = 992,[148] previously described. The applicant explained that additionally, many studies evaluated THERANOVA's impacts over an extended period, including year-long evaluations after patients transitioned from conventional therapy to HDx therapy, for example, Sanabria et al.[149] and Ariza et al.,[150]

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[136] Fishbane S, Maesaka JK, Iron management in end-stage renal disease, American Journal of Kidney Diseases, Volume 29, Issue 3, 1997, Pages 319–333, ISSN 0272–6386, Accessed at: *https://doi.org/10.1016/S0272-6386(97)90192-X*.

[137] Estimated cost to Medicare based on The Moran Company, an HMA Company analysis calculated using 2020 ESRD claims with IV iron valued at ASP+6%.

[138] Approximately one in three adults with diabetes also have CKD. See CDC, Diabetes and Chronic Kidney Disease, *https://www.cdc.gov/diabetes/managing/diabetes-kidney-disease.html*.

[139] Average cost per patient for insulin taken from KFF report on Part D spending, available at *https://www.kff.org/medicare/issue-brief/how-much-does-medicare-spend-on-insulin/*.

[140] Lim JH, Park Y, Yook JM, et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. Sci Rep. 2020;10(1):7780. Published 2020 May 8. doi:10.1038/s41598–020–64622-z.

[141] Lim JH, Jeon Y, Yook JM, et al. Medium cut-off dialyzer improves erythropoiesis stimulating agent resistance in a hepcidin-independent manner in maintenance hemodialysis patients: results from a randomized controlled trial. Sci Rep. 2020;10(1):16062. Published 2020 Sep 29. doi:10.1038/s41598–020–73124-x.

[142] Sanabria RM, Hutchison CA, Vesga JI, Ariza JG, Sanchez R, Suarez AM. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron 2021;145:179–187. doi: 10.1159/000513328.

[143] Ibid.

[144] Ariza, JG, Walton, SM, Suarez, AM, Sanabria, M, Vesga, JI. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia. Ther Apher Dial. 2021; 25: 621– 627. *https://doi.org/10.1111/1744-9987.13620*.

[145] Ibid.

[146] See for example, Dr. Peter Stenvinkel (Karolinska University Hospital) at *https://beta.regulations.gov/comment/CMS-2020-0079-0038;* Dr. Vincenzo Cantaluppi (Novara University Hospital) at *https://beta.regulations.gov/comment/CMS-2020-0079-0066;* Dr. Colin Hutchison (Central Hawkes Bay Health Centre) at *https://beta.regulations.gov/comment/CMS-2020-0079-0065;* Dr. Andrew Davenport (Royal Free Hospital) at *https://beta.regulations.gov/comment/CMS-2020-0079-0037;* Dr. Mario Cozzolino (University of Milan) at *https://beta.regulations.gov/comment/CMS-2020-0079-0062;* Dr. Jang-Hee Cho (Kyungpook National University Hospital) at *https://beta.regulations.gov/comment/CMS-2020-0079-0061*.

[147] Molano AP, Hutchison CA, Sanchez R, Rivera AS, Buitrago G, Dazzarola MP, Munevar M, Guerrero M, Vesga JI, Sanabria M, Medium Cut-Off Versus High-Flux Hemodialysis Membranes and Clinical Outcomes: A Cohort Study Using Inverse Probability Treatment Weighting, Kidney Medicine (2022), doi: *https://doi.org/10.1016/j.xkme.2022.100431*.

[148] Alarcon JC, Bunch A, Ardila F, et al. Impact of Medium Cut-Off Dialyzers on Patient-Reported Outcomes: COREXH Registry. Blood Purification. 2021; 50(1):110–118. DOI: 10.1159/000508803. PMID: 33176299.

[149] Sanabria RM, Hutchison CA, Vesga JI, Ariza JG, Sanchez R, Suarez AM. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron 2021;145:179–187. doi: 10.1159/000513328.

[150] Ariza, JG, Walton, SM, Suarez, AM, Sanabria, M, Vesga, JI. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization,

previously described. The applicant stated that it considers the studies supporting the application and their findings to be applicable and generalizable to the U.S. Medicare population, and that this generalizability is bolstered by the additional U.S.-specific information and findings. The applicant stated that while it does not believe that results in sample populations would significantly differ from results in the U.S. patient population, the application also now includes additional evidence that directly addressed U.S. patients, including: a new study on U.S. hospitalization rates; new survey data from U.S. patients, health care providers, and payers, which demonstrated THERANOVA's value, clinical improvements, and QoL enhancements; [151] and includes new testimonials in support of the TPNIES application for THERANOVA from U.S. kidney care providers: a nephrologist with 10 years of experience, dialysis nurse with 15 years of experience, and a pediatric dialysis nurse practitioner with over 10 years of experience. The applicant noted that the survey data came from three separate double-blinded surveys presented to each respondent group with information about THERANOVA's benefits and then assessed reactions—including patients' interest in switching from their current HD therapy to THERANOVA's HDx therapy, the likelihood that health care providers would recommend THERANOVA to patients and colleagues, and payers' evaluations of THERANOVA's potential to generate value for their health plans and patient enrollees. The applicant noted that overall, patients overwhelmingly wanted to use THERANOVA, health care providers strongly indicated that they would recommend THERANOVA to patients and peers, and payers identified several of THERANOVA's improvements as generating value. The applicant stated that the peer-validated studies, and additional evidence that further addresses the U.S. patient population, provide the support necessary to conclude that THERANOVA is a substantial clinical improvement over existing technologies.

The applicant also stated that in addition to THERANOVA's demonstrated effectiveness, additional evidence demonstrates THERANOVA's safety. The applicant explained that in the time since it submitted the CY 2021 TPNIES application to CMS, FDA reviewed THERANOVA's randomized, controlled clinical IDE trial and additional evidence supporting THERANOVA's safety and effectiveness, and granted marketing authorization. The applicant stated that the IDE trial demonstrated that THERANOVA's HDx therapy provides superior removal of harmful LMMs while maintaining adequate serum albumin levels.[152] The applicant noted that FDA's comprehensive review and subsequent approval of THERANOVA establishes THERANOVA's safety and effectiveness for its intended use: treatment of chronic kidney failure.

(b) CMS Assessment of Substantial Clinical Improvement Claims and Sources

As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38513), we noted that the applicant submitted the full, published peer-reviewed papers for several of the abstracts, posters, and incomplete manuscripts that were previously submitted with its CY 2021 TPNIES application,[153] [154] [155] [156] [157] [158] and the remaining evidence submitted with the CY 2023 application was new. We identified the following concerns regarding THERANOVA and the substantial clinical improvement eligibility criteria for the TPNIES.

With respect to the applicant's claim that THERANOVA leads to reduced hospitalization rates, we noted that the applicant included studies from the previous submission and supplemented with newer studies, such as the Tran et. al. (2021) poster abstract. We noted that the poster abstract was a post hoc analysis of a previous open-label study,[159] which had an average follow-up period of 4.5 months in the THERANOVA group. We questioned whether this short time period is sufficient to see changes in hospitalization from interventions aimed at increasing clearance of uremic toxins. We stated that it may be helpful to see if this outcome is sustained in longer term follow-up.[160]

We also noted that, although authors in the Molano et. al. (2022) study used inverse probability treatment weighting (IPTW), the study was unblinded and could influence treatment decisions in the group using the THERANOVA dialyzer. Moreover, we noted that patients seemed healthier in the THERANOVA arm, and had more fistulas, fewer catheters, and higher Karnofsky indices. We also noted that the THERANOVA arm had more intensive dialysis at baseline and throughout the duration of the study (Kt/V of 1.7 vs. 1.6), suggestive of more intensive small molecule clearance and more intensive dialysis overall. Therefore, we stated that it is unclear whether the outcome differences between the two arms could be due to factors other than the dialyzer type. We questioned whether IPTW would be sufficient to overcome these biases, especially the Kt/V bias, which persisted even after the baseline period.[161]

In addition, we noted that the studies by Ariza et. al. (2021) [162] and Sanabria

costs, and patient utility in Colombia. Ther Apher Dial. 2021; 25: 621– 627. *https://doi.org/10.1111/1744-9987.13620.*

[151] Patient Preference for a Future Dialyzer Study, prepared by Beghou Consulting on behalf of Baxter International. Survey results; December 2021.

[152] Weiner D, et al. Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Controlled Trial, CJASN15: 1310–1319, 2020. doi: 10.2215/CJN.01210120.

[153] Alarcon JC, Bunch A, Ardila F, et al. Impact of Medium Cut-Off Dialyzers on Patient-Reported Outcomes: COREXH Registry. Blood Purification. 2021; 50(1):110–118. DOI: 10.1159/000508803. PMID: 33176299.

[154] Ariza, JG, Walton, SM, Suarez, AM, Sanabria, M, Vesga, JI. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia. Ther Apher Dial. 2021; 25: 621–627. *https://doi.org/10.1111/1744-9987.13620.*

[155] Bolton S, Gair R, Nilsson LG, Matthews M, Stewart L, McCullagh N. Clinical Assessment of Dialysis Recovery Time and Symptom Burden: Impact of Switching Hemodialysis Therapy Mode. Patient Relat Outcome Meas.2021;12:315–321 *https://doi.org/10.2147/PROM.S 325016.*

[156] Lim JH, Jeon Y, Yook JM, et al. Medium cut-off dialyzer improves erythropoiesis stimulating agent resistance in a hepcidin-independent manner in maintenance hemodialysis patients: results from a randomized controlled trial. Sci Rep. 2020;10(1):16062. Published 2020 Sep 29. doi:10.1038/s41598–020–73124-x.

[157] Lim JH, Park Y, Yook JM, et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. Nature Sci Rep. 2020;10(1):7780. Published 2020 May 8. doi:10.1038/s41598–020–64622-z.

[158] Sanabria RM, Hutchison CA, Vesga JI, Ariza JG, Sanchez R, Suarez AM. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron 2021;145:179–187. doi: 10.1159/000513328.

[159] Weiner D, et al. Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Controlled Trial, CJASN15: 1310–1319, 2020. doi: 10.2215/CJN.01210120.

[160] Tran H, Falzon L, Bernardo A, Beck W, Blackowicz M. Reduction in all-cause Hospitalization Events Seen in a Randomized Controlled Trial Comparing Expanded Hemodialysis vs High-Flux Dialysis. Annual Dialysis Conference. Abstract #1070. Published 2021 Jan 28.

[161] Molano AP, Hutchison CA, Sanchez R, Rivera AS, Buitrago G, Dazzarola MP, Munevar M, Guerrero M, Vesga JI, Sanabria M, Medium Cut-Off Versus High-Flux Hemodialysis Membranes and Clinical Outcomes: A Cohort Study Using Inverse Probability Treatment Weighting, Kidney Medicine (2022), doi: *https://doi.org/10.1016/j.xkme.2022.100431.*

[162] Ariza, JG, Walton, SM, Suarez, AM, Sanabria, M, Vesga, JI. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization,

Continued

et. al. (2021),[163] using the same study sample population, were limited by absence of a control group, and had non-significant differences in hospitalization rate between baseline HF–HD and after switching to HDx: 0.77 (95 percent CI: 0.60–0.98, 61 events) to 0.71 (95 percent CI: 0.55–0.92, 57 events), p = 0.6987.

With respect to the applicant's claim that THERANOVA leads to improved QoL, we noted that in the study by Lim, Park, et. al. (2020), it is unclear if these findings could result from chance alone, when considering the many QoL outcomes examined, due to multiple-hypothesis testing concerns. In particular, we noted that differences associated with use of THERANOVA were statistically significant in only 2 out of 26 QoL outcomes assessed, and in both cases the p-value was greater than 0.04. We also noted that although the THERANOVA group had lower mean scores for morning pruritus distribution (p = 0.034), there was a non-significant difference in afternoon pruritis distribution between the two groups (p = 0.347).[164]

Overall, we noted that most of studies in the updated evidence submitted for the CY 2023 application are open-label and observational, which may potentially bias results. We also noted that many of the studies are single-arm studies that do not employ a control group, which may make it difficult to determine if observed improvements in clinical outcomes are due to the use of THERANOVA or if the improvements may have also occurred with previously available dialysis membranes.[165] [166] [167] [168]

We invited public comment as to whether THERANOVA meets the TPNIES substantial clinical improvement criteria.

We received many comments on the substantial clinical improvement claims made in the TPNIES application for THERANOVA, ranging from commenters with concerns about the claims, including clinicians and dialyzer companies, to comments in support of the application from clinicians, patients, and the applicant. The comments pertaining to the substantial clinical improvement claims made by the applicant, and our responses to the comments, are set forth below.

Comment: We received a comment from the applicant in support of the TPNIES approval for THERANOVA. The applicant reiterated its substantial clinical improvement claims; submitted additional evidence in support of its claims; provided responses to CMS concerns identified in the CY 2023 ESRD PPS proposed rule; and included a discussion pertaining to albumin loss associated with THERANOVA.

In reiterating its substantial clinical improvement claims, the applicant stated that THERANOVA demonstrated reduced hospitalization rate by up to 45%, improved recovery time by up to 2 hours, improved quality of life in two Kidney Disease Quality of Life (KDQoL) survey domains, reduced pruritus, demonstrated improvement in London Evaluation of Illness (LEVIL) survey scores, reduced prevalence of restless leg syndrome, reduced the need and use of erythropoietin stimulating agents (ESAs), reduced the need for iron, and reduced the need for insulin.

The applicant submitted additional evidence, including a peer-reviewed article by Blackowicz et al.,[169] that was a follow-on to the Tran et al. abstract [170] to demonstrate a statistically significant lower hospitalization rate in the cohort using THERANOVA compared to the cohort using a high flux dialyzer (IRR = 0.55; p = 0.042). The applicant noted that this new study affirms the initial findings in the Tran et al. abstract,[171] determining that the all-cause hospitalization rate was 45% lower with THERANOVA as compared to HD with a high-flux dialyzer (IRR = 0.55; p = 0.042). The applicant also noted a $6,098 lower average annual cost of hospitalization for the THERANOVA group compared to the conventional high-flux dialyzer group.

The applicant submitted a peer-reviewed follow-on [172] to the Molano-Triviño et al. abstract [173] stating that it found a statistically significant lower hospitalization rate in the THERANOVA group compared to the high-flux dialyzer group. The applicant stated its belief that this new study affirms the initial findings in the Molano-Triviño abstract and confirms the reduced hospitalization rate finding.

In response to the CMS question of whether the average follow-up period of 4.5 months is sufficient to see changes in hospitalization, the applicant stated that Blackowicz et al.,[174] affirmed findings in the Tran et al. abstract [175] and stated that if the study had not been long enough, it would not have reached statistical significance on the hospitalization rate endpoint. The applicant also stated that the ability of the study to detect a statistically significant difference in hospitalization events throughout the study period

costs, and patient utility in Colombia. Ther Apher Dial. 2021; 25: 621–627. *https://doi.org/10.1111/1744-9987.13620.*

[163] Sanabria RM, Hutchison CA, Vesga JI, Ariza JG, Sanchez R, Suarez AM. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron 2021;145:179–187. doi: 10.1159/000513328.

[164] Lim JH, Park Y, Yook JM, et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. Nature Sci Rep. 2020;10(1):7780. Published 2020 May 8. doi:10.1038/s41598–020–64622-z.

[165] Bolton S, Gair R, Nilsson LG, Matthews M, Stewart L, McCullagh N. Clinical Assessment of Dialysis Recovery Time and Symptom Burden: Impact of Switching Hemodialysis Therapy Mode. Patient Relat Outcome Meas.2021;12:315–321 *https://doi.org/10.2147/PROM.S 325016.*

[166] Penny J, Jarosz P, Salerno F, Lemoine S, McIntyre CW. Impact of Expanded Hemodialysis Using Medium Cut-off Dialyzer on Quality of Life: Application of Dynamic Patient-Reported Outcome Measurement Tool. Kidney Medicine. Published 2021, Jul. 29. *https://doi.org/10.1016/j.xkme.2021.05.010.*

[167] Alarcon JC, Bunch A, Ardila F, et al. Impact of Medium Cut-Off Dialyzers on Patient-Reported Outcomes: COREXH Registry. Blood Purification. 2021; 50(1):110–118. DOI: 10.1159/000508803. PMID: 33176299.

[168] Lim JH, Jeon Y, Yook JM, et al. Medium cut-off dialyzer improves erythropoiesis stimulating agent resistance in a hepcidin-independent manner in maintenance hemodialysis patients: results from a randomized controlled trial. Sci Rep. 2020;10(1):16062. Published 2020 Sep 29. doi:10.1038/s41598–020–73124-x.

[169] Blackowicz MJ, Falzon L, Beck W, Tran H, Weiner DE. Economic evaluation of expanded hemodialysis with the Theranova 400 dialyzer: A post hoc evaluation of a randomized clinical trial in the United States. Hemodial Int. 2022 Jul;26(3):449–455. doi:10.1111/hdi.13015. Epub 2022 Apr 19. PMID: 35441486.

[170] Tran H, Falzon L, Bernardo A, Beck W, Blackowicz M. Reduction in all-cause Hospitalization Events Seen in a Randomized Controlled Trial Comparing Expanded Hemodialysis vs High-Flux Dialysis. Annual Dialysis Conference. Abstract #1070. Published 2021 Jan 28.

[171] Tran H, Falzon L, Bernardo A, Beck W, Blackowicz M. Reduction in all-cause Hospitalization Events Seen in a Randomized Controlled Trial Comparing Expanded Hemodialysis vs High-Flux Dialysis. Annual Dialysis Conference. Abstract #1070. Published 2021 Jan 28.

[172] Molano A, et al. Medium Cutoff Versus High-Flux Hemodialysis Membranes and Clinical Outcomes: A Cohort Study Using Inverse Probability Treatment Weighting, Kidney Med. 4(4):100431. Published online February 7, 2022. Doi:10.1016/j.xkme.2022.100431.

[173] Molano-Triviño A, Sanabria M, Vesga J, Buitrago G, Sánchez R, Rivera A. MO880: Effectiveness of Medium Cut- Off vs. High Flux Dialyzers: A Propensity Score Matching Cohort Study, Nephrology Dialysis Transplantation, Vol. 36, Issue Sup. 1, 2021, May. gfab100.005, *https://doi.org/10.1093/ndt/gfab 100.005.*

[174] Blackowicz MJ, Falzon L, Beck W, Tran H, Weiner DE. Economic evaluation of expanded hemodialysis with the Theranova 400 dialyzer: A post hoc evaluation of a randomized clinical trial in the United States. Hemodial Int. 2022 Jul;26(3):449–455. doi: 10.1111/hdi.13015. Epub 2022 Apr 19. PMID: 35441486.

[175] Tran H, Falzon L, Bernardo A, Beck W, Blackowicz M. Reduction in all-cause Hospitalization Events Seen in a Randomized Controlled Trial Comparing Expanded Hemodialysis vs High-Flux Dialysis. Annual Dialysis Conference. Abstract # 1070. Published 2021 Jan 28.

suggests a sufficiently large magnitude of effect in hospitalization events and that a study with longer follow-up periods would likely affirm this difference in hospitalization rates.

The applicant described an ongoing prospective interventional control trial currently being conducted in Canada to assess THERANOVA's impact on patient quality of life versus HD with a high flux dialyzer.[176] The applicant stated that the investigator expanded the trial and is currently recruiting U.S. participants. The primary outcomes assessed are changes in symptoms burden and health-related quality of life (HRQoL) using a dynamic patient-reported outcome measurement (PROM) tool [London Evaluation of Illness (LEVIL)]. Patients receiving HD with a high-flux dialyzer at baseline are switched to THERANOVA and assessed at regular intervals. The applicant stated that 48 patients are enrolled in the Canadian arm and also outlined preliminary results. The applicant stated that when comparing baseline measurements using a high flux dialyzer to THERANOVA at the three-month interval, the investigator's preliminary analysis shows a statistically significant improvement in overall HRQoL ($p = 0.03$), energy levels ($p = 0.006$), sleep quality ($p = 0.003$) and pruritus ($p = 0.008$). Additionally, 83 percent of the study population had a 10 percent or greater directional improvement in at least one of 11 symptom domains studied, including 'recovery time,' 'energy,' 'pruritus,' 'sleep quality,' 'general well-being,' 'bodily pain,' and 'restless leg syndrome.'

In response to the CMS concern regarding Lim et al.,[177] as to whether the quality of life improvement findings could result from chance alone due to multiple-hypothesis testing, the applicant stated that the study analyzed all KDQoL domains validated in the literature and that comprehensive statistical analysis of all the individual KDQoL domains must contend with similar potential multiple-hypothesis testing concerns.

In response to the CMS concern regarding Lim et al.,[178] regarding the non-significant difference in afternoon pruritus distribution, the applicant stated that quality of life improvement findings, including improvement in two KDQoL survey domains and reduced morning pruritus distribution, are supported by findings in Penny et al.[179] which achieved high levels of significance (for example, $p < 0.001$), suggesting that these results would remain statistically significant even after applying a correction for multiple hypothesis testing.

In response to the CMS concern regarding differences in baseline characteristics of the two groups in Molano et al.,[180] the applicant stated that the study employed inverse probability of treatment weighting (IPTW) which re-adjusts characteristics across the two groups to increase similarities and mitigate differences and that FDA recognizes the utility of inverse probability weighting as a statistical method to control for potential bias.

In response to the CMS concern regarding the design of several studies included in the THERANOVA application, the applicant stated that observational study designs inform how interventions work in a real-world setting and provide results with a larger sample size and greater generalizability to the target patient population over a longer period of time. The applicant also noted that conducting randomized control trial (RCT) studies in the ESRD patient population remains a continuing challenge and that major RCT studies conducted in dialysis populations run into challenges due to unexpectedly low event rates and high dropout and crossover rates. The applicant stated that these challenges make it difficult to generate large enough sample sizes to establish efficacy for RCT study designs within dialysis populations and that there is a risk that randomization does not evenly distribute observable characteristics without large enough sample sizes.

In support of its data with historical controls, the applicant stated that self-controlled case studies (SCCS), whereby individuals act as their own control, could be used to generate statistical inferences with relatively small sample sizes and are effective for highly complex and heterogenous patient populations, like patients with ESRD who have multiple comorbidities. The applicant stated that an SCCS provides an opportunity to control for unobservable characteristics in a real-world setting, as long as time does not serve as a confounding characteristic since the same patient serves as control and treatment. The applicant reiterated that supporting evidence from SCCS studies in the CY 2023 THERANOVA TPNIES application is a significant strength, given the sustained improvements over time, as ESRD patients typically have a rapidly deteriorating health profile and that similar results were found in multiple SCCS studies, in different environments and at different times making it very unlikely that unobservable confounders might be credited with the observed change.

Finally, the applicant referred to FDA affirmation that THERANOVA is safe and effective for its intended use. Per the applicant, studies, such as Molano et al.[181] show no difference in serum albumin levels for THERANOVA compared to high-flux dialyzers and that a randomized controlled study showed that the albumin loss associated with THERANOVA is considerably less than the transperitoneal albumin losses seen in peritoneal dialysis.[182]

We also received many comments from clinicians and patients supporting the THERANOVA application for TPNIES for CY 2023. Some comments from individuals identifying as patients noted improved energy associated with the use THERANOVA and expressed a general desire for more innovative products and concerns in paying for the dialyzer. Other comments were from individuals identifying as clinicians providing general support, expressing a desire for more innovation, and reiterating evidence and data from the application.

Response: We thank the commenters for their input and have taken this information into consideration in our determination of whether THERANOVA meets the eligibility criteria at § 413.236(b)(5) and § 412.87(b)(1). We

[176] NCT03640858; *clinicaltrials.gov*.

[177] Lim JH, Park Y, Yook JM, et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. Nature Sci Rep. 2020;10(1):7780. Published 2020 May 8. doi:10.1038/s41598–020–64622–z.

[178] Lim JH, Park Y, Yook JM, et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. Nature Sci Rep. 2020;10(1):7780. Published 2020 May 8. doi:10.1038/s41598–020–64622–z.

[179] Penny J, Jarosz P, Salerno F, Lemoine S, McIntyre CW. Impact of Expanded Hemodialysis Using Medium Cut-off Dialyzer on Quality of Life: Application of Dynamic Patient-Reported Outcome Measurement Tool. Kidney Medicine. Published 2021, Jul. 29. *https://doi.org/10.1016/j.xkme.2*021.05.010.

[180] Molano-Triviño A, Sanabria M, Vesga J, Buitrago G, Sánchez R, Rivera A. MO880: Effectiveness of Medium Cut- Off vs. High Flux Dialyzers: A Propensity Score Matching Cohort Study, Nephrology Dialysis Transplantation, Vol. 36, Issue Sup. 1, 2021, May. gfab100.005, *https://doi.org/10.1093/ndt/gfab* 100.005.

[181] Molano A, et al. Medium Cutoff Versus High-Flux Hemodialysis Membranes and Clinical Outcomes: A Cohort Study Using Inverse Probability Treatment Weighting, Kidney Med. 4(4):100431. Published online February 7, 2022. Doi: 10.1016/j.xkme.2022.100431.

[182] Kirsch AH, Lyko R, Nilsson LG, et al. Performance of hemodialysis with novel medium cut-off dialyzers [published correction appears in Nephrol Dial Transplant. 2021 Jul 23;36(8):1555–1556]. Nephrol Dial Transplant. 2017;32(1):165–172. doi:10.1093/ndt/gfw310.

have responded in further detail to comments discussing the significant clinical improvement claims for THERANOVA at the end of this section of the final rule.

Comment: We received many comments from clinicians and dialyzer companies with concerns about the applicant's substantial clinical improvement claims. One commenter described weaknesses in the evidence that was used to support the applicant's claims of improved recovery time, improved quality of life, and reduced restless leg syndrome. The commenter reiterated and supported CMS' earlier concerns about quality of evidence. The commenter highlighted the studies by Bolton et al., Lim et al., Alarcon et al., Sanabria et al., and Ariza et al.,[183] [184] [185] [186] [187] noting that they were small in size, retrospective, had high withdrawal rates, based on a single-site, unblinded, uncontrolled, occurred outside the U.S., had Type I errors, and/or short-duration. Specifically, with Bolton et al., the commenter stated that it is also unclear when medium cutoff membrane dialyzers replaced high flux dialyzers as the standard of care and if the comparison was appropriate.

The commenter also stated that with regard to quality-of-life outcomes, there was no difference in the Palliative Care Outcome Scale Symptoms Renal total symptom score at 12 months in poor mobility, difficulty sleeping, pain, shortness of breath, drowsiness, restless legs, skin changes, constipation, poor appetite or diarrhea. The commenter also stated that the Lim et al. study did not analyze change from baseline. The commenter stated that because the Weiner et. al. study was the only randomized control trial of health-related quality of life with medium cutoff dialyzers conducted in the U.S., it believed it to be the most relevant patient population but stated that no differences among groups (high flux vs. medium cutoff) were seen in any of the measures.[188]

A commenter stated that the two new publications, Blackowicz et al. and Molano et al., do not establish THERANOVA as clinically superior to other dialyzers in outcomes related to hospitalization. This commenter noted that the Blackowicz et al. analysis included causes of hospitalization that can be considered unrelated to dialysis and all occurred in the non-THERANOVA group. With the small sample size, these five hospitalizations are highly influential. However, once hospitalizations for causes unrelated to dialysis were removed, the reduction in hospitalization rate was not statistically significant between the study groups. The commenter also stated that the Molano et al. study was conducted in Columbia and may not be generalizable to the Medicare population. Additionally, the commenter noted issues with the unblinded and observational nature of the study leading to potential patient selection bias. Additional criticisms involved unbalanced patient characteristics between study groups and patients in the high flux (non-THERANOVA) group had comorbid conditions that may not have been accounted for in the weighting. The commenter agreed with CMS that patients in the THERANOVA group appeared to have more intensive dialysis at baseline with higher blood and dialysate flows compared to the high-flux group, facilitating better removal of uremic toxins overall.

The commenter submitted its own meta-analysis and stated that it found the number of studies, availability of data, and quality of available studies were not sufficient to make a conclusion on any benefit or detriment of the use of medium cutoff dialyzers in chronic HD patients. The commenter stated that with regard to the patient reported outcome data considered by the analysis, the observational studies showed varying results. The commenter also stated that studies without a comparator group may be prone to bias and thus, difficult to interpret. The commenter cited a randomized clinical trial conducted in the U.S. on medium cutoff dialyzers and stated that it found no difference in quality of life.[189]

The same commenter voiced concerns about the overall evidence in support of the applicant's substantial clinical improvement claims, noting that the CY 2023 application relies largely on the same studies as the application that was submitted for CY 2021. The commenter cited its own meta-analysis comparing hospital admissions and patient-reported outcomes, including quality of life, between patients dialyzed with THERANOVA versus high-flux (HF) dialyzers from published literature. The commenter stated that existing data was too weak and heterogenous to conduct such an analysis. The commenter also stated that the meta-analysis demonstrated lack of clinical benefit.

Finally, the commenter raised concerns about the use of patient survey data included in the CY2023 application, stating it did not believe weak evidentiary sources should be dispositive or substitute for high quality clinical evidence. The commenter stated that such information may be a useful supplement, but it cautioned CMS against relying on it too heavily.

Several commenters expressed concerns about albumin loss. One stated that the applicant presented no compelling information to address CMS' previously articulated concerns regarding albumin loss and its impact on patient health outcomes. One commenter cited several sources pertaining to albumin loss [190] [191] [192] and stated that these studies support the use of high-flux, as opposed to medium cutoff dialyzers, in patients with hypoalbuminemia because of higher protein removal with medium cutoff compared to high flux membranes.

Response: We appreciate the commenters' input regarding whether THERANOVA meets the TPNIES innovation criterion at § 413.236(b)(5)

[183] Bolton S, Gair R, Nilsson LG, Matthews M, Stewart L, McCullagh N. Clinical Assessment of Dialysis Recovery Time and Symptom Burden: Impact of Switching Hemodialysis Therapy Mode. Patient Relat Outcome Meas. 2021;12:315–321 *https://doi.org/10.2147/PROM.S* 325016.

[184] Lim J.H., Park Y., Yook J.M., et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. Nature Sci Rep. 2020;10(1):7780. Published 2020 May 8. doi:10.1038/s41598–020–64622–z.

[185] Alarcon J, Bunch A, Ardila F, Zuniga E, Vesga J, Rivera A, Sanchez R, Sanabria M. Real world evidence on the impact of expanded hemodialysis (HDx) therapy on Patient Reported Outcomes (PROs): CPREXH Registry (in submission).

[186] Sanabria RM, Hutchison CA, Vesga JI, Ariza JG, Sanchez R, Suarez AM. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron. 2021;145(2):179–187. doi: 10.1159/000513328.

[187] Ariza JG, Walton SM, Suarez AM, Sanabria M, Vesga JI. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia. Ther Apher Dial. 2021 Oct;25(5):621–627. doi: 10.1111/1744–9987.13620.

[188] Weiner D, et al. Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Controlled Trial, CJASN15: 1310–1319, 2020. doi: 10.2215/CJN.01210120.

[189] Weiner DE, Falzon L, Skoufos L, Bernardo A, Beck W, Xiao M, Tran H. Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Controlled Trial. Clin J Am Soc Nephrol. 2020 Sep 7;15(9):1310–1319. doi: 10.2215/CJN.01210120. Epub 2020 Aug 25. PMID: 32843372; PMCID: PMC7480550.

[190] Kalantar-Zadeh K, Ficociello LH, Bazzanella J, Mullon C, Anger MS. Slipping Through the Pores: Hypoalbuminemia and Albumin Loss During Hemodialysis. Int J Nephrol Renovasc Dis. 2021 Jan 20;14:11–21. doi:10.2147/IJNRD.S291348. PMID: 33505168; PMCID: PMC7829597.

[191] Zhou M, Ficociello LH, Mullon C, Mooney A, Williamson D, Anger MS. Real-World Performance of High-Flux Dialyzers in Patients With Hypoalbuminemia. ASAIO J. 2022 Jan 1;68(1):96–102. doi:10.1097/MAT.0000000000001511. PMID: 34172639; PMCID: PMC8700293.

[192] *https://www.asn-online.org/education/kidneyweek/archives/KW21Abstracts.pdf.*

and substantial clinical improvement criteria at § 412.87(b)(1).

We acknowledge the additional data supplied by the applicant regarding claims for reduced hospitalization, as well as expansion of an ongoing trial on quality of life, and the challenges associated with generating adequate sample sizes with randomized and matched cohorts. The updated studies on hospitalizations (Blackowicz et al. and Molano et al.) that have now been published in peer reviewed journals included important details about the study design and population that were not available in the previously-submitted abstracts.

Despite this additional information, we remain concerned with potential bias in both studies. While Blackowicz et al, demonstrated a statistically significant reduction in hospitalizations among patients randomized to the THERANOVA membrane, the study was unblinded and was complicated by a high dropout rate in both the treatment and control groups. Because the choice to hospitalize patients can be subjective, the lack of blinding to the investigators introduces potential bias that weakens the quality of evidence. Some of the patients who did not complete the study might have otherwise contributed important information, such as patients who did not complete the study due to missed treatments or adverse events. The published study results focus on a marginally significant p-value that does not account for the testing of multiple outcomes. We also note that a small number of hospitalizations unrelated to dialysis have outsized statistical weight and may weaken the claim that the dialyzer plausibly reduces hospitalizations. Rather, we question whether the difference in hospitalizations may be better explained by the study design or potential spurious results due to small sample size.

The follow-on study by Molano et al. addresses some of the limitations from Blackowicz et al. Compared to the Blackowicz et al. study, this study included more patients and followed patients over a longer time period. However, patients were not randomized and there remains a possibility of bias due to imbalances between the comparison groups. For example, patients in the high flux dialyzer group had comorbidities that may not have been accounted for by the weighting. Even if the patient groups were balanced on baseline characteristics, it appears that the two groups were treated differently throughout the duration of the study, with the medium cutoff membrane group receiving more intensive dialysis. Furthermore, the results from Molano et. al. and comments reflecting clinician experience practicing outside the United States may not be generalizable to dialysis as practiced in the United States.

While the applicant responded to the issue of short-term outcomes in hospitalization by stating that statistical significance was reached at 4.5 months, suggestive of a sufficiently large magnitude of effect, we clarify that based on the evidence provided, and in the absence of a longer-term study, it is not clear whether the observed rapid reduction in hospitalizations may be better explained by bias in the study design. More specific information about the types of hospitalizations that were reduced (for example, cardiovascular, nutrition or immune related admissions) would help to address this concern by linking reductions in hospitalizations to proposed mechanisms of disease related to middle molecules. It would then be helpful to see if hospitalizations remain significantly different between the two groups after removing hospitalizations that were unlikely related to the dialyzer membrane. We also have secondary concerns about statistical significance. After correcting for multiple hypothesis testing, as is standard in high-quality clinical trials, the significance is borderline. We also agree with one commenter that some of the hospitalization differences appear to be driven by non-dialysis related hospitalizations.

As the applicant noted, inverse probability weighting can account for differences in observed features between the treatment and matched control groups. However, the approach does not correct for two additional sources of bias. First, the possibility of unobserved differences between the groups remains. The tables included in the published study do not describe the comparison groups prior to matching and do not provide the information needed to identify evidence of this potential source of bias. And second, the finding that Kt/V throughout the duration of the study was significantly different between the matched groups (higher in the medium cutoff dialyzer group) is suggestive of potential imbalances in unobserved features. Moreover, because the medium cutoff dialyzer group systematically received more intensive dialysis, we cannot deduce whether improved outcomes are attributable to the THERANOVA membrane itself or more intensive dialysis. Even an RCT where one arm systematically received more dialysis would not be able to resolve this potential bias. A comparison of the two dialyzers, where both arms receive equivalent small-molecule clearance (*i.e.,* equivalent Kt/V urea, which should be unaffected by the intervention) may be helpful in addressing this concern.

We also note that the Penny et al. article referenced by the applicant had several limitations including small in size, single-center, non-U.S., and lacking a control group. Future studies of patient reported outcomes could provide support by verifying that the specific domains identified in initial exploratory analyses represent areas where the new technology improves aspects of quality of life and/or pruritis and by comparing patients treated with the intervention to a control population.

With respect to the issue of multiple-hypothesis testing and non-significant differences in afternoon pruritus in Lim et al., we agree with the applicant that multiple outcomes would be a concern in any study that examines multiple quality-of-life domains. However, this does not address the specific concern. The statistics literature provides multiple strategies to correct p-values for multiple statistical tests. Additionally, as stated above, the Penny et al. article does not provide sufficient corroboration of the finding due to its own limitations. Future studies could provide reassurance by verifying that the specific domains identified in these initial exploratory analyses represent areas where the new technology improves quality of life. As the applicant notes, these studies should be robust to concerns about multiple statistical testing (given the multiple quality-of-life domains) and could attempt to minimize bias by providing comparison to an appropriate control group.

Although crossover trials have some advantages as noted by the applicant (primarily in that they use the same patient as an internal control group), we also would like to clarify that crossover trials could be designed to overcome study design flaws that may introduce bias. First, the trial should consider blinding participants and study coordinators, since an unblinded crossover trial that assesses subjective outcomes is prone to observer and recall bias. Second, because regression to the mean is common particularly with quality-of-life studies that depend on survey responses, crossover trials should consider employing randomization, where patients are randomly assigned to the sequence of crossover intervention. Finally, we note that in the renal literature especially, high-quality crossover trials have been effectively employed to demonstrate the

physiological benefits of a dialysis-related intervention.

In accordance with TPNIES policy and § 412.87(b)(1)(i), we consider the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. In addition, per 412.87(b)(1)(iii), CMS considers a range of evidence from published or unpublished information sources, including other appropriate information sources not otherwise listed under § 412.87(b)(1)(iii).

After carefully reviewing the application, the information submitted by the applicant addressing our concerns raised in the CY 2023 ESRD PPS proposed rule, as well as the many comments submitted by the public, we have determined that THERANOVA has not shown that it represents an advance that substantially improves, relative to renal dialysis services previously available, the treatment of Medicare beneficiaries. For the reasons discussed previously, we conclude that THERANOVA does not meet the TPNIES innovation criteria under § 413.236(b)(5) and § 412.87(b)(1).

(6) Capital-Related Assets Criterion (§ 413.236(b)(6))

With respect to the sixth TPNIES eligibility criterion under § 413.236(b)(6), limiting capital-related assets from being eligible for the TPNIES, except those that are home dialysis machines, the applicant did not address this criterion within its application. However, THERANOVA does not meet the definition of a capital-related asset, as defined in § 413.236(a)(2), because it is not an asset that the ESRD facility has an economic interest in through ownership and is subject to depreciation.[193] We welcomed comments on THERANOVA's status as a non-capital-related asset.

The applicant stated that THERANOVA is not an asset that the ESRD facility has an economic interest in through ownership, and THERANOVA is not subject to depreciation. Based on the information provided by the applicant, we agree THERANOVA does not meet the definition of a capital-related asset, as defined in § 413.236(a)(2).

Final Rule Action: After a consideration of all the public comments received, we have determined that the evidence and public comments submitted are not sufficient to demonstrate that THERANOVA meets all eligibility criteria to qualify for the TPNIES for CY 2023. As a result, THERANOVA will not be paid for using the TPNIES per § 413.236(d). We note that in the CY 2021 ESRD PPS final rule (85 FR 71412), CMS indicated that entities would have 3 years beginning on the date of FDA marketing authorization in which to submit their applications for the TPNIES. Based on the THERANOVA FDA marketing authorization date of August 28, 2020, the applicant is eligible to apply for the TPNIES for CY 2024, and CMS would review any new information provided for the CY 2024 rulemaking cycle.

D. Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2023

In this section of the final rule, we provide a table that identifies the one item that was approved for the TPNIES for CY 2022 [194] and which is still in the TPNIES payment period, as specified in § 413.236(d)(1), for CY 2023. CMS will continue paying for this item using the TPNIES for CY 2023. This table also identifies the item's HCPCS coding information as well as the payment adjustment effective date and end date.

TABLE 14: Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies

HCPCS Code	Long Descriptor	Payment Adjustment Effective Date	Payment Adjustment End Date
E1629	Tablo hemodialysis system for the billable dialysis service	1/1/2022	12/31/2023

E. Continuation of Approved Transitional Drug Add-On Payment Adjustments for New Renal Dialysis Drugs or Biological Products for CY 2023

Under § 413.234(c)(1), a new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the TDAPA for 2 years. In December 2021, CMS approved KORSUVA™ (difelikafalin) for the TDAPA under the ESRD PPS, effective April 1, 2022. Implementation instructions are specified in CMS Transmittal 11295,[195] dated March 15, 2022, and available at: *https://www.cms.gov/files/document/r11295CP.pdf.*

In this section of the final rule, we provide a table that identifies the one new renal dialysis drug that was approved for the TDAPA effective in CY 2022, and for which the TDAPA payment period as specified in § 413.234(c)(1) will continue in CY 2023. This table also identifies the product's HCPCS coding information as well as the payment adjustment effective date and end date.

[193] See also: CMS Provider Reimbursement Manual, Chapter 1, Section 104.1. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.*

[194] 86 FR 61889 through 61906.

[195] CMS Transmittal 11295 rescinded and replaced CMS Transmittal 11278, dated February 24, 2022.

TABLE 15: Continuation of Approved Transitional Drug Add-On Payment Adjustments for New Renal Dialysis Drugs or Biological Products

HCPCS Code	Long Descriptor	Payment Adjustment Effective Date	Payment Adjustment End Date
J0879	Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)	4/1/2022	3/31/2024

F. Summary of Request for Information About Addressing Issues of Payment for New Renal Dialysis Drugs and Biological Products After Transitional Drug Add-On Payment Adjustment (TDAPA) Period Ends

1. Background on the TDAPA

Section 217(c) of PAMA required the Secretary to establish a process for including new injectable and intravenous (IV) products into the ESRD PPS bundled payment as part of the CY 2016 ESRD PPS rulemaking. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process based on our longstanding drug designation process that allowed us to include new injectable and intravenous products into the ESRD PPS bundled payment and, when appropriate, modify the ESRD PPS payment amount. We codified this process in our regulations at 42 CFR 413.234. We finalized that the process is dependent upon the ESRD PPS functional categories, consistent with the drug designation process we have followed since the implementation of the ESRD PPS in 2011. As we explained in the CY 2016 ESRD PPS final rule (80 FR 69014), when we implemented the ESRD PPS, drugs and biological products were grouped into functional categories based on their action. This was done to add new drugs or biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs are commercially available so beneficiaries have access to them. As we stated in the CY 2011 ESRD PPS final rule, we did not specify all the drugs and biological products within these categories because we did not want to inadvertently exclude drugs that may be substitutes for drugs we identified and we wanted the ability to reflect new drugs and biological products developed or changes in standards of practice (75 FR 49052).

In the CY 2016 ESRD PPS final rule, we finalized the definition of an ESRD PPS functional category in § 413.234(a) as a distinct grouping of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD (80 FR 69077).

We finalized a policy in the CY 2016 ESRD PPS final rule that if a new renal dialysis injectable or IV product falls within an existing functional category, the new injectable drug or IV product is considered included in the ESRD PPS bundled payment and no separate payment is available. The new injectable or IV product qualifies as an outlier service. We noted in that rule that the ESRD bundled market basket updates the ESRD PPS base rate annually and accounts for price changes of the drugs and biological products.

We also finalized in the CY 2016 ESRD PPS final rule that, if the new renal dialysis injectable or IV product does not fall within an existing functional category, the new injectable or IV product is not considered included in the ESRD PPS bundled payment and the following steps occur. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or IV product is used to treat or manage. Next, the new injectable or IV product is paid for using the TDAPA codified in § 413.234(c). Finally, the new injectable or IV product is added to the ESRD PPS bundled payment following payment of the TDAPA.

In the CY 2016 ESRD PPS final rule, we finalized a policy in § 413.234(c) to pay the TDAPA until sufficient claims data for rate setting analysis for the new injectable or IV product are available, but not for less than 2 years. The new injectable or IV product is not eligible as an outlier service during the TDAPA period. We established that following the TDAPA period, the ESRD PPS base rate will be modified, if appropriate, to account for the new injectable or IV product in the ESRD PPS bundled payment.

In CYs 2019 and 2020 ESRD PPS final rules (83 FR 56927 through 56949 and 84 FR 60653 through 60677, respectively), we made several revisions to the drug designation process regulations at § 413.234. In the CY 2019 ESRD PPS final rule, we revised regulations at § 413.234(a), (b), and (c) to reflect that the process applies for all new renal dialysis drugs and biological products that are FDA approved regardless of the form or route of administration. In addition, we revised § 413.234(b) and (c) to expand the TDAPA to all new renal dialysis drugs and biological products, rather than just those in new ESRD PPS functional categories. In the CY 2020 ESRD PPS final rule, we revised § 413.234(b) and added paragraph (e) to exclude from TDAPA eligibility generic drugs approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act and drugs for which the new drug application is classified by the FDA as Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the ''parent NDA'' is a Type 3, 5, 7, or 8, effective January 1, 2020.

Under our current TDAPA policy at § 413.234(c), a new renal dialysis drug or biological product that falls within an existing ESRD PPS functional category is considered included in the ESRD PPS base rate and is paid the TDAPA for 2 years. After the TDAPA period, the base rate will not be modified. If the new renal dialysis drug or biological product does not fall within an existing ESRD PPS functional category, it is not considered included in the ESRD PPS base rate, and it will be paid the TDAPA until sufficient claims data for rate setting analysis is available, but not for less than 2 years. After the TDAPA period, the ESRD PPS base rate will be modified, if appropriate, to account for the new renal dialysis drug or biological product in the ESRD PPS bundled payment.

As discussed in the CY 2019 and CY 2020 ESRD PPS final rules, for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provides additional payments for such associated costs, and promotes competition among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative (83 FR 56935; 84 FR 60654). For new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category, the TDAPA is a pathway toward a potential base rate modification (83 FR 56935).

For the complete history of the TDAPA policy, including the pricing methodology, please see the CY 2016 ESRD PPS final rule (80 FR 69023 through 69024), CY 2019 ESRD PPS final rule (83 FR 56932 through 56948), and CY 2020 ESRD PPS final rule (84 FR 60653 through 60681).

2. Current Issues and Concerns of Interested Parties

In the CY 2019 ESRD PPS final rule, we discussed that a commenter stated concern over beneficiary access issues at the end of the TDAPA period. We responded by noting the drug or biological product will become eligible under the outlier policy after the TDAPA period if it is not considered to be a composite rate drug. We stated that we expect that if a beneficiary is responding well to a drug or biological product paid for using the TDAPA that they will continue to have access to that therapy after the TDAPA period ends (83 FR 56941). Since 2019, dialysis associations and pharmaceutical representatives have expressed concerns to CMS about payment following the TDAPA period for new renal dialysis drugs and biological products that are paid for using the TDAPA. They stated that unless money is added to the ESRD PPS base rate for these drugs and biological products, similar to what occurred with calcimimetics (85 FR 71406 through 71410), then it is unlikely that ESRD facilities will be able to sustain the expense of these drugs and biological products when the TDAPA period ends. Further, they cautioned that uncertainty about payment could affect ESRD facility adoption of these drugs and biological products during the TDAPA period. To date, calcimimetics are the only renal dialysis drugs or biological products that have been paid for using the TDAPA and incorporated into the ESRD PPS bundled payment following the TDAPA payment period. There have been no other renal dialysis drugs or biological products that have completed their TDAPA payment period, and as a result CMS does not yet have data on other drugs or biological products to evaluate the specific risks and access challenges that interested parties have raised.

As mentioned in the CY 2019 (83 FR 56941) and CY 2020 (84 FR 60672 and 60693) ESRD PPS final rules, many commenters suggested a rate-setting exercise at the end of TDAPA for all new renal dialysis drugs and biological products. We responded by noting that we do not believe adding dollars to the ESRD PPS base rate would be appropriate for new drugs that fall into the ESRD PPS functional categories given that the purpose of the TDAPA for these drugs is to help ESRD facilities incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provide additional payments for such associated costs, and promote competition among the products within the ESRD PPS functional categories. In addition, we explained that the ESRD PPS base rate already includes money for renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. Under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average patient, and there will be patients whose treatment costs at an ESRD facility will be more or less than the ESRD PPS payment amount. A central objective of the ESRD PPS and of prospective payment systems in general is for facilities to be efficient in their resource use.

In the CY 2023 ESRD PPS proposed rule, we presented this information and noted that price changes to the ESRD PPS bundled payment are updated annually by the ESRDB market basket, which includes a pharmaceuticals cost category weight, as noted in section II.B.1.a.(1)(b) of this final rule. In addition, we noted that our analysis of renal dialysis drugs and biological products paid for under the ESRD PPS has found costs and utilization to have decreased over time relative to market basket growth for some high volume formerly separately billable renal dialysis drugs. Therefore, we stated that we believed that any potential methodology for an add-on payment adjustment in these circumstances should adapt to changes in price and utilization over time.

3. Suggestions for Possible Methodologies for an Add-On Payment Adjustment for Certain Renal Dialysis Drugs and Biological Products Within an Existing Functional Category

Section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment—(I) for pediatric providers of services and renal dialysis facilities; (II) by a geographic index, such as the index referred to in paragraph (12)(D), as the Secretary determines to be appropriate; and (III) for providers of services or renal dialysis facilities located in rural areas. In response to the patient access concerns discussed previously in this section of the final rule, in the CY 2023 ESRD PPS proposed rule (87 FR 38522 through 38523), we stated that we were considering whether it would be appropriate to establish an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after their TDAPA period ends. We noted that any add-on payment adjustment would be subject to the Medicare Part B beneficiary co-insurance payment under the ESRD PPS. In the CY 2023 ESRD PPS proposed rule, we discussed several methods that could be used to develop an add-on payment adjustment for these drugs and biological products. As noted in the proposed rule, the methods presented below differ in terms of which formerly separately billable renal dialysis drugs and biological products will be considered for a potential add-on payment adjustment. We noted that under these potential options, we would apply a reconciliation methodology only when an add-on payment adjustment will align resource use with payment for a renal dialysis drug or biological product in an existing ESRD PPS functional category.

- Reconcile the average expenditure per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in the expenditure per treatment across all other formerly separately billable renal dialysis drugs and biological products. For example, if the reduction in the cost of all formerly separately billable renal dialysis drugs and biological products per treatment excluding the renal dialysis drug or biological product that was paid for using the TDAPA is $5 and the cost per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA is $10, the add-on payment adjustment per

treatment would be $10 minus $5, which is $5. The reductions in formerly separately billable renal dialysis drug and biological products expenditures per treatment would be calculated by using the difference between these expenditures in the most recent year with claims data available and these expenditures in the current base year for the ESRDB market basket, which is CY 2020 as discussed in section II.B.1.a.(1)(c) of this final rule. For example, if the rule year for which we are calculating the add-on payment adjustment is CY 2023 and the base year for the ESRDB market basket is CY 2020, the reduction in formerly separately billable renal dialysis drugs and biological products expenditures would be the difference between these expenditures in CY 2021 (the year with the most recent claims data) and those in CY 2020.

- Reconcile the average expenditure per treatment for the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in expenditures for other formerly separately billable renal dialysis drugs or biological products, where such reduction can be empirically attributed to the renal dialysis drug or biological product that was paid for using the TDAPA. For example, if the utilization of the renal dialysis drug or biological product that was paid for using the TDAPA was found to be statistically associated with reduction in expenditure of one drug in an ESRD PPS functional category amounting to $1 per treatment, and the cost per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA is $10, the add-on payment adjustment per treatment would be $10 minus $1, which is $9.
- Reconcile the average expenditure per treatment for the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in expenditures for other formerly separately billable renal dialysis drugs that fall into one or more ESRD PPS functional categories, where such expenditure reduction is data-driven, based on end action effect, to be attributable to the renal dialysis drug or biological product that was paid for using the TDAPA. Such a data-driven determination would be made by CMS. For example, if the cost per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA is $10 and the reduction in the expenditure for other clinically related formerly separately billable renal dialysis drugs is $0.50 per treatment, the add-on payment adjustment would be $10 minus $0.50, which is $9.50.
- Only use the average expenditure per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA. For example, if the per treatment cost of the renal dialysis drug or biological product that was paid for using the TDAPA is $10, this would be the amount of the add-on payment adjustment.

4. Summary of Request for Information on an Add-On Payment Adjustment After the TDAPA Period Ends

In the CY 2023 ESRD PPS proposed rule (87 FR 38464), we sought comment on options regarding an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends. We issued a request for information (RFI) to seek feedback from the public on whether an add-on payment adjustment would be needed, what the appropriate criteria would be for determining whether renal dialysis drugs or biological products should receive such an adjustment, and what methodology would be most appropriate for calculating such an adjustment.

5. Summary of Comments Received

We received 27 public comments in response to our RFI, including from large, small, and non-profit dialysis organizations; an advocacy organization; a coalition of dialysis organizations; a large non-profit health system; and MedPAC. A high-level description of these comments is included in the following subsections of this CY 2023 ESRD PPS final rule. We will provide more detailed information about the commenters' recommendations in a future posting on the CMS website located at the following link: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources*.

While we will not respond to these comments in this CY 2023 ESRD PPS final rule, we intend to take them into consideration during potential future policy development. We thank the commenters for their detailed and thoughtful comments.

a. Need for Establishing an Add-On Payment Adjustment

We received 23 comments that supported CMS establishing an add-on payment adjustment for new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends. Most commenters expressed their belief that an add-on payment adjustment of this nature is necessary to support the adoption of new renal dialysis drugs and biological products. Numerous commenters expressed support for using an add-on payment adjustment to improve patient access to innovative drugs. MedPAC opposed this type of add-on payment adjustment by stating that it would undermine competition with existing drugs in the ESRD PPS bundled payment and encourage higher launch prices.

b. Criteria for Receiving Add-On Payment Adjustment

Most commenters supported CMS allowing all new renal dialysis drugs and biological products to be eligible to receive an add-on payment adjustment after the TDAPA period ends. MedPAC recommended that CMS limit the add-on payment adjustment to new renal dialysis drugs and biological products that show a substantial clinical improvement compared with existing products reflected in the ESRD PPS bundled payment. Several commenters, including a trade association, also recommended that CMS consider applying a similar add-on payment adjustment for the equipment, supplies, and capital-related assets that are paid for under the TPNIES.

c. Calculating an Add-On Payment Adjustment

Several commenters supported reconciling the expenditure of the new renal dialysis drug or biological product with any reduction in expenditures for other formerly separately billable renal dialysis drugs that are clinically or statistically related to the introduction of the new renal dialysis drug in the bundle. Several commenters expressed their belief that the FDA-approved label for primary indication should be used to determine clinical association, rather than end-action effect. MedPAC expressed opposition to calculating any add-on payment adjustment for new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends, but noted that if an add-on payment adjustment were applied, it would be appropriate to use an offset, similar to the approach used with the TPNIES, to avoid duplicative payment for renal dialysis services already included in the ESRD PPS base rate.

d. Public Comments on the TDAPA and TPNIES

We received several comments regarding the TDAPA and TPNIES policies, including new payment adjustments and length of the payment period. Commenters urged CMS to apply the TPNIES and TDAPA for at least three years to allow for two full

years of data collection, and then increase the base rate to reflect the value of any improved outcomes for patients, including improved quality of life, once the TDAPA or TPNIES period ends. An LDO also suggested that the TDAPA payment amount be restored to the original ASP + 6 percent amount. Commenters also suggested that we create a pathway for incorporation of new clinical diagnostic laboratory tests related to the treatment of ESRD, either through an expansion of the TPNIES or the adoption of a parallel, Transitional Laboratory Add-on Payment Adjustment (TLAPA). We thank the commenters for their input. We did not include any proposals on these topics in the CY 2023 ESRD PPS proposed rule, and therefore we believe these comments are out of scope for this rulemaking. However, we will consider these comments for potential future refinements to ESRD PPS payment policies.

G. Summary of Requests for Information on Health Equity Issues Within the ESRD PPS With a Focus on Pediatric Payment

1. Background

CMS is committed to achieving equity in health care for our beneficiaries by recognizing and working to redress inequities in our policies and programs that serve as barriers to access to care and quality health outcomes. CMS policy objectives, including its commitment to advancing health equity which stands as the first pillar of the CMS Strategic Plan [196] and reflect the goals of the Biden administration, as stated in Executive Order 13985.[197]

In this final rule, ''health equity means 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.'' [198]

Numerous studies have shown that among Medicare beneficiaries, individuals belonging to a racial or ethnic minority group often experience delays in care, receive lower quality of care, report dissatisfactory experiences of care, and experience more frequent hospital readmissions and procedural complications than white patients and patients with higher levels of income.[199] [200] [201] [202] [203] [204] When compared to FFS beneficiaries not receiving renal dialysis services, FFS beneficiaries receiving renal dialysis are disproportionately young, male, Black/African-American, low income as measured by dually eligible Medicare and Medicaid status, have disabilities, and reside in an urban setting [205] In the CY 2023 ESRD PPS proposed rule (87 FR 38464), we requested information on advancing health equity under the ESRD PPS, including an additional request focused on health disparities faced by pediatric ESRD patients within the ESRD PPS (87 FR 38523 through 38529).

2. Summary of Requests for Information on Health Equity Issues Within the ESRD PPS

We received comments on these issues from approximately 13 commenters that directly and indirectly addressed these RFI topics. Below we provide a short synopsis of the comments for each of the RFI topics discussed in the CY 2023 ESRD PPS proposed rule. We will provide a more detailed summary of the comments received on this RFI on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/ESRDpayment/Educational_Resources.html*. While we will not respond to these comments here, we will take them into consideration during future policy development. We thank the commenters for their detailed and thoughtful comments.

a. Refinements To Mitigate Health Disparities

CMS requested information on what kind of refinements to the ESRD PPS payment policy could mitigate health disparities and promote health equity. In response, many commenters expressed support for CMS's efforts to reduce disparities and improve equity in the delivery of ESRD care. One commenter noted that traditional incentives for health care providers and payers to deliver high quality care efficiently may require change so that incentives are applied fairly and do not undermine access to care. Commenters offered a number of suggestions, including: add-on payments and other adjustments to the facility payor mix to provide for social work staffing and complex care coordination; add-on payments for higher percentages of dual eligible home dialysis patients and patients with housing or food insecurities; and an extension of kidney disease patient education services benefits to Medicare beneficiaries are who not yet on dialysis but who have Stage V CKD as well as to those within the first 6 months of ESRD. A few commenters supported adoption of a payment model similar to the CMS's ESRD Treatment Choices (ETC) Model to improve health equity; one commenter advocated for allowing facility-employed social workers, dieticians, and others to work with physicians to provide KDE services to beneficiaries. One commenter suggested that CMS expand equitable access to life-saving dialysis care by issuing guidance to all states to encourage expansion of Emergency Medicaid to undocumented people with kidney failure.

b. Comorbidities

CMS asked whether specific comorbidities should be examined when calculating the case-mix adjustment that would better represent the ESRD population and help address health disparities. Several commenters provided feedback on the role of comorbidities on the health outcomes of ESRD patients and recommendations around the use of comorbidities in the ESRD PPS. Several commenters opined that the current comorbidity case mix adjusters are methodologically unsound and should be eliminated from the ESRD PPS. One commenter explained that its analysis showed effects of comorbidities on resource utilization for separately billable items, independent of the onset of dialysis, and noted that costs are higher for patients with comorbidities during the first 4 months

[196] *https://www.cms.gov/cms-strategic-plan.*

[197] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[198] *https://www.cms.gov/pillar/health-equity.*

[199] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[200] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[201] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. Racial disparities in knee and hip total joint arthroplasty: an 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec; 73(12):2107–15.

[202] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[203] 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.

[204] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[205] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf.*

of treatment. One commenter suggested development of patient-level adjusters to account for patients with left ventricular assist device, tracheostomy, cardiomyopathy with ejection fraction at or under 20, significant mental health conditions, non-weight bearing transfers, and patients who chose to skip >50 percent of treatments in a given month. A few commenters remarked upon the role of mental health and neurological conditions (for example, cognitive impairment), noting that such conditions affect patients' ability to function and adhere to care regimens. Two commenters referenced research produced by MedPAC and The Moran Company as resources to inform CMS policy on comorbidities and claims adjustment.

c. Subpopulations

CMS requested comment about specific subpopulations whose needs may not adequately accounted for by the current ESRD PPS payment policy and should be evaluated for potential health disparities. Several commenters remarked upon the large percentage of ESRD patients who are dual eligible and who have higher costs of care despite similar utilization. Several commenters supported the inclusion of social determinants of health (SDOH) measures identified by CMS in the CY 2023 ESRD PPS proposed rule as health-related social needs (HRSN): food insecurity, housing instability, transportation problems, utility help needs, interpersonal safety, mental health needs, and non-English speaking. Other commenters spoke to the lack of caregiver support, the burden of caregiver fatigue, and concerns about storage and supplies management as factors contributing to health disparities, including the lack of access to home dialysis. Another commenter noted the lack of health literacy as a contributing factor to disparities. One commenter cited the lack of high-speed internet as a contributor to disparities in telehealth access and thus in access to home dialysis.

CMS also asked how existing data sources could be used to better identify unmet needs among specific subpopulations that could result in health disparities. In response, one commenter noted that mental health conditions are coded using ICD–10 codes and should be available in claims data. The same commenter also suggested that CMS develop and use Z codes to track SDOH, but, until these were operational, CMS might instead use dual eligible status or Area Deprivation Index (ADI) and Social Vulnerability Index (SVI) at the 9-digit ZIP code level. The commenter noted that frequent address changes in CMS claims for a given patient might indicate housing instability. One commenter recommended screening for CKD using the CMS–2728 patient registration form.

d. Demographic Information and Social Determinants of Health

CMS asked for comments suggesting ways to address, define, collect, and use accurate and standardized, self-identified demographic information (including information on race and ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, and language preference) for the purposes of reporting, stratifying data by population, and other data collection efforts that would mitigate disparities and refine ESRD PPS payment policy. In response, commenters indicated support for collecting SDOH, but also cautioned against the accompanying increased administrative burden on staff. A provider advocacy organization suggested working with facilities already tracking SDOH through electronic medical records and then engaging vendors to extract the data. A large dialysis organization advocated for a voluntary pilot study to (1) support the uniform collection and analysis of patient-level SDOH data and (2) test interventions. A few commenters suggested the use of Z codes to collect data on common SDOH such as housing and food insecurity and minimal caregiver support. One commenter advocated for CMS's use of the HRSN screening tool and mental health variables to identify subgroups in need; the commenter also suggested looking to past studies on HRSNs from the early 1980s and how these were used to develop DRGs for data on empirical estimates of the additional costs from HRSNs. One commenter noted its own success with SDOH collection and suggested that CMS look to the standardized data collection methods described in the 2009 Institute of Medicine reporting on standardized collection of race, ethnicity, and language data.

e. Revisions to Case-Mix Categories in the ESRD PPS

CMS sought comment on what revisions to case-mix categories in the ESRD PPS could be made to better represent underserved populations. One commenter recommended that CMS adopt a payment adjustment for ESRD facilities treating a large proportion of patients with SDOH challenges that would be similar to the Disproportionate Share Hospital (DSH) payment available to hospitals under the IPPS. One commenter suggested CMS use the Complication or Comorbidity (CC) or a Major Complication or Comorbidity (MCC) approach, as used in IPPS. That is, the existing categories could be modified to include two or three levels of HRSNs as modifiers, with higher levels of HRSNs being associated with higher payments. The commenter noted that this approach would leave the basic case-mix system unchanged but would add a HRSN concept exactly analogous to the CC modifier—an additional, orthogonal factor that contributes to cost and can contribute to payment.

f. Renal Dialysis Technologies, Treatments, and Clinical Tools

CMS asked for comment regarding what actions CMS could potentially consider under the ESRD PPS to help prevent or mitigate potential bias in renal dialysis technologies, treatments, or clinical tools that rely on clinical algorithms. One commenter suggested that CMS work with the HHS Office for Civil Rights to address health literacy issues and improve education materials. Another commenter suggested that CMS incorporate the use of peer mentors and navigators to assist in education of ESRD patients as well as to help with minority recruitment into primary care settings and nephrology training. Similarly, one commenter suggested that CMS incentivize medical students to pursue nephrology. A non-profit dialysis center discouraged CMS from over-adjusting for SDOH in a way that would move the payment system away from bundled payments and towards an FFS approach and accordingly in their view undermine the ESRD PPS.

3. Responses to the Request for Information on Health Equity Issues Within the ESRD PPS Focusing on Pediatric Payment

a. Pediatric Dialysis Overview [206]

Compared to the Medicare dialysis adult population, the Medicare dialysis pediatric population is much smaller, comprising approximately 0.14 percent of the total ESRD patient population in 2019. Pediatric facilities have higher direct patient care labor expenditures than adult facilities. CMS has continued to hear concerns from organizations associated with pediatric dialysis about underpayment of pediatric renal dialysis services under the current ESRD PPS payment model. Some organizations emphasized that pediatric renal dialysis services require significantly different staffing and supply needs from those of adults. Most of these organizations agree there is a need for more finely tuned cost data for pediatric dialysis. Many of these organizations support CMS efforts to explore ways to improve collecting pediatric-specific data to better characterize the necessary resources and associated costs of delivering pediatric ESRD care. During the December 2020 TEP, some panelists provided suggestions for the pediatric dialysis payment adjustment.[207]

b. Summary of Comments

CMS plans to continue working with health care providers, the public, and other key interested parties on these important issues to identify policy solutions that achieve the goals of attaining health equity for all patients. In the CY 2023 ESRD PPS proposed rule, we requested comments on improving CMS's ability to detect and reduce health disparities within the ESRD PPS for pediatric patients receiving renal dialysis services. Our goal in publishing the RFI in the CY 2023 ESRD PPS proposed rule was to solicit input on topics such as circumstances and health inequities unique to the pediatric dialysis population, possible refinements to the ESRD PPS payment policy to mitigate health disparities for this population, the possible inclusion of a specific payment modifier on the claim indicating pediatric dialysis, and putting more emphasis on pediatric comorbidities.

We received comments on these issues from approximately 10 commenters that directly and indirectly addressed the RFI topics stated in the previous paragraph. Below we provide a short synopsis of the comments for each of the topics discussed in the CY 2023 ESRD PPS proposed rule. We will provide a more detailed summary of the comments received on this RFI on the CMS website: *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/ESRDpayment/Educational_Resources.html*.

Some commenters stated that they appreciated that CMS acknowledges the unique and complex care needs of the pediatric dialysis patient population that typically requires a much higher intensity of labor-related services and additional supplies. These unique and complex care needs contribute to the higher cost of pediatric ESRD and CKD care. Some commenters thanked CMS for our continued engagement with them regarding this specialized population.

All commenters stated that they agree there are health disparities faced by pediatric patients receiving dialysis that are different than adults receiving dialysis. Some commenters reiterated the health disparities faced by Black pediatric dialysis patients, noting that Black pediatric patients are disproportionally impacted by CKD overall. Some commenters pointed to data showing Black children receiving dialysis are more likely to be on hemodialysis than White patients and wait longer, and are less likely, to receive a kidney transplant. These differences are significant because home dialysis, and ultimately transplant, are the preferred treatments for ESRD in the pediatric population. While outside the scope of the RFI, a few commenters expressed concern with the algorithms, including race as a factor, used to match kidneys of deceased donors to pediatric kidney transplant recipients, noting it may negatively impact overall access to transplantation for children. Commenters also pointed to socioeconomic and demographic factors that contribute to the disparity of Black children receiving transplants.

c. Factors Affecting the Cost of Pediatric Dialysis Treatment and the Need for Data Collection

Almost all the commenters discussed economic determinants of health and SDOH. They pointed to factors such as lack of adequate housing, nutrition, and transportation as problems these children face that contribute to the disparity for this sub-population. Housing insecurity was one of the SDOH discussed in the comments. Nutritional concerns were another topic of discussion by several commenters. Some commenters highlighted the need to address food insecurity and access to nutritional foods to address disparities and advance health equity. SDOH are not currently collected as part in the ESRD PPS case mix adjustment model, but commenters noted their value in accessing the care needs of the pediatric dialysis population.

In addition to discussing SDOH, interested parties expressed concern that there is other information not currently collected that affects the true costs of pediatric dialysis treatment within the ESRD PPS. For example, they stated that other existing medical conditions are not factored into case-mix adjustment for pediatric patients, nor are the costs associated with the type of specialized treatment required by the youngest patients and those with developmental and other disabilities and special needs. All the commenters suggested factors to consider for the pediatric patient level case-mix adjuster. Commenters requested CMS consider the additional unreported expenses for the key support personnel responsible for addressing the unique challenges related to cognitive, physical, and developmental disabilities in these patients.

In the CY 2023 ESRD PPS proposed rule (87 FR 38464), CMS asked whether a pediatric dialysis payment should include a specific payment modifier on the claim so that costs for providing pediatric dialysis can be further delineated with alternative payment sub-options. Some commenters supported the inclusion of a modifier; others supported the formation of a separate pediatric ESRD PPS.

Response: We appreciate all the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our ESRD payment policy as we work to address health disparities in the pediatric dialysis population. We will continue to take the comments into account as we work on improving CMS's ability to detect and reduce health disparities within the ESRD PPS for pediatric patients receiving renal dialysis services. While we will not be responding to specific comments submitted in response to this RFI, we intend to use this input to inform future policy development. CMS would propose any potential changes to payment policies through a separate notice and comment rulemaking.

[206] ESRD TEP Summary Report of TEP held on December 10–11, 2020, p. 18–19. *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf*.

[207] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf*.

III. Calendar Year (CY) 2023 Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with acute kidney injury (AKI). Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a subsection (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies to implement subsection (r) of section 1834 of the Act and the amendments to section 1881(s)(2)(F) of the Act, including the payment rate for AKI dialysis (81 FR 77866 through 77872 and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD PPS base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the CY 2023 Payment for Renal Dialysis Services Furnished to Individuals With AKI

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'' (87 FR 38464 through 38586), referred to as the ''CY 2023 ESRD PPS proposed rule,'' appeared in the June 28, 2022 version of the **Federal Register**, with a comment period that ended on August 22, 2022. In that proposed rule, we proposed to update the AKI dialysis payment rate for CY 2023. We received 13 public comments on our proposal from a coalition of dialysis organizations, a non-profit dialysis association, a device manufacturer, a network of dialysis organizations and regional offices, a home dialysis advocacy organization, a home dialysis stakeholder alliance, a professional association, a professional organization of nephrologists, two trade associations, a national organization of patients and kidney healthcare professionals, a coalition of healthcare organizations, and a large dialysis organization.

In this final rule, we provide a summary of each proposed provision, a summary of public comments received and our responses to them, and the policies we are finalizing for CY 2023 payment for renal dialysis services furnished to individuals with AKI.

C. Annual Payment Rate Update for CY 2023

1. CY 2023 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including the applicable annual productivity-adjusted market basket payment update, geographic wage adjustments, and any other discretionary adjustments, for such year. We note that ESRD facilities have the ability to bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis.

As discussed in section II.B.1.d of this final rule, the CY 2023 ESRD PPS base rate is $265.57, which reflects the application of the CY 2023 wage index budget-neutrality adjustment factor of 0.999730 and the CY 2023 ESRDB market basket increase of 3.1 percent reduced by the productivity adjustment of 0.1 percentage point, that is, 3.0 percent. Accordingly, we are finalizing a CY 2023 per treatment payment rate of $265.57 for renal dialysis services furnished by ESRD facilities to individuals with AKI. This payment rate is further adjusted by the wage index, as discussed in the next section of this final rule.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and regulations at § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRDB market basket and reduced by the productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS and discussed in section II.B.1.b of this final rule. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. As stated previously, we are finalizing a CY 2023 AKI dialysis payment rate of $265.57, adjusted by the ESRD facility's wage index. The wage index floor increase (discussed in section II.B.1.b.(3) of this final rule) and the permanent 5-percent cap on wage index decreases (discussed in section II.B.1.b.(2) of this final rule) that we are finalizing the ESRD PPS will apply in the same way to AKI dialysis payments to ESRD facilities.

The comments and our responses to the comments on our AKI dialysis payment proposal are set forth below.

Comment: Many commenters, including two trade associations, a national organization of patients and kidney healthcare professionals, a coalition of healthcare organizations, a home dialysis stakeholder alliance, a non-profit dialysis association, and a large dialysis organization, requested that CMS change Medicare AKI policies to include at-home hemodialysis and peritoneal dialysis for AKI beneficiaries. Some commenters also sought to have the ESRD PPS cover staff-assisted dialysis at home, patient education, and home training sessions. A few commenters advocated for home dialysis waivers that would extend to outpatient AKI dialysis under the current PHE for COVID–19. Several commenters reported that they were finding home dialysis to be a safe and effective modality, as many patients with AKI have received home dialysis under a waiver applicable to acute hospital care delivered at home under

CMS' Hospitals Without Walls program. Many commenters also advocated for the home dialysis modality, arguing that home dialysis options for AKI patients would advance health equity, noting that Black people are more likely than White people to experience AKI.

Response: We thank the commenters for their input. We did not include any proposals on these topics in the CY 2023 ESRD PPS proposed rule, and therefore we believe these comments are out of scope for this rulemaking. However, we will consider these comments for future refinements to AKI payment policies. We note that currently CMS will only pay for renal dialysis services at an ESRD facility for patients with AKI, and we did not propose to change this policy in the CY 2023 ESRD proposed rule. Current AKI dialysis payment policy was implemented under the CY 2017 ESRD PPS final rule (81 FR 77866 through 77872, and 77965). Over the years, we have received several comments regarding the site of renal dialysis services for Medicare beneficiaries with AKI. We have solicited comments in the recent past, including in the CY 2022 ESRD PPS proposed rule (86 FR 36322, 36408), when we requested information regarding potentially modifying the site of renal dialysis services for patients with AKI and payment for AKI in the home setting. CMS continues to believe that this population requires close medical supervision by qualified staff during their dialysis treatment.

Comment: A few commenters, including a coalition of dialysis organizations and a large dialysis organization, urged CMS to share information about any specific data elements and monitoring plans, as well as the data it is collecting and analyzing while monitoring the AKI benefit.

Response: We appreciate the commenters' support for continued claims data monitoring and analysis. These issues were not the subject of proposals for CY 2023 and therefore are out of scope for this rulemaking. However, we note that we have been monitoring the trends of AKI beneficiaries in ESRD facilities and acute inpatient hemodialysis. This has included quantification of drugs, laboratory tests and other services provided on acute inpatient dialysis claims. We also examine other diagnoses recorded before an acute inpatient dialysis claim. We continue to analyze costs, utilization, patient characteristics, sites of service, as well as data for COVID–19 patients who have experienced AKI. The results of the data analysis will be shared in the future in public use files on the ESRD PPS website and we plan to engage with interested parties further on this issue.

Final Rule Action: We are finalizing the AKI payment rate as proposed, that is, the AKI payment rate is based on the finalized ESRD PPS base rate. Specifically, the final CY 2023 ESRD PPS base rate is $265.57. Accordingly, we are finalizing a CY 2023 per treatment payment rate of $265.57 for renal dialysis services furnished by ESRD facilities to individuals with AKI.

IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the End-Stage Renal Disease Quality Incentive Program's (ESRD QIP's) background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the following final rules:

- CY 2011 ESRD PPS final rule (75 FR 49030);
- CY 2012 ESRD PPS final rule (76 FR 628);
- CY 2012 ESRD PPS final rule (76 FR 70228);
- CY 2013 ESRD PPS final rule (77 FR 67450);
- CY 2014 ESRD PPS final rule (78 FR 72156);
- CY 2015 ESRD PPS final rule (79 FR 66120);
- CY 2016 ESRD PPS final rule (80 FR 68968);
- CY 2017 ESRD PPS final rule (81 FR 77834);
- CY 2018 ESRD PPS final rule (82 FR 50738);
- CY 2019 ESRD PPS final rule (83 FR 56922);
- CY 2020 ESRD PPS final rule (84 FR 60648);
- CY 2021 ESRD PPS final rule (85 FR 71398); and
- CY 2022 ESRD PPS final rule (86 FR 61874).

We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and § 413.178.

B. Flexibilities for the ESRD QIP in Response to the Public Health Emergency (PHE) Due to COVID–19

1. Measure Suppression Policy for the Duration of the COVID–19 PHE

In the CY 2022 ESRD PPS final rule, we finalized a measure suppression policy for the duration of the COVID–19 Public Health Emergency (PHE) (86 FR 61910 through 61913). 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 facilities' control. We identified this need because we would like to ensure that facilities 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 PHE for COVID–19 that enables us to suppress the use of measure data for scoring and payment adjustments if we determine that circumstances caused by the COVID–19 PHE have affected the 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 an ESRD QIP measure for one or more program years where the baseline or performance period of the measure overlaps with the PHE for COVID–19. The finalized Measure Suppression Factors are as follows:

- *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 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 COVID–19 PHE.
- *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 stated that we will still provide confidential feedback reports to facilities 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 will publicly report suppressed measure data with appropriate caveats noting the limitations of the data due to the PHE for COVID–19. We 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 ESRD QIP.

We did not propose any changes to the measure suppression policy.

2. Suppression of Seven ESRD QIP Measures for PY 2023

a. Background

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 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.[208] Provisional life expectancy data for CY 2020 showed that COVID–19 reduced life expectancy by 1.5 years overall, with the estimated impact disproportionately affecting minority communities.[209] According to this analysis, the estimated life expectancy reduction for Black and Latino populations is three times the estimate when comparing to the white population.[210] With a death toll surpassing that of the 1918 influenza pandemic, COVID–19 is the deadliest disease in American history.[211]

Additionally, impacts of the pandemic 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 was up to 60 percent more transmissible than the previously dominant Alpha variant in 2020.[212] Further, in November 2021, the number of COVID–19 deaths for 2021 surpassed the total deaths for 2020. According to Centers for Disease Control and Prevention (CDC) data, the total number of deaths involving COVID–19 reached 385,453 in 2020 and 451,475 in 2021.[213] With this increased transmissibility and morbidity associated with the Delta variant, we remain concerned about using measure data that is significantly impacted by COVID–19 for scoring and payment purposes for the PY 2023 program year.

In the CY 2022 ESRD PPS final rule (86 FR 61913 through 61917), we finalized the suppression of the following measures for the PY 2022 program year:

- Standardized Hospitalization Ratio (SHR) clinical measure
- Standardized Readmission Ratio (SRR) clinical measure
- Long-Term Catheter Rate clinical measure
- In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration clinical measure

Since the publication of the CY 2022 ESRD PPS final rule, we have conducted analyses on all ESRD QIP measures to determine whether and how COVID–19 has impacted the validity of the data used to calculate these measures for PY 2023. Our findings from these analyses are discussed below. Based on those analyses, in the CY 2023 ESRD PPS proposed rule (87 FR 38531 through 38538), we proposed to suppress the following measures for PY 2023:

- SHR clinical measure (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 compared to historical performance during the immediately preceding program years);
- SRR clinical measure (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 compared to historical performance during the immediately preceding program years);
- Long-Term Catheter Rate clinical measure (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 compared to historical performance during the immediately preceding program years);
- In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration clinical measure (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 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; or
  ++ patient case volumes or facility-level case mix);
- Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure (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 compared to historical performance during the immediately preceding program years; and Measure Suppression Factor 4, Significant national shortages or rapid or unprecedented changes in:
  ++ patient case volumes or facility-level case mix); and
- Kt/V Dialysis Adequacy clinical measure (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 compared to historical performance during the immediately preceding program years).

Although we had previously finalized that the mTPS for PY 2023 would be 57, as well as an associated payment reduction scale (85 FR 71471), we proposed in the CY 2023 ESRD PPS proposed rule to update the mTPS and payment reduction scale to reflect our proposal to suppress six measures for PY 2023, which together constitute nearly half of the ESRD QIP measure set (87 FR 38532). We also proposed to amend 42 CFR 413.178(a)(8) to state that the definition of the mTPS does not apply to PY 2023. The measures that we proposed to score for PY 2023 were the Clinical Depression Screening and Follow-Up reporting measure, the Standardized Fistula Rate clinical measure, the Hypercalcemia clinical measure, the Standardized Transfusion Ratio (STrR) reporting measure, the Ultrafiltration Rate reporting measure, the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) reporting measure, the National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI)

[208] *https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/index.html.*

[209] Arias E, Tejada-Vera B, Ahmad F, Kochanek KD. Provisional life expectancy estimates for 2020. Vital Statistics Rapid Release; no 15. Hyattsville, MD: National Center for Health Statistics. July 2021. DOI: *https://dx.doi.org/10.15620/cdc:107201.*

[210] Andrasfay, T., & Goldman, N. (2021). Reductions in 2020 U.S. 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.*

[211] Branswell, Helen. Covid overtakes 1918 Spanish flu as deadliest disease in U.S. history. STAT. September 20, 2021. Available at: *https://www.statnews.com/2021/09/20/covid-19-set-to-overtake-1918-spanish-flu-as-deadliest-disease-in-american-history/.*

[212] 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.

[213] *https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm.*

clinical measure, and the NHSN Dialysis Event reporting measure. In the CY 2023 ESRD PPS proposed rule, we stated that the proposed re-calculated mTPS for PY 2023 will be 80. We also stated that if one or more of our measure suppression proposals is not finalized, then we would revise the mTPS for PY 2023 so that it includes all measures that we finalize for scoring for PY 2023 (87 FR 38532). We also proposed to codify these proposals in our regulations by adding a new 42 CFR 413.178(i), which will specify that we will calculate a measure rate for each of the suppressed measures, but will not score facility performance on those suppressed measures or include them in the facility's TPS for PY 2023. We stated that proposed § 413.178(i) would also define the mTPS for PY 2023 as the total performance score that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national ESRD facility performance on the measures described in proposed § 413.178(i)(2). We note that § 413.178(i) is updated in this final rule to reflect our additional suppression of the Standardized Fistula Rate clinical measure for PY 2023, which we discuss in IV.B.2.d of this final rule. As discussed in section IV.C of this final rule, we are also finalizing our proposal to calculate the performance standards for PY 2023 using CY 2019 data, and we are finalizing our proposal to revise our regulations at § 413.178(d)(2) to reflect this finalized policy.

We continue to be concerned about the impact of the COVID–19 PHE, but we are encouraged by the rollout of COVID–19 vaccinations and treatment for those diagnosed with COVID–19 and we believe that facilities 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 incentivizing quality care tied to payment. The ESRD QIP is an example of our long-standing effort to link payments to health care quality in the dialysis facility setting.[214]

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, health care providers have gained experience managing the disease, surges of COVID–19 infection, and adjusting to supply chain fluctuations. In 2022 and the upcoming years, we anticipate continued availability and increased uptake in the use of vaccinations,[215] including the availability and use of vaccination for young children ages 5 to 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.[216] [217] Additionally, 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.[218] [219] Finally, the Biden-Harris Administration has mobilized efforts to distribute home test kits,[220] N–95 masks,[221] and increase COVID–19 testing in schools,[222] providing more treatment and testing to the American people. Therefore, our goal is to continue resuming the use of all measure data for scoring and payment adjustment purposes beginning with the PY 2024 ESRD QIP. That is, for PY 2024, for each facility, we will plan to calculate measure scores for all of the measures in the ESRD QIP measure set for which the facility reports the minimum number of cases. We will then calculate a TPS for each eligible facility and use the established methodology to determine whether the facility will receive a payment reduction for the given payment year. We understand that the PHE for COVID–19 is ongoing and unpredictable in nature, and we would continue to assess the impact of the PHE on measure data used for the ESRD QIP.

We received public comments on our measure suppression proposals, and we respond to them below.

Comment: Many commenters expressed support for our proposal to suppress six measures for PY 2023. Several commenters expressed support for the proposed measure suppressions because national performance has been distorted due to the impact of the PHE. One commenter noted that the substantial impact of the PHE on ESRD patients due to increased risk of infection, reinfection, and complications from COVID–19 is also underscored by the workforce shortage.

Response: We thank commenters for their support.

Comment: A few commenters supported the policy to publicly report suppressed measure data and PY 2023 performance scores with appropriate caveats.

Response: We thank commenters for their support.

Comment: Several commenters recommended that CMS suppress all measures for PY 2023. A few commenters requested that CMS suppress all ESRD QIP measures for PY 2023 due to current economic conditions, workforce shortages, and continued challenges stemming from the impact of the COVID–19 PHE on facilities. One commenter suggested that remaining ESRD QIP measures could be suppressed under Measure Suppression Factor 4 due to severe staffing and supply shortages that impacted facilities in CY 2021.

Response: We thank the commenters for their recommendation and acknowledge commenters' concerns

[214] 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.*

[215] 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.*

[216] 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/.*

[217] *https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-vaccination-trends/.*

[218] 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.*

[219] 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.*

[220] 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/.*

[221] 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.*

[222] 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/.*

regarding economic conditions, workforce shortages, and continued challenges due to the COVID–19 PHE. However, we disagree with these commenters that measure suppression is necessary for all ESRD QIP measures for PY 2023 because our analyses do not indicate that all ESRD QIP measures are eligible for suppression under our previously finalized Measure Suppression Factors. Following publication of the CY 2023 ESRD PPS proposed rule, we considered public comments and updated our analyses to determine whether measure suppression continued to be appropriate for the measures we proposed to suppress, and also whether measure suppression was warranted for any of the measures we did not propose to suppress in the proposed rule. With the exception of the Standardized Fistula Rate clinical measure, which we are finalizing for suppression as discussed in section IV.B.2.d of this final rule, we concluded that the remaining non-suppressed measures have not been affected by the COVID–19 PHE such that measure suppression would be warranted under our previously finalized Measure Suppression Factors. For example, our analyses of measure score distributions for non-suppressed measures for PY 2023 indicate that they are generally consistent with historical measure score distributions for those measures. Therefore, we concluded that non-suppressed measures did not experience significant deviation in national performance during the COVID–19 PHE in PY 2023 and would not be eligible for measure suppression under Measure Suppression Factor 1. Nothing in our analyses indicated that these measures would be eligible for measure suppression under Measure Suppression Factor 2, clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the COVID–19 PHE, or 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. Although Measure Suppression Factor 4 permits measure suppression where there have been significant national shortages or rapid or unprecedented changes in healthcare personnel, such as in the ICH CAHPS measure and the PPPW clinical measure (as discussed in IV.B.2.e and IV.B.2.f of this final rule), our analyses did not indicate that the remaining measures were significantly impacted due to such changes. We note that general changes in economic conditions are not justifications for measure suppression under our previously finalized measure suppression policy. Although we appreciate the continuing impact of the COVID–19 PHE on facilities in CY 2021, we believe that facilities have had time to adjust to the new COVID–19 health care landscape and should be scored on those measures which our analyses have indicated were not significantly impacted by the COVID–19 PHE in CY 2021. We disagree with the commenter's suggestion that all remaining ESRD QIP measures could be suppressed due to severe staffing and supply shortages in CY 2021. Although we are aware of anecdotal reports indicating the impact of staffing and supply shortages on facilities, our analyses did not support measure suppression under Measure Suppression Factor 4 for non-suppressed measures.

Comment: One commenter recommended that CMS suppress the NHSN BSI clinical measure under Measure Suppression Factor 3 due to changes in clinical guidelines and care delivery in response to the COVID–19 PHE. The commenter noted that the COVID–19 PHE has created challenges in care delivery and treatment related to catheter removal and fistula insertion, which has led to the use of more catheters and increased likelihood of infection.

Response: Suppressing the NHSN BSI clinical measure would not be appropriate under Measure Suppression Factor 3 based on our analyses. To be eligible for measure suppression under Measure Suppression Factor 3, there must be 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. Our analyses did not indicate the existence of such an impact on the number of new positive blood culture events based on blood cultures drawn as an outpatient or within one calendar day after a hospital admission, nor is such impact reflected in measure score distributions for the NHSN BSI clinical measure for PY 2023. Although challenges in care delivery and treatment related to catheter removal and arteriovenous fistula (AVF) creation may have resulted in an increased likelihood of patient infection in certain cases, our analyses did not indicate that either of those circumstances directly resulted in patients developing more bloodstream infections due to the COVID–19 PHE.

Comment: One commenter recommended that CMS suppress the Ultrafiltration Rate reporting measure, noting that the Ultrafiltration Rate measure requires input of a Kt/V date and the Kt/V Dialysis Adequacy measure is proposed for suppression for PY 2023. The commenter expressed concern that this will impact a provider's ability to report the Ultrafiltration Rate measure and therefore the Ultrafiltration Rate reporting measure should also be suppressed.

Response: We disagree that it is necessary to suppress the Ultrafiltration Rate reporting measure because the measure specifications include data that are also used to calculate the Kt/V Dialysis Adequacy clinical measure. Although we proposed (and are finalizing below) that we would suppress the Kt/V Dialysis Adequacy measure for PY 2023 for use in scoring, facilities will still be required to report data on that measure (as well as on all other PY 2023 suppressed measures), including the Kt/V date. Therefore, the suppression of the Kt/V Dialysis Adequacy clinical measure should not impact a facility's ability to complete the data submission requirements for the Ultrafiltration Rate reporting measure.

Comment: One commenter recommended that CMS also suppress the Hypercalcemia clinical measure for PY 2023, stating that it does not make sense to score the measure in light of CMS's proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning with PY 2025. The commenter also stated that the Hypercalcemia measure should be suppressed under Measure Suppression Factor 4 due to shortages in prescription drugs needed to treat hypercalcemia.

Response: We disagree with the commenter's suggestion that we should suppress the Hypercalcemia clinical measure in PY 2023 because we proposed to convert that measure to a reporting measure beginning with PY 2025. Whether a measure is a clinical measure or a reporting measure is irrelevant to whether suppression is warranted under our previously finalized measure suppression policy, which enables us to suppress the use of measure data for scoring and payment purposes if we determine that circumstances caused by the COVID–19 PHE have affected a given measure. Our analyses indicate that facility

performance on the Hypercalcemia clinical measure was not significantly impacted by the COVID–19 PHE in CY 2021 for PY 2023, as the scoring simulations for the Hypercalcemia clinical measure showed that measure performance was consistent with performance from previous years. Therefore, the measure would not be eligible for measure suppression under Measure Suppression Factor 1. We did not observe any data for CY 2021 indicating a proximate relationship between bone mineral metabolism to the health impacts of the COVID–19 PHE. Therefore, the measure would not be eligible for measure suppression under Measure Suppression Factor 2. To be eligible for measure suppression under Measure Suppression Factor 3, there must be 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. Our data showed that measure performance remained high and did not indicate the existence of such an impact on the number of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL or missing, nor is such impact reflected in measure score distributions for the Hypercalcemia clinical measure for PY 2023. Finally, we did not observe that the measure was affected by significant national shortages or rapid or unprecedented changes in patient-case volumes or facility-level case mix to be eligible for suppression under Measure Suppression Factor 4. Therefore, we concluded that suppression of the Hypercalcemia clinical measure is not warranted under any of our previously finalized Measure Suppression Factors.

Comment: Many commenters recommended that, in addition to measure suppression, CMS suspend scoring and payment penalties for PY 2023 similar to the special scoring and payment policy for PY 2022. Several commenters recommended that CMS avoid enforcing penalties for the PY 2023 ESRD QIP due to continued challenges faced by facilities during the COVID–19 PHE, such as current economic conditions, workforce shortages, patient reluctance to seek care for fear of COVID–19 infection, and increased rates of kidney failure because of COVID–19. A few commenters expressed concern that the PHE has impacted facilities' ability to report data and that the decreased data submissions will skew data results. One commenter also cited data integrity issues in EQRS as a reason for suspending penalties in PY 2023. A few commenters suggested that suspending scoring and penalties for PY 2023 will align with the approach taken by the Hospital Value-Based Purchasing (VBP) Program, stating that the scoring methodology will not accurately reflect facility performance during the COVID–19 PHE.

Response: We thank the commenters for their suggestions, but we disagree that a special scoring and payment policy for PY 2023 is necessary. Although we finalized a special scoring and payment rule for PY 2022 in the CY 2022 ESRD PPS final rule, we note that the circumstances surrounding that policy were quite different. First, the PY 2022 performance period was shortened by an ECE granted by CMS during the beginning of the COVID–19 PHE, which allowed dialysis facilities to focus on pandemic response instead of reporting quality measure data for the first and second quarter CY 2020 data. Second, in light of data submission issues associated with the transition to EQRS, we were concerned about the amount of reliable CY 2020 data that would be available for scoring. In CY 2021 for PY 2023, although some of the measures are still impacted by the PHE, we believe that facilities have had time to begin adjusting to the new COVID–19 health care landscape and should be scored on those measures which our analyses have indicated were not significantly impacted by the PHE. Our analyses indicate that data submissions for non-suppressed measures have not decreased so significantly such that they will skew data results, and that we have resolved any issues with EQRS that could impact the integrity of the data for PY 2023 and for subsequent years going forward. Regarding the comments recommending that we suspend scoring and payment to align with other VBP programs, we note that although certain VBP programs included special scoring and payment rules for FY 2023 in the FY 2023 IPPS/LTCH PPS final rule, we believe the circumstances are different for the ESRD QIP. In the CY 2023 ESRD PPS proposed rule, we proposed to suppress less than half of the total measures in the ESRD QIP measure set for PY 2023 and facilities will still be eligible to be scored on measures in three out of the four total domains (87 FR 38531 through 38538). By contrast, the Hospital VBP Program suppressed more than half of the measures in its program and hospitals would only be eligible to be scored on measures in two out of the four total domains (87 FR 49094 through 49105). Although we are now suppressing half of the current ESRD QIP measures with the additional suppression of the Standardized Fistula Rate measure, which we discuss in section IV.B.2.d of this final rule, facilities will still be eligible to be scored on measures in three out of the four total domains.

Comment: Several commenters expressed concern that scoring facilities on non-suppressed measures will not produce a meaningful representation of a facility's quality performance due to a skewed TPS, resulting in unfair penalties for facilities. A few commenters expressed concern on the proposal to recalculate the mTPS for non-suppressed measures for PY 2023. One commenter noted that 80 is a very high mTPS especially in light of the ongoing pandemic and that resulting PY 2023 penalties for clinics may be higher than they would otherwise be with a full measure set. A few commenters noted that the impact of the suppressed measures on the mTPS would skew the scoring of non-suppressed measures by significantly shifting the weight of measures such as the Clinical Depression reporting measure, the Standardized Fistula Rate measure, and the STrR reporting measure. One commenter also expressed concern with the resulting increased weights of the Hypercalcemia measure and the NHSN BSI clinical measure in scores for PY 2023.

Response: Although we acknowledge these commenters' concerns, we believe that it is appropriate to score facilities on non-suppressed measures. We are not suppressing these particular measures because our analyses have indicated that they were not significantly impacted by the COVID–19 PHE to fit within the scope of our measure suppression policy, as applied to PY 2023. Scoring a facility on non-suppressed measures will provide meaningful information to patients and caregivers regarding that facility's performance on those non-suppressed measures. Therefore, we believe that it is appropriate to finalize our proposal to update the mTPS for PY 2023 so that it only includes non-suppressed measures. We note that, with the additional suppression of the Standardized Fistula Rate clinical measure as discussed in section IV.B.2.d of this final rule, the recalculated mTPS for PY 2023 will be 83. We provide the updated payment reduction scale for PY 2023 in Table 16 below:

TABLE 16: Finalized Payment Reduction Scale for PY 2023 Based on the Most Recently Available Data

Total performance score	Reduction (%)
100-83	0%
82-73	0.5%
72-63	1.0%
62-53	1.5%
52-0	2.0%

Although the recalculated mTPS for PY 2023 is higher than we proposed in the proposed rule, we estimate that fewer facilities will receive payment reductions for PY 2023. We anticipate that only approximately 10.5 percent of facilities will receive payment reductions for PY 2023 with the recalculated mTPS of 83. For comparison, in the CY 2021 ESRD PPS final rule, we estimated that approximately 24.2 percent of facilities would receive payment reductions for PY 2023 based on our previously finalized mTPS of 57 (85 FR 71480). Although we acknowledge that certain measures may be weighted more heavily due to the reduced measure set, we do not believe this will result in facilities being unfairly penalized for their performance on those measures because our analyses indicate that facility performance on those measures remains high.

Comment: One commenter expressed support for CMS's intention to resume the use of all measure data for the PY 2024 ESRD QIP, and noted its appreciation for CMS's flexibilities in response to the PHE thus far.

Response: We thank the commenter for its support.

Final Rule Action: After considering public comments, we are finalizing our proposal to amend 42 CFR 413.178(a)(8) to state that the definition of the mTPS does not apply to PY 2023. Additionally, we are finalizing the addition of a new § 413.178(i). The version of § 413.178(i) that we are finalizing is different than the proposed § 413.178(i) due to our additional suppression of the Standardized Fistula Rate clinical measure for PY 2023, which we discuss in IV.B.2.d of this final rule. Section 413.178(i) will specify that we will calculate a measure rate for each of the suppressed measures listed in § 413.178(i)(1), but will not score facility performance on those suppressed measures or include them in the facility's TPS for PY 2023. Section 413.178(i) will also specify that we will score facility performance on each of the non-suppressed measures listed in § 413.178(i)(2).

b. Suppression of the SHR Clinical Measure for PY 2023

In the proposed rule, we proposed to suppress the SHR clinical measure for the PY 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 (87 FR 38532 through 38533). We referred readers to the CY 2022 ESRD PPS final rule for previous analysis on the impact of the COVID–19 PHE on SHR clinical measure performance (86 FR 61914 through 61915). The SHR clinical measure is an all-cause, risk-standardized rate of hospitalizations during a 1-year observation window. The standardized hospitalization ratio is defined as the ratio of the number of hospital admissions that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of hospitalizations that will be expected given the characteristics of the facility's patients and the national norm for facilities. This measure is calculated as a ratio but can also be expressed as a rate. The intent of the SHR clinical measure is to improve health care delivery and care coordination to help reduce unplanned hospitalization among ESRD patients.

In the CY 2023 ESRD PPS proposed rule, we stated that based on our analysis of Medicare dialysis patient data from January 2021 through September 2021, we found that hospitalizations involving patients diagnosed with COVID–19 resulted in higher mortality rates, higher rates of discharge to hospice or skilled nursing facilities, and lower rates of discharge to home than hospitalizations involving patients who were not diagnosed with COVID–19 (87 FR 38533). Specifically, the hospitalization rate for Medicare dialysis patients diagnosed with COVID–19 was up to three times greater than the hospitalization rate during the same period for Medicare dialysis patients who were not diagnosed with COVID–19, which is much greater than the relative risk of hospitalization for any other comorbidity. Similar to our analysis in the CY 2022 ESRD PPS final rule (86 FR 61915), we stated our belief that this indicates that COVID–19 has had a significant impact on the hospitalization rate for dialysis patients. Because COVID–19 Medicare dialysis patients are at significantly greater risk of hospitalization, and the SHR clinical measure was not developed to account for the impact of COVID–19 on this patient population, we stated that we continue to be concerned about the effects of the observed COVID–19 hospitalizations on the SHR clinical measure. We also noted that the waves of the Delta and Omicron variants during 2021 affected different regions of the country at different rates depending on factors like time of year, geographic density, State and local policies, and health care system capacity.[223] [224]

[223] Cuadros DF, Miller FD, Awad S, Coule P, MacKinnon NJ. Analysis of Vaccination Rates and New COVID–19 Infections by US County, July-August 2021. *JAMA Netw Open.* 2022;5(2):e2147915. doi:10.1001/jamanetworkopen.2021.47915.

Continued

Because of the increased hospitalization risk associated with COVID–19 and the Medicare dialysis patient population, we stated our concern that these regional differences in COVID–19 rates have led to distorted hospitalization rates such that we could not reliably make national, side-by-side comparisons of facility performance on the SHR clinical measure.

We also analyzed data from January 2020 through September 2021, which indicates that hospitalization [225] and mortality rates [226] were 6 times higher in the ESRD population. Although our initial measure suppression analysis focused on CY 2020 and CY 2021 data and we only had partial CY 2021 data available at the time of the proposed rule, our updated analyses indicate that the remaining 2021 data continued to show similar trends. Not only are there effects on patients diagnosed with COVID–19, but our data indicates that the presence of the virus continued to strongly affect hospital admission patterns of dialysis patients through December 2021.

Following emergence of the Delta variant in 2021, we noted that we have also observed disproportionate increases in COVID–19 cases and related deaths among ESRD beneficiaries. Similarly, emergence of the Omicron variant in December 2021 was followed by another mortality spike. Because the COVID–19 pandemic generally, and the Delta and Omicron waves specifically, swept through geographic regions of the country unevenly, we stated that we were additionally concerned that facilities in different regions of the country would have been affected differently throughout 2021, thereby skewing measure performance and affecting national comparability. Based on the impact of COVID–19 on SHR results, including the continued deviation in measurement, we stated our belief that the SHR clinical measure meets our criteria for Factor 1 where performance data would significantly deviate from historical data performance and would be considered unreliable. Therefore, we believed that the resulting performance measurement on the SHR clinical measure would not be sufficiently reliable or valid for use in the ESRD QIP for scoring and payment adjustment purposes.

In the proposed rule, we stated our belief that the SHR clinical measure is an important part of the ESRD QIP measure set. However, we were concerned that the COVID–19 PHE will continue affecting measure performance on the current SHR clinical measure such that we will not be able to score facilities fairly or equitably on it for PY 2023. We proposed to continue to collect the measure's claims data from participating facilities so that we can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We also proposed to continue providing confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We noted our intent to publicly report PY 2023 data where feasible and appropriately caveated.

In the CY 2022 ESRD PPS final rule, we stated that we were currently exploring ways to adjust effectively for the systematic effects of the COVID–19 PHE on hospital admissions for the SHR clinical measure (86 FR 61915). We discussed our technical specifications update to the SHR clinical measure to risk-adjust for patients with a history of COVID–19 in section IV.B.3 of the CY 2023 ESRD PPS proposed rule (87 FR 38538).

We welcomed public comment on our proposal to suppress the SHR clinical measure for PY 2023. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for our proposal to suppress six measures for PY 2023, including our proposal to suppress the SHR clinical measure. Several commenters expressed support for the proposed measure suppression because national performance has been distorted due to the impact of the COVID–19 PHE.

Response: We thank commenters for their support. Since the publication of the proposed rule, an updated analysis showed a continued deviation in SHR clinical measure performance throughout CY 2021. We believe that this updated analysis confirms our earlier concerns regarding the impact of the COVID–19 PHE on national performance and justifies suppression of the SHR clinical measure under Measure Suppression Factor 1.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the SHR clinical measure for PY 2023. We will also publicly report the data with appropriate caveats.

c. Suppression of the SRR Clinical Measure for PY 2023

In the proposed rule, we proposed to suppress the SRR clinical measure for the PY 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 compared to historical performance during the immediately preceding program years (87 FR 38533 through 38534). We referred readers to the CY 2022 ESRD PPS final rule for previous analysis on the impact of the COVID–19 PHE on SRR clinical measure performance (86 FR 61915 through 61916). The SRR clinical measure assesses the number of readmission events for the patients at a facility, relative to the number of readmission events that will be expected based on overall national rates and the characteristics of the patients at that facility as well as the number of discharges. The intent of the SRR clinical measure is to improve care coordination between ESRD facilities and hospitals to improve communication prior to and post discharge.

In the proposed rule, we stated that based on our analysis, we have found that index discharge hospitalizations involving dialysis patients diagnosed with COVID–19 resulted in lower readmissions and higher mortality rates within the first 7 days in 2021. We used index hospitalizations occurring from January 2020 through August 2021 to identify eligible index hospitalizations and unplanned hospital readmissions. Focusing on the partial year data for 2021, we found that total hospital readmissions, average number of index discharges, and average number of readmissions were lower than in full-year data for 2018 and 2019. We noted that our analysis of 2020 data revealed that overall average readmission rates were similar to pre-COVID years, but that hospitalization in COVID–19 patients resulted in very different outcomes, with increased in-hospital and early post-discharge death and increased discharge to subacute rehabilitation facilities. We stated that although our measure suppression focuses on CY 2021 data and we only have partial CY 2021 data available at this time, we believed that the remaining 2021 data will continue to show similar trends. Our analysis of partial year data for 2021 found that

[224] Iuliano AD, Brunkard JM, Boehmer TK, et al. Trends in Disease Severity and Health Care Utilization During the Early Omicron Variant Period Compared with Previous SARS–CoV–2 High Transmission Periods—United States, December 2020–January 2022. MMWR Morb Mortal Wkly Rep 2022;71:146–152. DOI: *http://dx.doi.org/10.15585/mmwr.mm7104e4external* icon.

[225] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-services-through-2021–08–21.pdf.*

[226] Turgutalp, K., Ozturk, S., Arici, M. et al. Determinants of mortality in a large group of hemodialysis patients hospitalized for COVID–19. BMC Nephrol 22, 29 (2021). *https://doi.org/10.1186/s12882–021–02233–0.*

average re-admission rates were slightly lower overall compared to 2018 and 2019. Although we noted that we were still analyzing the data for 2021, we believed that similar to 2020, these competing outcomes of index hospitalization continued to have a significant effect on readmission rates, affecting interpretation of hospitalization outcomes between COVID-associated and non-COVID events. Based on this demonstrated association between recent COVID–19 infection and altered patterns of hospitalization and readmission compared to those for non-infected ESRD patients, we remained concerned about the effects of these observations on the calculations for the SRR clinical measure. We noted that our preliminary analyses only looked at data through August 2021, which would not fully capture readmission data from the Delta or Omicron surges of the COVID–19 PHE. Based on the impact of COVID–19 on SRR results, including the continued deviation in measurement, we stated our belief that the SRR clinical measure meets our criteria for Factor 1 where performance data would significantly deviate from historical data performance and would be considered unreliable. Therefore, we believed that the resulting performance measurement on the SRR clinical measure would not be sufficiently reliable or valid for use in the PY 2023 ESRD QIP for scoring and payment adjustment purposes. Since the proposed rule, our updated analyses found that COVID–19 infection continued to impact the SRR clinical measure throughout CY 2021.

In the proposed rule, we stated our belief that the SRR clinical measure is an important part of the ESRD QIP Program measure set. However, we remained concerned that the PHE for the COVID–19 pandemic continued to affect measure performance on the current SRR clinical measure such that we would not be able to score facilities fairly or equitably on it for PY 2023. Additionally, we proposed continuing to collect the measure's claims data from participating facilities so that we can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We noted our intent to publicly report PY 2023 data where feasible and appropriately caveated.

In the CY 2022 ESRD PPS final rule, we stated that we were currently exploring ways to adjust effectively for the systematic effects of the COVID–19 PHE on hospital admissions for the SRR clinical measure (86 FR 61916). We discussed our technical specifications update to the SRR clinical measure to risk-adjust for patients with a history of COVID–19 in section IV.B.3 of the CY 2023 ESRD PPS proposed rule (87 FR 38538).

We welcomed public comment on our proposal to suppress the SRR clinical measure for PY 2023. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for our proposal to suppress six measures for PY 2023, including our proposal to suppress the SRR clinical measure. Several commenters expressed support for the proposed measure suppression because national performance has been distorted due to the impact of the COVID–19 PHE.

Response: We thank commenters for their support. Since the publication of the proposed rule, an updated analysis showed a continued deviation in SRR clinical measure performance throughout CY 2021. We believe that this updated analysis confirms our earlier concerns regarding the impact of the COVID–19 PHE on national performance and justifies suppression of the SRR clinical measure under Measure Suppression Factor 1.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the SRR clinical measure for PY 2023. We will also publicly report the data with appropriate caveats.

d. Suppression of the Long-Term Catheter Rate Clinical Measure for PY 2023

In the proposed rule, we proposed to suppress the Long-Term Catheter Rate clinical measure for PY 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 (87 FR 38534 through 38535). We referred readers to the CY 2022 ESRD PPS final rule for previous analysis on the impact of the COVID–19 PHE on the Long-Term Catheter Rate clinical measure for PY 2022 (86 FR 61917).

In the CY 2018 ESRD PPS final rule, we finalized the inclusion of the Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure in the ESRD QIP measure set beginning with the PY 2021 program (82 FR 50778). The Long-Term Catheter Rate clinical measure is defined as the percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access. The measure is based on vascular access data reported in CMS' ESRD Quality Reporting System (EQRS) (previously, CROWNWeb) and excludes patient-months where a patient has a catheter in place and has a limited life expectancy. The measure evaluates the vascular access type used to deliver hemodialysis. The intent of the Long-Term Catheter Rate clinical measure is to improve health care delivery and patient safety.

In the CY 2023 ESRD PPS proposed rule, we stated that our analysis based on the available data indicated that long-term catheter use rates increased significantly during the COVID–19 PHE (87 FR 38534). Average long-term catheter rates were averaging around 12 percent during the period CY 2017 through early CY 2020. As we noted in the CY 2022 ESRD PPS final rule, we observed an increase in long-term catheter rates during the pandemic in CY 2020, with rates reaching a peak of 14.7 percent in June 2020 and declining slightly to 14.3 percent in July and August 2020 (86 FR 61917). After remaining around 12 percent for 3 consecutive years, in the CY 2022 ESRD PPS final rule we stated that we view a sudden 2 percent increase in average long-term catheter rates as a significant deviation compared to historical performance during immediately preceding years (86 FR 61917). In the CY 2023 ESRD PPS proposed rule, we noted that since then, we have observed a steady rate increase throughout CY 2021, with unadjusted catheter rates reaching a peak of 17.9 percent in September 2021 (87 FR 38534). By contrast, the unadjusted catheter rates in CY 2019 peaked at 12 percent. We stated our belief that the steep increase in catheter rates during CY 2021 indicates a significant deviation in performance on the Long-Term Catheter Rate clinical measure. We were concerned that the COVID–19 PHE continued to impact the ability of ESRD patients to seek treatment from medical providers regarding their catheter use, either due to difficulty accessing treatment due to COVID–19 precautions at health care facilities, or due to increased patient reluctance to seek medical treatment because of risk of COVID–19 precautions at health care facilities, or due to increased patient reluctance to seek medical treatment because of risk of COVID–19 exposure and increased associated health risks,

and that these contributed to the significant increase in long-term catheter use rates.

We stated our belief that the Long-Term Catheter Rate clinical measure is an important part of the ESRD QIP measure set. However, we were concerned that the PHE for COVID–19 affected measure performance on the current Long-Term Catheter Rate clinical measure such that we would not be able to score facilities fairly or equitably on it for PY 2023. Additionally, we stated that participating facilities would continue to report the measure's data to CMS so that we could monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We noted that we would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also stated our intent to publicly report PY 2023 data where feasible and appropriately caveated.

We welcomed public comment on our proposal to suppress the Long-Term Catheter Rate clinical measure for PY 2023. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for our proposal to suppress six measures for PY 2023, including our proposal to suppress the Long-Term Catheter Rate clinical measure. Several commenters expressed support for the proposed measure suppression because national performance has been distorted due to the impact of the COVID–19 PHE.

Response: We thank commenters for their support. Since the publication of the proposed rule, an updated analysis showed a continued deviation in Long-Term Catheter Rate clinical measure performance throughout CY 2021. We believe that this updated analysis confirms our earlier concerns regarding the impact of the COVID–19 PHE on national performance and justifies suppression of the Long-Term Catheter Rate clinical measure under Measure Suppression Factor 1.

Comment: Several commenters recommended that CMS also suppress the Standardized Fistula Rate measure, expressing concern that performance on the Standardized Fistula Rate measure is directly linked to the Long-Term Catheter Rate measure that was proposed for suppression and noting that the same factors impacting the Long-Term Catheter Rate measure also impacted the Standardized Fistula Rate measure because the COVID–19 PHE impacted patient access to vascular access related procedures. A few commenters noted that vascular access procedures were halted and slowed due to the PHE, which meant that patients were not able to access fistula-related procedures or treatment, leading to an increase in long-term catheter use and a decrease in the placement of fistulas. A few commenters requested that CMS suppress the Standardized Fistula Rate measure under Measure Suppression Factor 1 because the measure experienced a significant deviation in national performance during the pandemic. One commenter recommended that CMS suppress the Standardized Fistula Rate measure under Measure Suppression Factor 4, due to shortages in healthcare personnel. The commenter stated that due to the personnel shortage, facilities have had challenges finding available vascular surgeons for fistula placements.

Response: We thank commenters for their feedback. Although we initially considered proposing suppression of the Standardized Fistula Rate measure, we concluded at the time we developed the proposed rule that the measure should not be suppressed under any of the Measure Suppression Factors based on the data available at that time. However, since the proposed rule, we have updated our analyses and have reviewed newly available updated measure data that captures national fistula rates over the entirety of CY 2021. Based on these updated data, as described in Tables 17, 18, and 19 below, we have concluded that the Standardized Fistula Rate clinical measure should be suppressed PY 2023 under 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 as compared to historical performance during the immediately preceding program years. Table 17 shows that we have found significant (p-value <0.001) deviation in national fistula rates in CY 2021 compared to CY 2019. Table 18 shows the significant decline in national fistula rates over the course of CY 2021, which we believe aligns with COVID–19 surges throughout that year. Finally, Table 19 shows the relationship between long-term catheter rates and standardized fistula rates during CY 2021—that is, as catheter rates increased, fistula rates correspondingly decreased. We believe these updated analyses, which now capture national fistula rates for all of CY 2021, support the suppression of both vascular access type measures under Measure Suppression Factor 1.

TABLE 17: Regression Slopes for Monthly Measure Rates in 2019 and Afterwards

Measure	(a) Slope 2019	(b) Slope 7/2020 – 12/2020	a vs. b p-value	(c) Slope 1/2020 – Dec-21	a vs. c p-value	(d) slope 2021	a vs. d p-value
Fistula rate	-0.0212	-0.0366	0.742	-0.0967	<0.001	-0.1068	<0.001
Catheter rate	0.0373	-0.003	0.162	0.1129	<0.001	0.1381	<0.001

TABLE 18: Unadjusted Fistula Rates, January 2018 - March 2022

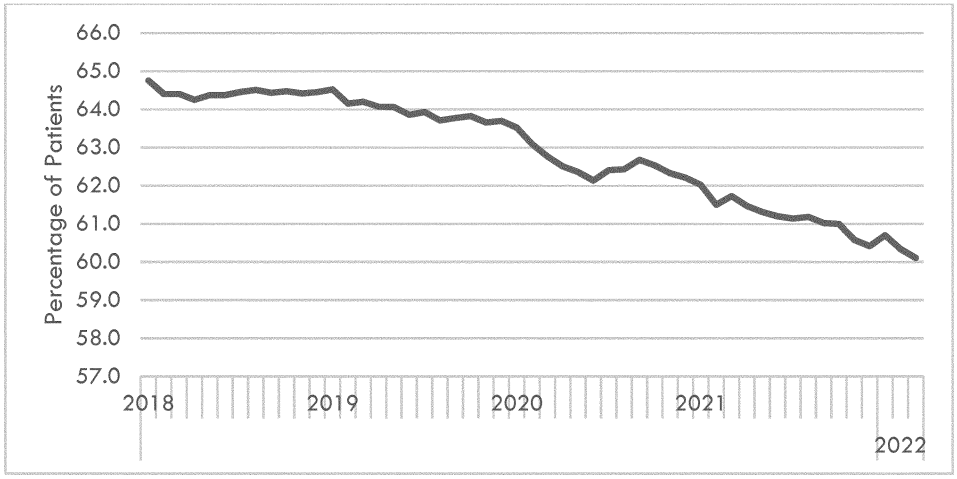
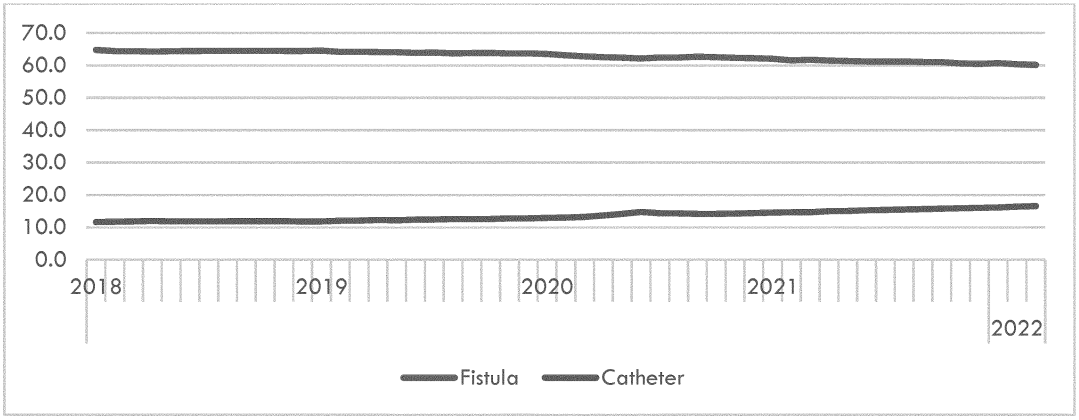


TABLE 19: Vascular Access Type Unadjusted Rates, January 2018 - March 2022



Although we did not propose suppression of the Standardized Fistula Rate measure in the CY 2023 ESRD PPS proposed rule, we believe that the circumstances caused by the COVID–19 PHE that have significantly affected the Long-Term Catheter Rate clinical measure have also affected Standardized Fistula Rate clinical measure and resulting performance score. The same barriers to surgical care for catheter reduction also prevented patients from receiving surgical care for AV Fistulas. During various times throughout the COVID–19 PHE, vascular access procedures were halted and slowed in many areas around the country as COVID–19 volumes surged. The lack of procedures likely meant that fistulas were not created in many cases. For those patients who received an AV fistula, some were not able to undergo procedures required to assist in the maturation of the fistula. In other instances, patients whose access failed were not able to access the services to repair them. All of these factors led to an increase in long-term catheter use and a decrease in the placement of fistulas during CY 2021, as indicated by the data shown in Tables 17 and 19 above, resulting in significant deviation in national performance on both measures during the PHE for COVID–19 in PY 2023. Therefore, we believe that suppression of the Standardized Fistula Rate measure in this final rule is appropriate under Measure Suppression Factor 1.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the Long-Term Catheter Rate clinical measure for PY 2023. We are also finalizing the suppression of the Standardized Fistula Rate clinical measure for PY 2023. We will also publicly report the data for these measures with appropriate caveats.

e. Suppression of the ICH CAHPS Clinical Measure for PY 2023

In the CY 2023 ESRD PPS proposed rule, we proposed to suppress the ICH CAHPS measure for the PY 2023 program year under 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 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 and patient case mix (87 FR 38535 through 38536). We stated that we would calculate facilities' ICH CAHPS measure rates, but we would not use these measure rates to generate achievement or improvement points for this measure. Participating facilities 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 noted that we would continue to provide confidential feedback reports to facilities as part of program activities to allow facilities to track the changes in performance rates that we observe. We also stated our intent to publicly report CY 2021 measure rate data where feasible and appropriately caveated. As we noted in section IV.B.1 of the 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 (87 FR 38531).

In the CY 2022 ESRD PPS final rule (86 FR 61916 through 61917), we finalized our proposal to suppress the ICH CAHPS clinical measure for the PY 2022 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 compared to historical performance during the immediately preceding program years. Based on our analysis of CY 2020 ICH CAHPS data, we finalized our proposal to suppress the ICH CAHPS clinical measure for PY 2022 because we found a significant decrease in response scores as compared to previous years. In the CY 2023 ESRD PPS proposed rule, we noted that our most recent analysis that included Spring 2021 ICH CAHPS data showed a continued deviation in ICH CAHPS scores (87 FR 38535).

The ICH CAHPS clinical measure is scored based on three composite measures and three global ratings.[227] Global ratings questions employ a scale of 0 to 10, worst to best; each of the questions within a composite measure use either ''Yes'' or ''No'' responses, or response categories ranging from ''Never'' to ''Always'' to assess the patient's experience of care at a facility. Facility performance on each composite measure is determined by the percent of patients who choose ''top-box'' responses (that is, most positive or ''Always'') to the ICH CAHPS survey questions in each domain. The ICH CAHPS survey is administered twice yearly, once in the spring and once in the fall.

In the proposed rule, we stated that our most recent data indicated that, although the number of participating facilities that submitted data had increased from pre-COVID–19 levels, the number of completed interviews had dropped dramatically. For example, in Spring and Fall 2019, facilities reported 98,868 and 96,255 completed interviews, respectively. By contrast, in Spring and Fall 2021, only 82,987 and 61,930 completed interviews were submitted, respectively. In other words, although a larger number of facilities are submitting ICH CAHPS data, fewer patients within each of those facilities are completing interviews and, as a result, a fewer number of facilities are meeting the survey minimum to be included in the measure for ESRD QIP scoring purposes because of the continuing impact of the PHE.

We stated our belief that these data may also reflect a rapid and unprecedented change in healthcare personnel, as staffing shortages may have had an impact on some of the top box rating scores.

During the course of the PHE, an unprecedented number of healthcare personnel have left the workforce or ended their employment in healthcare settings.[228] 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 shortages hospitals reported in 2020.[229] Although we noted that there was no specific data regarding the healthcare personnel shortages in facilities, reports indicated that facilities have experienced similar staffing shortages.[230] Healthcare workers, especially those in areas with higher infection rates, have reported serious psychological symptoms, including anxiety, depression, and burnout.[231] [232]

Additionally, in the proposed rule we noted that reports of 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.[233] 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. We stated our belief that these staffing shortages reported by hospitals were similar to those experienced by facilities, and that the shortages experienced by ESRD facilities may be even worse due to the highly specialized nature of nephrology staff. Given the wide variance in reported staffing shortages, and the impact staffing shortages may have on ICH CAHPS top box rating scores, we believed our proposal to suppress the ICH CAHPS measure fairly addresses the geographic disparity in the impact of the COVID–19 PHE on participating facilities.

Due to the emergence of COVID–19 variants, such as the Delta and Omicron variants that have arisen from COVID–19 and our belief that facilities have experienced worsening staffing shortages in Q3 and Q4 2021,[234] [235] we anticipated that Fall 2021 data would continue to demonstrate a deviation in national performance such that scoring this measure would not allow us to reliably make national, side-by-side comparisons of facility performance on the ICH CAHPS measure. We stated our

[227] Groupings of questions and composite measures can be found at *https://ichcahps.org/Portals/0/SurveyMaterials/ICH_Composites_English.pdf*.

[228] 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/*.

[229] *https://healthdata.gov/Hospital/COVID-19-Reported-Patient-Impact-and-Hospital-Capa/g62h-syeh*.

[230] National Kidney Foundation, *COVID–19 and its Impact on Kidney Patients Utilizing U.S. Dialysis Centers* (Jan. 18, 2022), *https://www.kidney.org/news/covid-19-and-its-impact-kidney-patients-utilizing-u-s-dialysis-centers*. See also, Becker's Hospital Review, *Supply shortages disrupt dialysis care in Texas* (Jan. 28, 2022), *https://www.beckershospitalreview.com/supply-chain/supply-shortages-disrupt-dialysis-care-in-texas.html*. WBIW, *Pandemic causing supply shortages for dialysis patients, staffing shortage for providers* (Feb. 22, 2022), *https://www.wibw.com/2022/02/22/pandemic-causing-supply-shortages-dialysis-patients-staffing-shortage-providers/*. Spectrum News, Worker shortage sends dialysis patients scrambling for treatment (October 4, 2021), *https://spectrumlocalnews.com/nys/hudson-valley/news/2021/10/01/worker-shortage-sends-dialysis-patients-scrambling-for-treatment*.

[231] 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*.

[232] 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*.

[233] 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*).

[234] 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).

[235] Fresenius Medical Care Press Release, Statement regarding COVID–19 related supply and staff shortages. Available at: *https://fmcna.com/company/covid-19-resource-center/*.

belief that suppressing this measure for the PY 2023 would address concerns about the potential unintended consequences of penalizing facilities for deviations in measure performance resulting from the impact of the COVID–19 PHE.

Therefore, we proposed to suppress the ICH CAHPS measure for the PY 2023 ESRD QIP under Measure Suppression Factors 1 and 4.

We welcomed public comment on this proposal. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for our proposal to suppress six measures for PY 2023, including our proposal to suppress the ICH CAHPS clinical measure. Several commenters expressed support for the proposed measure suppression because national performance has been distorted due to the impact of the COVID–19 PHE.

Response: We thank commenters for their support. Since the publication of the proposed rule, an updated analysis including Fall 2021 ICH CAHPS data showed a continued deviation in ICH CAHPS scores, with completed survey numbers declining by more than 20,000 from the previous Spring 2021 survey administration. We believe that this updated analysis confirms our earlier concerns regarding the impact of the COVID–19 PHE on national performance and justifies suppression of the ICH CAHPS measure under Measure Suppression Factor 1.

Comment: One commenter recommended that CMS not suppress the ICH CAHPS measure because the survey requires no staff time as it is administered outside the dialysis facility. One commenter disagreed with the rationale for suppressing the ICH CAHPS measure under Measure Suppression Factor 4, believing the labor shortages are not solely attributed to COVID–19, but rather a workforce demographic shift.

Response: Although the administration of the survey itself may not require staff time, facilities are scored based on the patient's responses reflecting the patient's experience of care at the facility, the substance of which is significantly impacted by staffing levels and staff capacity to attend to patients. For example, the ICH CAHPS asks patients questions such as, ''In the last 3 months, how often did the dialysis center staff spend enough time with you?'' [236] We believe that patients receiving care at facilities experiencing staffing shortages are more likely to respond negatively to such questions about their experience of care. Although we acknowledge that commenter may be correct in its assessment that overall staffing shortages may not be solely attributed to the COVID–19 PHE, we believe that the PHE was an important catalyst related to the workforce demographic shifts in CY 2021. Since the performance on the ICH CAHPS measure is directly impacted by staffing shortages because it measures the patient's experience of care with regards to facility staff, suppressing the ICH CAHPS measure based on staffing shortages is appropriate under Measure Suppression Factor 4.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the ICH CAHPS measure for PY 2023. We will also publicly report the data with appropriate caveats.

f. Suppression of the PPPW Clinical Measure for PY 2023

In the proposed rule, we proposed to suppress the PPPW clinical measure for PY 2023 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, as well as under Measure Suppression Factor 4, significant national shortages or rapid or unprecedented changes in patient case volumes or facility-level case mix (87 FR 38536 through 38537).

The PPPW clinical measure is a process measure that assesses the percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period. Given the importance of kidney transplantation to patient survival and quality of life, as well as the variability in waitlist rates among facilities, we adopted the PPPW clinical measure in the CY 2019 ESRD PPS final rule to encourage facilities to coordinate care with transplant centers to waitlist patients (83 FR 57003 through 57008).

In the CY 2022 ESRD PPS final rule (86 FR 61914), several commenters recommended that CMS suppress the PPPW clinical measure, noting that the COVID–19 PHE had a significant negative impact on transplant surgeries, referrals, and waitlists, as well as other related areas. A few commenters also noted that waitlist additions significantly decreased during the COVID–19 PHE. At the time, we responded that our analysis of the relevant data available at the time of the proposed rule indicated temporal declines in waitlist removal among prevalent patients and similarly a decline in waitlisting and transplants in incident ESRD patients in March 2020 through May 2020 compared to prior years. We also observed that trends generally returned to normal starting in June and July 2020 and reflected data similar to prior years. However, we also indicated that we would continue to monitor and review the data and will consider proposing in a future rulemaking to suppress one or more individual ESRD QIP measures for a future ESRD QIP payment year if we conclude that circumstances caused by the COVID–19 PHE have affected those measures and the resulting TPSs based on CY 2021 data.

After reviewing data for the PPPW clinical measure for CY 2021, in the CY 2023 ESRD PPS proposed rule, we stated that we believed that circumstances caused by the COVID–19 PHE had affected our ability to make reliable national, side-by-side comparisons of facility performance on the PPPW measure. Recent analyses indicated that measure performance had declined over the course of the COVID–19 PHE. Although the initial disruptions in care and associated effects on the PPPW measure at the beginning of the COVID–19 PHE initially stabilized, we noted that we have since observed a continuous decrease in the levels of PPPW clinical measure performance. We believed this decrease was indicative overall of the significant impact of the COVID–19 PHE on the measure. For example, in January 2019, the monthly PPPW rate was 19 percent. By contrast, the monthly PPPW rate for December 2021 was 16.9 percent, which we believed reflects a significant deviation in national performance on the measure. We stated that we have also observed that a greater number of facilities would receive lower scores in PY 2023 as compared to PY 2022, reflecting poorer performance overall on the measure. For example, our simulations indicated that the percentage of facilities receiving scores lower than 5 (out of 10; a higher score reflects better performance) had increased at almost every data point. Notably, the percentage of facilities estimated to receive a score of 0, 1, or 2 increased the most between the PY 2022 and PY 2023, indicating that facilities were more likely to receive a lower score in PY 2023. Moreover, the percentage of facilities receiving scores higher than 5 on the PPPW clinical measure in PY 2023 had decreased at

[236] *https://ichcahps.org/Portals/0/SurveyMaterials/ICH_Composites_English.pdf.*

each data point. Given the correlation between decreasing scores and the pandemic's impact on care delivery and patient ability to access the appropriate level of care in light of COVID–19 precautions, we stated our belief that the COVID–19 PHE continued to have a significant impact on the PPPW clinical measure during CY 2021.

In the proposed rule, we stated that our analysis of the available data indicates that the COVID–19 PHE has had significant effects on the PPPW clinical measure and would result in significant deviation in national performance on the measure during the COVID–19 PHE. We noted that not only were there effects on patients diagnosed with COVID–19, but the presence of the virus strongly affected treatment patterns of dialysis patients in CY 2020 and continued to do so in CY 2021, and we were concerned that similar effects would be seen in the balance of the 2021 calendar year as the PHE had continued. Because the Delta variant and the Omicron variant surged through geographic regions of the country unevenly, we stated our concern that facilities in different regions of the country would have been affected differently throughout the 2021 year, thereby skewing measure performance and affecting national comparability due to significant and unprecedented changes in patient case volumes or facility-level case mix. Given the limitations of the data available to us for CY 2021, we believed the resulting performance measurement on the PPPW clinical measure would not be sufficiently reliable or valid for use in the ESRD QIP for scoring and payment adjustment purposes.

In the proposed rule, we stated our belief that the PPPW clinical measure is an important part of the ESRD QIP measure set. However, we were concerned that the ongoing COVID–19 PHE had affected measure performance on the current PPPW clinical measure such that we would not be able to score facilities fairly or equitably on it. Additionally, we noted that we would continue to collect the measure's data from participating facilities so that we could monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also stated our intent to publicly report PY 2023 data where feasible and appropriately caveated.

We noted that we were currently exploring ways to adjust effectively for the systematic effects of the COVID–19 PHE on the PPPW clinical measure. However, we stated that we were still working to improve these COVID–19 adjustments and verify the validity of a potential modified version of the PPPW clinical measure as additional data become available. As an alternative, we considered whether we could exclude patients with a diagnosis of COVID–19 from the PPPW clinical measure cohort, but we determined suppression would provide additional time and months of data for us to more thoroughly evaluate a broader range of alternatives. We noted that we want to ensure that the measure reflects care provided to ESRD patients and we were concerned that excluding otherwise eligible patients may not accurately reflect the care provided, particularly given the unequal distribution of COVID–19 patients across facilities over time.

We welcomed public comment on our proposal to suppress the PPPW clinical measure for PY 2023. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for our proposal to suppress six measures for PY 2023, including our proposal to suppress the PPPW clinical measure. Several commenters expressed support for the proposed measure suppression because national performance has been distorted due to the impact of the COVID–19 PHE.

Response: We thank commenters for their support. Since the publication of the proposed rule, an updated analysis showed a continued deviation in PPPW clinical measure performance throughout CY 2021. We believe that this updated analysis confirms our earlier concerns regarding the impact of the COVID–19 PHE on national performance and justifies suppression of the PPPW clinical measure.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the PPPW clinical measure for PY 2023. We will also publicly report the data with appropriate caveats.

g. Suppression of the Kt/V Dialysis Adequacy Clinical Measure for PY 2023

In the proposed rule, we proposed to suppress the Kt/V Dialysis Adequacy clinical measure for PY 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 (87 FR 38537 through 38538). We referred readers to the CY 2022 ESRD PPS final rule for previous analysis on the overall impact of the COVID–19 PHE on ESRD quality measure performance (86 FR 61910 through 61913).

The Kt/V Dialysis Adequacy clinical measure is the percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period. The Kt/V Dialysis Adequacy clinical measure is defined as a measure of dialysis sufficiency where K is dialyzer clearance, t is dialysis time, and V is total body water volume. The measure evaluates the success of achieving the delivered dialysis dose. The intent of the Kt/V measure is to improve health care delivery by providing facilities with evidence-based parameters for optimizing ESRD patient outcomes over time.

In the CY 2022 ESRD PPS final rule (86 FR 61910), several commenters recommended that CMS suppress the Kt/V Dialysis Adequacy clinical measure, noting that the COVID–19 PHE had a significant impact on catheter rates, which has a corresponding impact on the Kt/V measure, as patients with catheters will have lower Kt/V rates. One commenter also noted the Kt/V Dialysis Adequacy clinical measure should be suppressed under Suppression Factor 1, due to significant deviation in national measure performance. At the time, we responded there was not sufficient data to determine whether suppression was appropriate for the Kt/V Dialysis Adequacy clinical measure. Although performance on the Kt/V Dialysis Adequacy clinical measure deviated temporarily, our analysis indicated that Kt/V rates stabilized shortly thereafter and reflected measure performance similar to prior years. Based on our analysis at the time, Kt/V rates in CY 2020 were similar to rates in CY 2019 until April where they dropped by an average of 0.4 percent. However, beginning in June 2020, Kt/V rates were the same as or higher than national average rates in March 2020.

After reviewing data for the Kt/V Dialysis Adequacy clinical measure for CY 2020 and CY 2021, in the CY 2023 ESRD PPS proposed rule we stated that we believed that circumstances caused by the COVID–19 PHE had affected the measure and the resulting TPS (87 FR 38537). Although the initial disruptions of care at the beginning of the COVID–19 PHE, associated with multiple transient changes to factors that contribute to dialysis adequacy (Kt/V), were temporary, we noted that we had observed continued deviations in Kt/V

clinical measure performance over the past 2 years and we believed that this was indicative of the significant impact of the COVID–19 PHE on the measure. Notably, delays in hemodialysis treatment, due to COVID–19 infection or logistical challenges with care delivery, exacerbated ESRD sequelae including hyperkalemia, uremic encephalopathy, and fluid volume overload.[237] The confluence of these factors likely contributed to declines in Kt/V clinical measure performance.

In the proposed rule, we noted that our simulations comparing PY 2022 scoring distributions with estimated PY 2023 scoring distributions showed that the percentage of facilities receiving scores less than 7 (out of 10; a higher score reflects better performance) had increased at almost every data point, whereas the percentage of facilities receiving scores higher than 7 had decreased at almost every data point. The percentage of facilities receiving a score of score of 0, 1, 2, 3, or 4 increased the most between the 2 years, indicating that facilities are more likely to receive a lower score in PY 2023. Given the correlation between decreasing scores and the pandemic's impact on care delivery and patient ability to access the appropriate level of care in light of COVID–19 precautions,[238] we stated our belief that the COVID–19 PHE continued to have a significant impact on the Kt/V clinical measure during CY 2021.

We noted that our analysis of the available data indicated that the COVID–19 PHE has had significant effects on the Kt/V Dialysis Adequacy clinical measure for ESRD patients and would result in significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly worse as compared to historical performance during the immediately preceding program years. Because the Delta variant and Omicron variant surged through geographic regions of the country unevenly, we were concerned that facilities in different regions of the country had been affected differently throughout the 2021 calendar year, resulting in skewing of measure performance and affecting national comparability due to significant and unprecedented changes in patient case volumes or facility-level case mix. We noted that our scoring simulations indicated that a high percentage of facilities would receive a score of zero for PY 2023. Given the limitation of the data available to us for CY 2021, we believed the resulting performance measurement of the Kt/V Dialysis Adequacy clinical measure would not be sufficiently reliable or valid for use in the ESRD QIP for scoring and payment adjustment purposes.

In the proposed rule, we stated our belief that the Kt/V Dialysis Adequacy clinical measure is an important part of the ESRD QIP measure set. However, we were concerned that the ongoing COVID–19 PHE had affected measure performance on the current Kt/V Dialysis Adequacy clinical measure such that we would not be able to score facilities fairly or equitably on it. Moreover, we noted that we would continue to collect the measure's data from participating facilities so that we could monitor the effect of the COVID–19 PHE circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also stated our intent to publicly report PY 2023 data where feasible and appropriately caveated.

We noted that we were currently exploring ways to adjust effectively for the systematic effects of the COVID–19 PHE on the Kt/V Dialysis Adequacy clinical measure. However, we were still working to improve these COVID–19 adjustments and verify the validity of a potential modified version of the Kt/V Dialysis Adequacy clinical measure as additional data become available.

We welcomed public comment on our proposal to suppress the Kt/V Dialysis Adequacy clinical measure for PY 2023. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for our proposal to suppress six measures for PY 2023, including our proposal to suppress the Kt/V Dialysis Adequacy clinical measure. Several commenters expressed support for the proposed measure suppression because national performance has been distorted due to the impact of the COVID–19 PHE. One commenter expressed support for our proposal to suppress the Kt/V Dialysis Adequacy clinical measure, noting that the PHE significantly limited the availability of vascular access procedures and many of the limitations that contributed to this persist today, including staffing shortages, fewer locations which has resulted in more blood stream infections, hospitalizations, and mortality.

Response: We thank commenters for their support.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the Kt/V Dialysis Adequacy clinical measure for PY 2023. We will also publicly report the data with appropriate caveats.

3. Technical Measure Specification Updates To Include a Covariate Adjustment for COVID–19 for the SHR and SRR Measures Beginning With PY 2025

In the CY 2013 ESRD PPS final rule, we finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the ESRD QIP (77 FR 67475 through 67477).

In the CY 2023 ESRD PPS proposed rule, we stated that as we continue to evaluate the effects of COVID–19 on the ESRD QIP measure set, we have observed both short-term effects on both hospital admissions and readmissions (87 FR 38538). In addition, we discussed that for some patients COVID–19 continues to have lasting effects, including but not limited to fatigue, cough, palpitations, and others potentially related to organ damage, post viral syndrome, and post-critical care syndrome.[239] We noted that these clinical conditions could affect a patient's risk of complications following an index admission or readmission and, as a result, impact a facility's performance on the SHR clinical measure or the SRR clinical measure. To account for case mix among facilities, the current risk adjustment approach for these measures included covariates for clinical comorbidities that are relevant and have relationships with the outcome, for example patient history of diabetes or obesity. Therefore, to adequately account for patient case mix, we stated that we were further modifying the technical measure specifications for the SHR and SRR measures to include a covariate adjustment for patient history of COVID–19. We stated that we believed these changes were technical in nature because they did not substantively change the measures themselves and,

[237] Connerney, M., Sattar, Y., Rauf, H., Mamtani, S., Ullah, W., Michaelson, N., Dhamrah, U., Lal, N., Latchana, S., & Stern, A. S. (2021). Delayed hemodialysis in COVID–19: Case series with literature review. *Clinical nephrology. Case studies, 9,* 26–32. *https://doi.org/10.5414/CNCS110240.*

[238] National Kidney Foundation, *COVID–19 and its Impact on Kidney Patients Utilizing U.S. Dialysis Centers* (Jan. 18, 2022), *https://www.kidney.org/news/covid-19-and-its-impact-kidney-patients-utilizing-u-s-dialysis-centers.*

[239] 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.

therefore, were not required to be implemented through rulemaking.

In the proposed rule, we stated that this inclusion of the covariate adjustment for patient history of COVID–19 would be effective beginning with the PY 2025 program year for the SHR clinical measure and the SRR clinical measure, and we would also apply this adjustment for purposes of calculating the performance standards for that program year. As discussed in section IV.E.1.b, we proposed to convert the STrR reporting measure to a clinical measure beginning with PY 2025. In the proposed rule, we noted that we were also considering whether it would be appropriate to add a covariate adjustment for patient history of COVID–19 to the STrR clinical measure, beginning with PY 2025, and will announce that technical update, if appropriate, at a later date.

For more information on the application of covariate adjustments, including the technical updates we announced in the proposed rule, please see the Technical Specifications for ESRD QIP Measures (available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications*) and the CMS ESRD Measures Manual (available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/06_MeasuringQuality*).

The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for including a covariate to adjust for patient history of COVID–19 in the SHR and SRR measures, noting the significant impact of the COVID–19 PHE on these measures. A few commenters recommended that CMS include the adjustment before PY 2025 if possible.

Response: We thank the commenters for their support. Although we considered implementing the technical measure specification updates before PY 2025, we ultimately concluded that PY 2025 was the earliest year feasible for including the covariate adjustment due to data collection timelines.

Comment: One commenter requested that CMS provide more information about the measures' technical specifications and how patient information regarding COVID–19 may be obtained. One commenter requested that CMS make available supporting analytics so that interested parties may review the impact of such a covariate on model performance.

Response: We will provide more information about the measures' technical specifications, including the updated specifications for the SHR and SRR clinical measures that include the covariate adjustments, in the CMS ESRD Measures Manual for the 2023 Performance Period, which will be available following publication of the CY 2023 ESRD PPS final rule at *https://www.cms.gov/files/document/esrd-measures-manual-v80.pdf*. As discussed in the Measures Manual, patient information regarding COVID–19 may be obtained from Medicare claims. We will determine the feasibility of making supporting analytics available for interested parties to review to model the impact of such a covariate on a facility's performance.

C. Updates to the Performance Standards Applicable to the PY 2023 Clinical Measures

In the CY 2023 ESRD PPS proposed rule (87 FR 38538), we stated that our current policy is to automatically adopt a performance and baseline period for each year that is 1 year advanced from those specified for the previous payment year (84 FR 60728). We noted that under this policy, CY 2021 is currently the performance period and CY 2020 is the baseline period for the PY 2023 ESRD QIP. However, we also stated that under the nationwide ECE that we granted in response to the COVID–19 PHE, first and second quarter data for CY 2020 are excluded from scoring for purposes of the ESRD QIP (85 FR 54829 through 54830). Accordingly, in the CY 2022 ESRD PPS final rule (86 FR 61922 through 61923), for PY 2024, we finalized calculating performance standards using CY 2019 data due to concerns about using partial year data (86 FR 61922 through 61923). Similarly, in the CY 2023 ESRD PPS proposed rule, we stated that we were concerned that it would be difficult to assess performance standards for PY 2023 based on partial year data. We noted that our preliminary analysis indicated that the effect of the excluded data could create inflated performance standards for PY 2023 and we would potentially be required to use these for future payment years due to the requirement that the prior year's standard cannot be higher than the current year's standard. This may skew achievement and improvement thresholds for facilities and therefore may result in performance standards that do not accurately reflect levels of achievement and improvement.

Our current policy substitutes the performance standard, achievement threshold, and/or benchmark for a measure for a performance year if final numerical values for the performance standard, achievement threshold, and/or benchmark are worse than the numerical values for that measure in the previous year of the ESRD QIP (82 FR 50764). We stated that we adopted this policy because we believe that the ESRD QIP should not have lower performance standards than in previous years and therefore, adopted flexibility to substitute the performance standard, achievement threshold, and benchmark in appropriate cases.

Although the lower performance standards would be substituted with those from the prior year, the higher performance standards would be used to set performance standards for certain measures, even though they would be based on partial year data. We stated that we continued to be concerned that this may create performance standards for certain measures that would be difficult for facilities to attain with 12 months of data.

Therefore, we proposed to calculate the performance standards for PY 2023 using CY 2019 data, which are the most recently available full calendar year of data we can use to calculate those standards. Due to the impact of CY 2020 data that are excluded from the ESRD QIP for scoring purposes, we stated our belief that using CY 2019 data for performance standard setting purposes is appropriate. We also proposed to amend 42 CFR 413.178(d)(2) to reflect both our proposed updates applicable to the PY 2023 performance standards, as well as our previously finalized update to the PY 2024 performance standards.

We welcomed public comments on this proposal. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for our proposal to use CY 2019 data for PY 2023 performance standards, noting that data collected during the COVID–19 PHE have been skewed. One commenter also supported the proposal to use CY 2019 data to calculate PY 2023 performance standards due to the impact of the shift to the EQRS data system. One commenter expressed support for our proposal to calculate performance standards for PY 2023 using CY 2019 data but emphasized that CY 2019 data does not reflect the impacts of the COVID–19 PHE on facilities.

Response: We thank commenters for their support. We acknowledge the commenter's observation that CY 2019 data does not reflect the impacts of the COVID–19 PHE on facilities. However, we note that one of the reasons we adopted our measure suppression policy for the duration of the COVID–19 PHE was to help minimize the impacts on

performance standards for certain measures that have been significantly affected by the COVID–19 PHE, which we believe will improve the comparability of pre-COVID–19 data from CY 2019 for purposes of calculating PY 2023 performance standards.

Comment: A few commenters noted the difficulty in creating reasonable benchmarks when comparing a facility's performance during the COVID–19 PHE to performance before the COVID–19 PHE and expressed concern that using pre-pandemic CY 2019 data as a baseline for assessing COVID–19 era data is not an appropriate comparison. One commenter pointed out the impact of measure suppressions on the number of clinical measures eligible for PY 2023 scoring. One commenter stated that comparing PY 2023 performance using CY 2019 baseline data would be inappropriate because the COVID–19 PHE has resulted in decreased patient adherence to treatment and has increased the complexity of ESRD patient care. One commenter expressed concern with CMS's proposal to use CY 2019 as the baseline year for the PY 2023 ESRD QIP because the combination of the COVID–19 PHE and CMS's focus on home dialysis has impacted the mix of patients at in-center ESRD facilities, which the commenter believes would make it difficult to compare performance in CY 2019 to performance in 2021. This commenter encouraged CMS to evaluate the impact of the COVID–19 PHE and increases in home dialysis use on the individual quality measures and adjust performance targets accordingly. One commenter recommended that CMS consider alternative approaches for updating the performance standards for PY 2023, such as suspending use of a baseline comparison this year and re-establish a new ''post-COVID'' baseline next year using the CY 2021 data or simulating early COVID–19 PHE data using 2019 data and then using these data as the baseline for PY 2023.

Response: We appreciate the commenters' concerns. We believe that the use of CY 2019 data as a baseline for assessing COVID–19 era data is an appropriate comparison in light of our measure suppression policy and the suppression of individual measures thereunder. We adopted our measure suppression policy to minimize the impact of the COVID–19 PHE on facility performance, and for PY 2023, we are suppressing certain measures that we believe were significantly impacted by the COVID–19 PHE. We did not suppress measures that we believe were not significantly impacted by the COVID–19 PHE. Given our determinations that these measures were not significantly impacted by the COVID–19 PHE, we believe that performance on these measures is generally comparable to CY 2019 performance, and therefore we believe those measures are appropriate to include in the calculation of PY 2023 performance standards for scoring purposes as comparable to CY 2019 pre-pandemic data. We note that this is a temporary update to our performance standards calculations made in response to an unprecedented PHE, and the impact is limited to those few clinical measures for which measure suppression was not warranted for PY 2023. We believe these updates are necessary to mitigate the impact of the ECE that CMS granted in response at the beginning of the COVID–19 PHE, as well as the COVID–19 PHE itself, on PY 2023 and PY 2024 performance standards calculations. However, we intend to resume our previously finalized performance standards methodology beginning with PY 2025, which will consist of ''post-COVID–19'' measure data. We appreciate that suppressed measures may have an impact on TPS scores for PY 2023. However, we believe that it is appropriate to score facilities on non-suppressed measures. Although the recalculated mTPS for PY 2023 may be higher, we believe that fewer facilities will be penalized as a result, particularly given that we are finalizing suppression of the Standardized Fistula Rate clinical measure for PY 2023, which we discuss in section IV.B.2.d of this final rule. We are finalizing for suppression the measures which we have identified as being significantly impacted by the COVID–19 PHE in CY 2021 for PY 2023. We also note that rapid or unprecedented changes to patient case volumes or facility-level case mix, either due to decreased adherence to treatment or changes to dialysis modality as a result of the COVID–19 PHE, would be considered for measure suppression under Measure Suppression Factor 4. Our analyses indicate that the patient case volumes and facility-level case mix were not significantly impacted in those measures that we are not suppressing for PY 2023 and therefore does not inhibit the use of CY 2019 data as the baseline for purposes of calculating PY 2023 performance standards. Finally, we appreciate the commenter's recommendations for alternative approaches to PY 2023 performance standards, but believe that our proposed approach is the most feasible option at this time.

Final Rule Action: After considering public comments, we are finalizing our proposal to calculate the performance standards for PY 2023 using CY 2019 data. We are also finalizing our proposal to amend 42 CFR 413.178(d)(2) to reflect both our finalized updates applicable to the PY 2023 performance standards, as well as our previously finalized update to the PY 2024 performance standards.

D. Technical Updates to the SRR and SHR Clinical Measures Beginning With the PY 2024 ESRD QIP

In the CY 2017 ESRD PPS final rule, we adopted the SHR clinical measure under the authority of section 1881(h)(2)(B)(ii) of the Act (81 FR 77906 through 77911). The SHR clinical measure is a National Quality Forum (NQF)-endorsed all-cause, risk-standardized rate of hospitalizations during a 1-year observation window. The standardized hospitalization ratio is defined as the ratio of the number of hospital admissions that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of hospitalizations that would be expected given the characteristics of the facility's patients and the national mean for facilities. In the CY 2015 ESRD PPS final rule, we adopted the SRR clinical measure under the authority of section 1881(h)(2)(B)(ii) of the Act (79 FR 66174 through 66182). The standardized readmission ratio is defined as the ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day hospital readmissions. Both the SHR clinical measure and the SRR clinical measure are calculated as a ratio, but can also be expressed as a rate.

In the CY 2023 ESRD PPS proposed rule, we noted that hospitalization and readmission rates vary across facilities even after adjustment for patient characteristics, suggesting that hospitalizations and readmissions might be influenced by facility practices (87 FR 38539). Both an adjusted facility-level standardized hospitalization ratio and an adjusted facility-level standardized readmissions ratio, accounting for differences in patients' characteristics, play an important role in identifying potential quality issues, and help facilities provide cost-effective quality health care to help reduce admissions or readmissions to the hospital for dialysis patients as well as limit escalating medical costs. We stated that we have weighted scoring of the SHR clinical measure and the SRR clinical measure to reflect the importance of the measures on the quality of patient care. In the CY 2019 ESRD PPS final rule, the SHR clinical

measure and the SRR clinical measure each accounted for 14 percent of the TPS (83 FR 56992). In CY 2019, with average weights of more than 15 percent (after reweighting of missing measures), the SHR clinical measure and the SRR clinical measure were the two measures with the largest weight in calculating the TPS for each facility.

In the CY 2013 ESRD PPS final rule, we finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the ESRD QIP (77 FR 67475 through 67477). In the CY 2023 ESRD PPS proposed rule, we announced that we are updating the technical specifications to revise how we express the results of the SHR clinical measure and the SRR clinical measure so that those results are expressed as a Risk-Standardized Hospitalization Rate (RSHR) and a Risk-Standardized Readmission Rate (RSRR), respectively (87 FR 38539). We noted that interested parties had previously expressed concern that the SHR clinical measure and the SRR clinical measure were difficult to interpret and track facility performance over time when expressed as ratios, and had recommended expressing those ratios as rates when scoring. We stated that although there are widespread national improvements in hospitalization rates and readmission rates, individual facilities may not see their own improvement reflected if their measure results are reflected as ratios because SHR and SRR measures effectively standardize the ratios to 1.0 each calendar year and all facilities' ratios are calculated using national-level performance in each calendar year. We noted that another concern interested parties raised was that the ratios were difficult to understand and it was difficult to determine how to use these ratios for quality improvement efforts.

In light of these concerns, we stated that we were updating the technical specifications to change the scoring methodology for the SRR clinical measure and the SHR clinical measure such that a facility's results are expressed as a rate in the performance period that is compared directly to its rate in the baseline period. We noted that, in response to public comments indicating a perception that overall facility performance on ESRD QIP measures was recently improving as payment reductions were increasing, we assessed trends in facility performance through 2019 to examine facility performance on the SHR clinical measure and the SRR clinical measure over time. We also calculated the RSHR and the RSRR. We calculated the RSHR by multiplying SHR by the national observed hospitalization rate (per patient-year at risk) in the calendar year. Similarly, we multiplied the SRR by the national observed readmission rate (per index discharge) in the calendar year to determine the RSRR. Both ESRD QIP and Dialysis Facility Reports (DFR) data were used in these analyses. Data from ESRD QIP were available from CYs 2018 to 2019 for the SRR clinical measure and from CYs 2015 to 2019 for the SHR clinical measure. Additionally, we used data from the publicly available DFRs from CYs 2010 to 2018 for the SHR clinical measure and from CYs 2014 to 2018 for the SRR clinical measure to compare to the ESRD QIP calculations.

We stated our belief that these changes were technical in nature because they did not substantively change the measures themselves and, therefore, were not required to be implemented through rulemaking. Our analysis found that expressing the measure performance as a rate instead of a ratio would communicate the same information in a clearer way. After the SHR clinical measure and the SRR clinical measure were added to the ESRD QIP measure set, that SHR and SRR distributions were similar from year to year. We noted that median SHR has consistently remained below 1.0, while median SRR has remained around 1.0 each year. RSHR and RSRR have remained stable since then as well. We stated that these trends showed that as ESRD QIP payment reductions were increasing from PY 2018 to PY 2020 (corresponding to CY 2016 to CY 2018 facility performance for most measures), we did not find evidence of overall declines in risk-adjusted hospitalization and readmission rates. Furthermore, in recent years, the national readmission or hospitalization rates have been relatively stable or slightly increasing. Therefore, we stated that revising how we express SHR or SRR measure results to be expressed as RSHR or RSRR, respectively, each year would not result in higher ESRD QIP scores.

Our analysis found that expressing the SHR clinical measure and SRR clinical measure results as rates would reflect the same level of measure performance as expressing those results as ratios, and we stated our belief that expressing the measure results as rates would help providers and patients better understand a facility's performance on the measures, and would be more intuitive for a facility to track its performance from year to year.

Further, we noted that this technical update would also more closely align with the measure result calculation methodology for the ESRD QIP with that used in the Dialysis Facility Compare Star Ratings Program. For star ratings calculations, an adjustment factor is applied for the standardized ratio measures, accounting for differences in population event rates between the baseline period and evaluation period data, so that an adjusted evaluation period ratio (a proxy for rate converted from ratio) value reflects the same value it would have in the baseline period.[240] We provided the currently finalized performance standards for the PY 2024 SHR and SRR clinical measures in Table 16 of the proposed rule, and the revised PY 2024 performances standards for the updated SHR and SRR clinical measures in Table 17 of the proposed rule (87 FR 38540). They are described in Table 20 and Table 21 in this final rule.

[240] The University of Michigan Kidney Epidemiology and Cost Center. (2018). Technical Notes on the Dialysis Facility Compare Quality of Patient Care Star Rating Methodology for the October 2018 Release. Available at: *https://dialysisdata.org/sites/default/files/content/Methodology/Updated_DFC_Star_Rating_Methodology_for_October_2018_Release.pdf.*

TABLE 20: Current Performance Standards for the PY 2024 ESRD QIP SHR and SRR Clinical Measures Using the Most Recently Available Data

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Standardized Readmission Ratio	1.268*	0.998*	0.629*
Standardized Hospitalization Ratio	1.230	0.971	0.691
*Values are also the final performance standards for those measures for PY 2023. In accordance with our longstanding policy, we are using those numerical values for those measures for PY 2024 because they are higher standards than the PY 2024 numerical values for those measures.			

Data sources: SRR, SHR: 2019 Medicare claims.

TABLE 21: Numerical Values for the Performance Standards for the Updated PY 2024 ESRD QIP SHR and SRR Clinical Measures, Expressed as Rates, Using the Most Recently Available Data

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Standardized Readmission Ratio[a]	34.27	26.97	17.02
Standardized Hospitalization Ratio[b]	187.80	148.33	105.54

[a]Rate calculated as a percentage of hospital discharges.

[b]Rate per 100 patient-years.

Data sources: SRR, SHR: 2019 Medicare claims.

We welcomed public comments on this technical update. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for expressing SHR and SRR results as rates, noting that this will allow for better year-over-year comparability at the facility level. A few commenters expressed appreciation for the technical updates because they will help to increase providers' and patients' understanding of the measures and will provide a clearer picture of facility performance.

Response: We thank commenters for their support.

Comment: A few commenters recommended that CMS use a consistent denominator to allow for comparability year-over-year at the facility level so that facilities may take steps to improve their performance. A few commenters recommended that CMS adopt the adjustment factor used in the Star Rating Program, which would translate the adjusted rates in the performance year to the same scale as those in the baseline year. These commenters expressed the belief that this approach will help with year-over-year comparability. One commenter expressed concern that SHR and SRR rates may be difficult to interpret due to a lack of understanding of how the denominator is calculated and inability to understand actual facility performance.

Response: As described in the proposed rule, the methodology for converting ratios to rates that we will move to in the ESRD QIP is equivalent to the methodology used in Dialysis Facility Compare (DFC) reporting. Specifically, in the Star Rating calculation under the DFC program, the ratio for the performance year is multiplied by the adjustment factor (national rate for performance year/national rate for the base year). In both the ESRD QIP and the DFC, this methodology results in rates that give credit for national changes in additional to individual facility changes that differ from the national rate change.

Regarding the comments about interpretability of the measure calculations, we note that the SHR and SRR have been used in public reporting and the ESRD QIP for multiple years. Both the DFC and the ESRD QIP programs have descriptions of how the measure is calculated and how to interpret the measure results for a given dialysis facility's results. Information that would help with understanding how the measures are calculated, such as the inclusion of various risk-adjustments and other factors contributing to denominator calculations, is generally available as part of the public displays and other information tools that CMS makes publicly available. Given the multiple sources of information available at various levels of detail, we believe that interpretation of results for both the SHR clinical measure and the SRR clinical should be achievable for most or all interested parties.

Comment: One commenter recommended that this policy apply to other standardized ratio measures as well.

Response: We thank the commenter for its recommendation, and note that we are incorporating a similar methodology as part of our proposal to convert the Standardized Transfusion Ratio (STrR) reporting measure to a

clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this final rule.

E. Updates to Requirements Beginning With the PY 2025 ESRD QIP

1. PY 2025 ESRD QIP Measure Set

Under our current policy, we retain all ESRD QIP measures from year to year unless we propose through rulemaking to remove them or otherwise provide notification of immediate removal if a measure raises potential safety issues (77 FR 67475). Accordingly, the PY 2025 ESRD QIP measure set would include the same 14 measures as the PY 2024 ESRD QIP measure set (85 FR 71465 through 71466). In section IV.E.1.a of the proposed rule, we also proposed to adopt a COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) reporting measure beginning in PY 2025 (87 FR 38542 through 38544). In section IV.E.1.b of the proposed rule, we proposed to convert the STrR reporting measure to a clinical measure beginning in PY 2025 (87 FR 38544 through 38545), and in section IV.E.1.c of the proposed rule, we proposed to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025 (87 FR 38545 through 38546). These measures are described in Table 18 in the proposed rule (87 FR 38541), and are described in Table 22 in this final rule. For the most recent information on each measure's technical specifications for PY 2025, we refer readers to the CMS ESRD Measures Manual for the 2022 Performance Period.[241]

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[241] *https://www.cms.gov/files/document/esrd-measures-manual-v70.pdf.*

TABLE 22: PY 2025 ESRD QIP Measure Set

National Quality Forum (NQF) #	Measure Title and Description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple testing tools.
2496	Standardized Readmission Ratio (SRR), a clinical measure* Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
Based on NQF #2979	Standardized Transfusion Ratio (STrR), a reporting measure** Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
2977	Hemodialysis Vascular Access: Standardized Fistula Rate clinical measure Measures the use of an arteriovenous (AV) fistula as the sole means of vascular access as of the last hemodialysis treatment session of the month.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a clinical measure*** Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463	Standardized Hospitalization Ratio (SHR), a clinical measure* Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on NQF #0418	Clinical Depression Screening and Follow-Up, a reporting measure Facility reports in End Stage Renal Disease Quality Reporting System (EQRS) one of six conditions for each qualifying patient treated during performance period.
N/A	Ultrafiltration Rate (UFR), a reporting measure Number of patient-months for which a facility reports the elements required for ultrafiltration rates for each qualifying patient.
Based on NQF #1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to the Centers for Disease Control and Prevention (CDC).
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure Percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.
N/A	COVID-19 Vaccination Coverage among Healthcare Personnel (HCP), a reporting measure**** Percentage of HCP who receive a complete COVID-19 vaccination course.

* We are updating the SHR clinical measure and the SRR clinical measure to be expressed as risk-standardized rates beginning in PY 2024, as discussed in section IV.D of this final rule.

**We are finalizing our proposal to convert the STrR reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this final rule.

***We are finalizing our proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this final rule.

****We are finalizing our proposal to adopt the COVID-19 Vaccination Coverage among HCP reporting measure beginning in PY 2025, as discussed in section IV.E.1.a of this final rule.

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We discuss our proposal to adopt the COVID–19 Vaccination Coverage among HCP reporting measure, our proposal to convert the STrR reporting measure to a

clinical measure, and our proposal to convert the Hypercalcemia clinical measure to a reporting measure in the following sections.

a. Adoption of the COVID–19 Vaccination Coverage Among HCP Reporting Measure Beginning With the PY 2025 ESRD QIP

(1) Background

On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID–19,[242] caused by a novel coronavirus, SARS–CoV–2. COVID–19 is a contagious respiratory infection [243] that can cause serious illness and death. Older individuals and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[244]

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 March 16, 2022, over 79 million COVID–19 cases, over 4.5 million new COVID–19 related hospitalizations, and almost 965,000 COVID–19 deaths have been reported in the U.S.[245]

According to available data, COVID–19 spreads when an infected person breathes out droplets and very small particles that contain the virus. These droplets and particles can be breathed in by other people or land on their eyes, noses, or mouth, and in some circumstances may contaminate surfaces they touch.[246] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed SARS–CoV–2 infection, regardless of whether the individual has symptoms.[247] Although personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, COVID–19 can spread between HCP and patients, or from patient to patient, given the close contact that may occur during the provision of care.[248] The CDC has emphasized that health care settings can be high-risk places for COVID–19 exposure and transmission.[249]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[250] On December 11, 2020, FDA issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[251] Subsequently, FDA issued EUAs for additional COVID–19 vaccines [252] and, after a rigorous review process, granted approval to two vaccines.[253]

In the CY 2023 ESRD PPS proposed rule, we stated our belief that it is important to incentivize and track HCP vaccination for COVID–19 in facilities through quality measurement to protect health care workers, patients, and caregivers, and to help sustain the ability of these facilities to continue serving their communities throughout the PHE and beyond (87 FR 38542). We recognized the importance of COVID–19 vaccination, and noted that we have finalized proposals to include a COVID–19 HCP vaccination measure in quality reporting programs for other care settings, such as the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the Hospital Inpatient Quality Reporting Program (86 FR 45374 through 45382), the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (86 FR 45428 through 45434), the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) (86 FR 45438 through 45446), the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) (86 FR 42385 through 42396), and the Skilled Nursing Facility Quality Reporting Program (86 FR 42480 through 42489).

HCP are at risk of carrying COVID–19 infection to patients, experiencing illness or death themselves as a result of contracting COVID–19, and transmitting COVID–19 to their families, friends, and the general public. For further information regarding the importance of vaccination among HCP, we refer readers to the ''Omnibus COVID–19 Health Care Staff Vaccination,'' an interim final rule with comment that was issued on November, 11, 2021, requiring COVID–19 vaccination of eligible staff at health care facilities that participate in the Medicare and Medicaid programs (such as facilities participating in ESRD QIP) (86 FR 61556 through 615560). In the proposed rule, we stated our belief that facilities should track the level of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19 within their facilities. HCP vaccination can potentially reduce illness that leads to work absence and limit disruptions to care.[254] Data from influenza vaccination demonstrates that provider uptake of the vaccine is associated with that provider recommending vaccination to patients,[255] and we noted that we believe that HCP COVID–19 vaccination in facilities could similarly increase

[242] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx*.

[243] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

[244] Ibid.

[245] *https://covid.cdc.gov/covid-data-tracker#datatracker-home*.

[246] Centers for Disease Control and Prevention. (2022). How COVID–19 Spreads. Accessed on October 16, 2022 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[247] Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html*.

[248] Centers for Disease Control and Prevention. (2021). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on April 2 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission*.

[249] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859. Available at: *https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm*.

[250] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on April 3, 2021 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[251] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/150386/download*. (as reissued on October 12, 2022).

[252] U.S. Food and Drug Administration. (2020). Moderna COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download* (as reissued on October 12, 2022); U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download* (as reissued on May 5, 2022). U.S. Food and Drug Administration. (2022). Novavax COVID–19 Vaccine, Adjuvanted EUA Letter of Authorization. Available at *https://www.fda.gov/media/159902/download* (as reissued September 12, 2022).

[253] FDA Approves First COVID–19 Vaccine, Available at *https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine*. Spikevax and Moderna COVID–19 Vaccine, Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine*.

[254] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm*.

[255] Measure Applications Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

uptake among that patient population. We also stated our belief that publishing the HCP vaccination rates would be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19 such as dialysis patients, as they choose facilities from which to seek treatment. We noted that patients undergoing hemodialysis face greater risk for adverse health outcomes if they contract COVID–19 and during the Delta and Omicron surges of 2021, increases in case rates were directly proportionate to vaccination rates at the county level across the United States.[256] [257] Under CMS' Meaningful Measures Framework, the COVID–19 HCP Vaccination measure would address the quality priority of ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

(2) Overview of Measure

The COVID–19 Vaccination Coverage among HCP measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in non-long-term care facilities such as ESRD facilities.

The denominator is the number of HCP eligible to work in the ESRD facility for at least one day during the reporting period (as described in section IV.E.1.a.(5)) excluding persons with contraindications to COVID–19 vaccination that are described by the CDC.[258] [259]

The numerator is the cumulative number of HCP eligible to work in the ESRD facility for at least one day during the reporting period (as described in section IV.E.1.a.(5)) and who received a complete vaccination course against COVID–19 using an FDA-authorized or approved vaccine for COVID–19. A completed primary series vaccination course may require one or more doses depending on the specific vaccine used.[260] [261] We stated that vaccination coverage is defined, for purposes of this measure, as the percentage of HCP eligible to work at the facility for at least 1 day who received a complete vaccination course against COVID–19. The specifications for this measure are available at *https://www.cdc.gov/nhsn/nqf/index.html.*

(3) Review by the Measure Applications Partnership

The COVID–19 Vaccination Coverage among HCP measure was included on the publicly available ''List of Measures under Consideration for December 21, 2020'' (MUC List), a list of measures under consideration for use in various Medicare programs.[262] When the Measure Applications Partnership (MAP) Hospital Workgroup convened on January 11, 2021, it reviewed measures on the MUC List including the COVID–19 Vaccination Coverage among HCP measure. The MAP Hospital Workgroup recognized that the proposed measure represents a promising effort to advance measurement for an ongoing and evolving national pandemic and that it would bring value to the ESRD QIP measure set by providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[263] The MAP Hospital Workgroup also stated that collecting information on COVID–19 vaccination coverage among HCP, and providing feedback to facilities, would allow facilities to benchmark coverage rates and improve coverage in their facility. The MAP Hospital Workgroup further noted that reducing rates of COVID–19 in HCP may reduce transmission among a patient population that is highly susceptible to illness and disease, and also reduce instances of staff shortages due to illness.[264]

In its preliminary recommendations, the MAP Hospital Workgroup did not support this measure for rulemaking, subject to potential for mitigation.[265] To mitigate its concerns, the MAP Hospital Workgroup believed that the measure needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.[266] Subsequently, the MAP Coordinating Committee reviewed the COVID–19 HCP Vaccination measure and the preliminary recommendation of the Hospital Workgroup, and decided to recommend conditional support for rulemaking contingent on CMS bringing the measure back to the MAP once the specifications were further refined.[267] In its final report, the MAP further noted that the measure would add value to the ESRD QIP measure set by providing visibility into an important intervention to limit COVID–19 infections in HCP and the ESRD patients for whom they provide care.[268]

In response to the MAP's request that CMS return with the measure once the specifications are further refined, we met with the MAP Coordinating Committee accompanied by the CDC on March 15, 2021 to address vaccine availability, the alignment of the COVID–19 HCP Vaccination measure as closely as possible with the Influenza HCP vaccination measure (NQF #0431) specifications, and the definition of HCP used in the measure. At this meeting, with the CDC, we also presented preliminary findings from ongoing testing of the numerator of COVID–19 Vaccination Coverage among HCP measure, which showed that the numerator data should be feasible and reliable.[269] Testing of the numerator, the number of HCP vaccinated, involved a comparison of vaccination data reported to the CDC by long-term care facilities (LTCFs) through the CDC's National Healthcare Safety Network (NHSN) with data reported to the CDC through the

[256] Cuadros DF, Miller FD, Awad S, Coule P, MacKinnon NJ. Analysis of Vaccination Rates and New COVID–19 Infections by US County, July–August 2021. *JAMA Netw Open.* 2022;5(2):e2147915. doi:10.1001/jamanetworkopen.2021.47915.

[257] Iuliano AD, Brunkard JM, Boehmer TK, et al. Trends in Disease Severity and Health Care Utilization During the Early Omicron Variant Period Compared with Previous SARS–CoV–2 High Transmission Periods—United States, December 2020–January 2022. MMWR Morb Mortal Wkly Rep 2022;71:146–152. DOI: *http://dx.doi.org/10.15585/mmwr.mm7104e4external* icon.

[258] Centers for Disease Control and Prevention. Contraindications and precautions. (2021) Accessed January 7, 2022 at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications.*

[259] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID–19 Vaccination Coverage Updated August 2021. (2021) Accessed March 29, 2022 at: *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf.*

[260] Measure Applications Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/*Project_Pages/MAP_Coordinating_Committee.aspx.

[261] Centers for Disease Control and Prevention. The National Healthcare Safety Network (NHSN) Safety Manual: Weekly COVID–19 Vaccination Protocol for Healthcare Personnel. Accessed October 14, 2022 at: *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/protocol-hcp-508.pdf.*

[262] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at: *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf* on January 29 2021.

[263] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[264] Ibid.

[265] Ibid.

[266] Ibid.

[267] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[268] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[269] For more information on testing results and other measure updates, please see the Meeting Materials (including Agenda, Recording, Presentation Slides, Summary, and Transcript) of the March 15, 2021 meeting available at *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

Federal pharmacy partnership program for delivering vaccination to LTC facilities. In the proposed rule, we noted that these two data collection systems are independent but show high correlation. In initial analyses of the first month of vaccination from December 2020 to January 2021, the number of HCP vaccinated in approximately 1,200 facilities was highly correlated between these two systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting.[270] Because of the high correlation across a large number of facilities, including ESRD facilities, and the high number of HCP within those facilities receiving at least one dose of the COVID–19 vaccine, in the proposed rule we stated our belief that these data indicate the measure is feasible and reliable for use in the ESRD QIP.

(4) NQF Endorsement

Section 1881(h)(2)(B)(i) of the Act states that subject to subparagraph (ii), any measure specified by the Secretary for the ESRD QIP must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract. Under section 1881(h)(2)(B)(ii) 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.

In the proposed rule, we noted that the proposed COVID–19 Vaccination Coverage among HCP measure was not NQF endorsed. The CDC, in collaboration with CMS, submitted the measure for consideration in the NQF Fall 2021 measure cycle.

Because this measure was not NQF-endorsed at the time we issued the proposed rule, we stated that we considered whether there were other available measures that assess COVID–19 vaccination rates among HCP. We noted that we found no other feasible and practical measures on the topic of COVID–19 vaccination among HCP, therefore the exception in section 1881(h)(2)(B)(ii) of the Act applied. We stated our belief that it was important to propose this measure as quickly as feasible to address the ongoing COVID–19 pandemic and to prepare for potential future waves of COVID–19 variants, including the potential continued negative impact of COVID–19 infection on the ESRD patient population as well as HCP staffing shortages due to COVID–19 infection among staff.

(5) Data Collection, Submission, and Reporting

We proposed quarterly reporting deadlines for the ESRD QIP and a 12-month performance period. Facilities would report the measure through the NHSN web-based surveillance system.[271] Facilities currently use the NHSN web-based system to report two ESRD QIP measures, the NHSN Bloodstream Infection (BSI) clinical measure and the NHSN Dialysis Event reporting measure.

To report this measure, we proposed that facilities would collect the numerator and denominator for the COVID–19 Vaccination Coverage among HCP measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet ESRD QIP requirements. While it would be ideal to have HCP vaccination data for every week of each month, in the proposed rule we stated that we were mindful of the time and resources that facilities would need to report the data. Thus, in collaboration with the CDC, we determined that data from at least one week of each month would be sufficient to obtain a reliable snapshot of vaccination levels among a facility's healthcare personnel while balancing the costs of reporting. If a facility submits more than one week of data in a month, the most recent week's data would be used to calculate the measure, as we believed the most recent week's data would provide the most currently available information. For example, if first and third week data are submitted, third week data would be used. If first, second, and fourth week data are submitted, fourth week data would be used. Each quarter, we proposed that the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each facility, which would be calculated by taking the average of the data from the three weekly rates submitted by the facility for that quarter. We stated that we would publicly report the most recent quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC.

As described in section IV.E.1.a.(2) of the proposed rule (87 FR 38543), facilities would report the number of HCP eligible to have worked at the facility during the self-selected week that the facility reports data for in NHSN (denominator) and the number of those HCP who have received a complete course of a COVID–19 vaccination (numerator) during the same self-selected week.

We welcomed public comment on our proposal to add a new measure, COVID–19 Vaccination Coverage among HCP, to the ESRD QIP measure set beginning with PY 2025. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for our proposal to add the COVID–19 Vaccination Coverage among HCP reporting measure to the ESRD QIP beginning with PY 2025. Several commenters expressed support for CMS's proposal to adopt the COVID–19 HCP Vaccination Coverage among HCP reporting measure, noting the importance of incentivizing and tracking HCP vaccination to protect health care workers, patients, and caregivers. A few commenters noted that although facilities have worked to reduce the risk of COVID–19 through vaccination efforts, more support from Federal agencies is needed to address significant opposition to vaccines that still exists in certain parts of the country. One commenter supported inclusion of the COVID–19 Vaccination Coverage among HCP reporting measure in the PY 2025 ESRD QIP to ensure consistency with other CMS programs.

Response: We thank these commenters for their support.

Comment: Although several commenters expressed support conceptually for the COVID–19 Vaccination Coverage among HCP reporting measure because tracking and reporting COVID–19 vaccination rates at facilities is important, these commenters expressed concern that the measure was not appropriate for the ESRD QIP. One commenter noted that currently all eligible dialysis HCP are required to be vaccinated against COVID–19 under CMS's Omnibus COVID–19 Health Care Staff Vaccination Interim Final Rule. A few commenters recommended that CMS include the COVID–19 Vaccination Coverage among HCP reporting measure in Dialysis Facility Compare (DFC). A few commenters noted that facilities are already required to report vaccination data and expressed concern that including a COVID–19 Vaccination Coverage among HCP reporting measure in the ESRD QIP would be duplicative and would impose an unnecessary

[270] Ibid.

[271] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on January 7, 2022.

reporting burden for facilities. A few commenters stated that the COVID–19 Vaccination Coverage among HCP measure was not appropriate for the ESRD QIP because they believe that tracking HCP vaccination status will not improve quality of ESRD care.

Response: We thank commenters for their input. We believe that the COVID–19 Vaccination Coverage among HCP reporting measure is appropriate for inclusion in the ESRD QIP. Although all eligible HCP are required to be vaccinated against COVID–19 under CMS's Omnibus COVID–19 Health Care Staff Vaccination Interim Final Rule (86 FR 61555), including the COVID–19 Vaccination Coverage among HCP reporting measure in the ESRD QIP will provide patients and their caregivers with information regarding the rates of HCP COVID–19 vaccination at individual facilities, and such information will help them make informed treatment decisions. We further believe that the COVID–19 Vaccination Coverage among HCP reporting measure will not create a new, ESRD QIP specific reporting burden for the majority of facilities because they are already reporting the same information via the ESRD Network program or to comply with State reporting requirements. To the extent the adoption of this measure for the ESRD QIP imposes a new reporting burden on some facilities, we believe the importance of collecting and reporting data on COVID–19 vaccination coverage among HCP is sufficiently beneficial to outweigh this burden. We are also collaborating with the CDC to minimize reporting burden to the extent feasible where facilities separately report the data to the CDC for other monitoring purposes. Finally, we strongly believe that tracking HCP vaccination status will have an impact on the quality of ESRD care. ESRD patients are more vulnerable to experiencing complications as a result of a COVID–19 infection. We believe that encouraging HCP vaccination against COVID–19 will help to protect HCP and the ESRD patients they care for by reducing the risk of COVID–19 transmission in facilities.

Comment: A few commenters requested that CMS define HCP for purposes of this measure to exclude HCP outside an organization's workforce, noting difficulties in tracking vaccination rates among HCP who are not in the scope of a provider's workforce. One commenter recommended that CMS allow facilities to exclude from the count staff with no direct in-person patient contact at any time. One commenter recommended that CMS consider allowing an attestation of vaccination status from the employer of contracted personnel to satisfy reporting obligations under the COVID–19 Vaccination Coverage among HCP reporting measure. This commenter expressed concern with the proposed COVID–19 Vaccination Coverage among HCP reporting measure because the required level of detail for NHSN reporting is greater than the detail it receives from such contractors regarding vaccination status. The commenter also expressed concern that its internal systems lack capacity to collect and store vendor data regarding individual vaccination status, noting that storing data for outside contractors increases the risk of data breaches, and compliance with the NHSN's level of specificity would require additional resources that may detract from the quality of patient care. Finally, the commenter noted that CMS has access to contracted vendor data through other channels.

Response: We acknowledge commenters' concerns regarding reporting burden associated with the specifications of this measure specifically around the definition of HCP. We note that given the highly infectious nature of the virus that causes COVID–19, we believe it is important to encourage all personnel within the facility, regardless of patient contact, role, or employment type, to receive the COVID–19 vaccination to prevent outbreaks within the facility which may affect resource availability and have a negative impact on patient access to care. We also note that CDC's guidance for entering data requires submission of HCP count at the facility level, and the measure requires reporting consistent with that guidance.[272] The decision to include or exclude HCP from the facility's HCP vaccination counts should be based on whether individuals meet the specified NHSN criteria and are physically working in a location that is considered any part of the facility that is being monitored.[273] Additionally, the CDC has provided a number of resources including a tool called the Data Tracking Worksheet for COVID–19 Vaccination among Healthcare Personnel to help facilities log and track the number of HCP who are vaccinated for COVID–19. Facilities would enter COVID vaccination data for each HCP in the tracking worksheet, and select a reporting week, and the data to be entered into the NHSN will automatically be calculated on the Reporting Summary.[274]

Comment: A few commenters sought clarification on how CMS will define ''complete vaccination course'' as well as the length of time CMS will give HCP to get boosters or new vaccines.

Response: HCP should be counted as vaccinated if they received COVID–19 vaccination any time from when it first became available in December 2020. A completed vaccination course, which is defined for purposes of this measure as the primary vaccination series, may require one or more doses depending on the specific vaccine used. The NHSN application automatically calculates the total value for ''Any completed COVID–19 vaccine series.'' This is the cumulative number of HCP who completed any COVID–19 vaccine series (dose 1 and dose 2 of COVID–19 vaccines requiring two doses for completion or one dose of COVID–19 vaccines requiring only one dose for completion) at the facility or elsewhere (for example, a pharmacy). For surveillance purposes, facilities are required to enter data in the NHSN application on the number of HCP who have received an additional or booster dose of the COVID–19 vaccine.[275] As vaccination protocols continue to evolve, we will work with the CDC to update relevant measure specifications as necessary.

Comment: A few commenters recommended that CMS exclude from the measure any HCP who have been granted a religious belief exemption under an individual facility's policies.

Response: The measure denominator excludes HCP who were determined to have a medical contraindication, defined as: severe allergic reaction (for example, anaphylaxis) after a previous dose or to a component of the COVID–19 vaccine or an immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine. Religious or personal beliefs are not approved exemptions for purposes of the COVID–19 Vaccination Coverage among HCP reporting measure. Under the measure specifications, any HCP who decline vaccination because of religious or

[272] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID–19 Vaccination Coverage. Available at: *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf.*

[273] Centers for Disease Control and Prevention. CMS Reporting Requirements FAQs. Accessed September 7, 2022 at: *https://www.cdc.gov/nhsn/PDFs/CMS/faq/FAQs-CMS-Reporting-Requirements.pdf.*

[274] Data Tracking Worksheet for COVID–19 Vaccination among Healthcare Personnel, available at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html.*

[275] *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/protocol-hcp-508.pdf.*

philosophical exemptions should be categorized as declined vaccination.

Comment: One commenter recommended that CMS seek NQF endorsement for this measure and develop a validation process for the measure prior to inclusion in the ESRD QIP.

Response: Although NQF endorsement was pending at the time we issued the proposed rule, the NQF endorsed this measure in July 2022.[276] We will also work with the CDC on developing a validation process.

Comment: One commenter expressed concern that the reporting frequency would increase burden and therefore recommended that reporting be required no more than twice per year.

Response: We disagree that the reporting frequency is overly burdensome and that facilities should report twice per year instead of quarterly because we believe that important public health initiatives outweigh this burden. We proposed that facilities report at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN HPS Component before the quarterly deadline. We note that the majority of facilities are already reporting these data on a weekly or monthly basis under the ESRD Network program or due to existing state reporting requirements. We proposed that for each quarter, the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each facility by taking the average of the data from the three weekly rates submitted by the facility for that quarter. CMS will publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC. Consistent monthly vaccination reporting by facilities will help patients and their caregivers identify facilities that have potential issues with vaccine confidence or slow uptake among staff.

Final Rule Action: After considering public comments, we are finalizing our proposal to add the COVID–19 Vaccination Coverage among HCP reporting measure to the ESRD QIP measure set beginning with PY 2025.

b. Updates to the Standardized Transfusion Ratio (STrR) Reporting Measure Beginning With PY 2025

Under section 1881(h)(2)(A)(iv)(I) of the Act, the ESRD QIP has a statutory requirement to include an anemia management measure in the Program's measure set, and the STrR reporting measure currently satisfies that statutory requirement. In the CY 2015 ESRD PPS final rule (79 FR 66192 through 66197), we finalized the adoption of the STrR clinical measure to address gaps in the quality of anemia management, beginning with the PY 2018 ESRD QIP. The NQF endorsed a revised version of the STrR clinical measure in 2016, and in the CY 2018 ESRD PPS final rule (82 FR 50771 through 50774), we adopted the revised version of the STrR clinical measure beginning with the PY 2021 ESRD QIP.

Commenters to the CY 2019 ESRD PPS proposed rule raised concerns about the validity of the modified STrR measure (NQF #2979) finalized for adoption beginning with PY 2021 (83 FR 56993 through 56994). Commenters specifically stated that due to the new level of coding specificity required under the ICD–10–CM/PCS coding system, many hospitals were no longer accurately coding blood transfusions. The commenters further stated that because the STrR clinical measure was calculated using hospital data, the rise of inaccurate blood transfusion coding by hospitals had negatively affected the validity of the STrR measure (83 FR 56993 through 56994).

In the CY 2020 ESRD PPS final rule (84 FR 60720 through 60723), we finalized our proposal to convert the STrR clinical measure to a reporting measure while we examined these validity concerns. Accordingly, we finalized that, beginning with PY 2022, we would score the STrR measure so that facilities that meet previously finalized minimum data and eligibility requirements would receive a score on the STrR reporting measure based on the successful reporting of data, not on the values actually reported. We stated our desire to ensure that the Program's scoring methodology results in fair and reliable STrR measure scores because those scores are linked to facilities' TPS and possible payment reductions. We also stated our belief that the most appropriate way to continue fulfilling the statutory requirement to include a measure of anemia management in the Program while ensuring that facilities are not adversely affected during our continued examination of the measure was to convert the STrR clinical measure to a reporting measure.

In November 2020, the NQF renewed its endorsement of the STrR clinical measure after performing an ad hoc review based on updates we made to the measure's specifications to address coding and validity concerns. Under the revised STrR clinical measure, inpatient transfusion events are identified using a broader definition that includes revenue center codes only, ICD procedure codes (alone or with revenue codes), or value codes alone or in combination. In the CY 2023 ESRD PPS proposed rule, we stated our belief that these updates would result in identification of a greater number of inpatient transfusion events compared to the previously implemented STrR clinical measure (87 FR 38545). In addition, we noted that the revised STrR clinical measure would effectively mitigate a provider coding bias that was exacerbated by the conversion from ICD–9 to ICD–10 code sets in late CY 2015.

In light of the NQF's endorsement and adoption of the updated STrR clinical measure specifications, we proposed to convert the STrR reporting measure to the revised STrR clinical measure using the revised specifications that were endorsed by the NQF (87 FR 38545). We stated our belief that previous validity concerns have been adequately examined and addressed, that facilities have had sufficient time to gain experience with the updated measure specifications through reporting the updated measure for Dialysis Facility Compare, and converting back to the STrR clinical measure would be consistent with our intent to more closely align with NQF measure specifications where feasible (84 FR 60724).

In addition to our proposal to convert the STrR reporting measure to a clinical measure, we also proposed to update the scoring methodology for the STrR clinical measure so that facilities that meet previously finalized minimum data and eligibility requirements would receive a score on the STrR clinical measure based on the actual clinical values reported by the facility, rather than the successful reporting of the data. We also proposed to express the proposed STrR clinical measure as a rate, rather than as a ratio. We stated our belief that converting the STrR clinical measure to be expressed as a rate would help providers and patients better understand a facility's performance on the measures and would be more intuitive for a facility to track its performance from year to year. To assess the impact of expressing STrR measure results as rates, we multiplied the facility level STrR by the national average transfusion rate. Our analysis found that the difference between the distribution of STrR measure scores expressed as a ratio and expressed as a rate was generally less than 1 percent. Therefore, in the proposed rule we stated our belief that expressing STrR measure results as a rate would not result in different ESRD QIP scores. This

[276] National Quality Forum, QPS Tool. Quarterly Reporting of COVID–19 Vaccination Coverage among Healthcare Personnel (NQF #3636). July 26, 2022. Available at *https://www.qualityforum.org/QPS/QPSTool.aspx.*

approach would also align with our technical updates to the SHR clinical measure and the SRR clinical measure, as discussed in section IV.D of the CY 2023 ESRD PPS proposed rule (87 FR 38539 through 38540).

We welcomed public comment on our proposals. The comments we received and our responses are set forth below.

Comment: One commenter supported our proposal to convert the STrR reporting measure to a clinical measure for PY 2025. However, this commenter urged CMS to do so only until the STrR measure can be replaced with a measure of hemoglobin (Hb) <10 g/dL measure, which commenter stated is supported by current evidence as the most actionable and operationally feasible anemia management measure for dialysis providers.

Response: We thank the commenter for its support. Although we are not aware of current data that clearly establishes a minimum hemoglobin threshold that reliably maximizes the primary outcomes of survival, hospitalization, and quality of life for most patients, we will reassess the feasibility of replacing the STrR clinical measure with a hemoglobin measure as part of our future measure development work as new evidence becomes available.

Comment: One commenter requested that CMS provide more information regarding the proposed STrR clinical measure, including the scoring methodology. One commenter requested that CMS increase transparency in transfusion data by providing facilities with a monthly transfusions data set to model the measure and make improvements based on that data.

Response: The STrR clinical measure is a ratio (which, like the SHR and SRR clinical measures, would be expressed as a rate) of the number of eligible red blood cell transfusion events observed in patients dialyzing at a facility, to the number of eligible transfusion events that would be expected under a national norm, after accounting for the patient characteristics within each facility. Eligible transfusions are those that do not have any claims pertaining to the comorbidities identified for exclusion, in the one year look back period prior to each observation window. This measure is calculated as a ratio but can also be expressed as a rate. We are finalizing this scoring methodology in this final rule as part of the finalized STrR clinical measure and will provide more details regarding technical specifications in the updated Measures Manual.

We appreciate commenter's request for increased transparency in transfusion data and will take its recommendation to provide facilities with a monthly transfusions data set to model the measure and make improvements based on that data under consideration.

Comment: Several commenters did not support our proposal to convert the STrR reporting measure to a clinical measure, recommending that the STrR remain a reporting measure. Several commenters expressed concern that facilities will be unfairly penalized as a result of our proposal to convert the STrR reporting measure to a clinical measure, noting that although patients often receive non-ESRD-related transfusions, hospitals will code non-ESRD transfusions erroneously due to differences in coding practices. A few commenters requested that CMS release data showing how previous coding and validity concerns were addressed, noting that measure inaccuracies could negatively impact patient care. Several commenters remained concerned about the STrR's continued use in the ESRD QIP because facilities do not have access to transfusion data and may have difficulty obtaining the information. Several commenters noted that the measure tracks hospital decision-making rather than facility activities and that facilities often do not have access to STrR information because it is maintained by hospitals. Without access to this relevant measure-related data, commenters stated that facilities are not able to act to improve measure performance. One commenter expressed concern that converting the STrR reporting measure to a clinical measure may discourage facilities from treating patients with an increased likelihood of transfusion.

Response: We believe that these concerns expressed by commenters have been mitigated by the recent NQF-endorsed revisions to the STrR clinical measure. For hospital inpatients, the previous version of the STrR clinical measure relied on a restricted transfusion event identification algorithm. The measure utilized only those reported transfusion events that include ICD procedure codes, ICD procedure codes with revenue center codes, or value codes. For the revised STrR clinical measure that is currently NQF-endorsed, inpatient transfusion events are identified using a broader definition that includes revenue center codes only, ICD procedure codes (alone or with revenue codes), or value codes alone or in combination. This revision will result in identification of a greater number of inpatient transfusion events compared to the currently implemented STrR. In addition, the revision will effectively mitigate a provider coding bias that was exacerbated by the conversion from ICD–9 to ICD–10 code sets in late CY 2015. Identification of outpatient transfusion events is identical in the two STrR versions, as the ICD–9 to ICD–10 transition does not impact outpatient transfusion claims submission (outpatient claims rely on HCPCS procedure codes instead). The NQF website's QPS Tool is a public tool which allows users to search for information on all endorsed measures, including the STrR clinical measure.[277] We refer commenters to this website for further information on how previous coding and validity concerns in the previous version of the STrR clinical measure were addressed in the revised STrR clinical measure. Additional information regarding the STrR clinical measure is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP*.

Although we appreciate commenters' concerns regarding the role of hospitals in the STrR clinical measure, we note that hospitals and facilities often work together to coordinate aspects of ESRD patient care. Anemia is a complication of end-stage renal disease that can be avoided if a patient's dialysis facility is undertaking proper anemia management. When anemia is not managed, patients are subjected to unnecessary transfusions that increase morbidity and mortality. The STrR measure is calculated using data reported by hospitals because poor anemia management results in transfusions that most often occur in hospitals and not dialysis facilities.

Comment: A few commenters expressed concern regarding the proposed STrR clinical measure, and recommended replacing it with the Hgb<10 g/dL measure. A few commenters strongly urged CMS to adopt a Hgb<10 g/dL measure, stating that such a measure will more accurately reflect a facility's anemia management performance. These commenters also noted that the Hgb<10 g/dL measure would provide more transparency than the STrR measure so that facilities have more actionable information regarding anemia management, resulting in a greater positive effect on patient care and outcomes. A few commenters further noted that the STrR has not had much of an impact on hemoglobin levels and recommended that CMS prioritize finding a more appropriate anemia management measure as it shifts toward

[277] *https://www.qualityforum.org/QPS/QPSTool.aspx.*

more patient-reported outcome measures.

Response: As we discussed in the CY 2020 ESRD PPS final rule, use of a hemoglobin threshold measure has been previously considered and was not implemented based on several concerns (84 FR 60722). First, studies reporting results of anemia management in chronic dialysis settings typically result in hemoglobin distributions with relatively large outcome variation, creating concern that attempts at achievement of a specific target will result in a substantial minority of treated patients either well above or below the target at any point in time. Given the significant concerns about potential clinical risks of overtreatment with Erythropoietin stimulating agents (ESAs), implementation of a hemoglobin threshold could result in increased risk of ESA-related complication for the subset of patients above the threshold. One major consequence of under treatment is increased transfusion risk. Emphasis on minimizing avoidable transfusions in this population focuses on avoiding a major consequence of under-treatment without explicitly contributing to the risks associated with over-treatment with ESAs. This approach is consistent with the Food and Drug Administration (FDA) guidance for use of ESAs in this population. In addition, the available literature has not clearly established a minimum hemoglobin threshold that reliably maximizes the primary outcomes of survival, hospitalization, and quality of life for most patients. However, we will review new evidence as it becomes available to reassess the feasibility of replacing the STrR clinical measure with a hemoglobin measure as part of our future measure development work.

Final Rule Action: After considering public comments, we are finalizing our proposal to convert the STrR reporting measure to a clinical measure. We are also finalizing our proposal to update the scoring methodology for the STrR clinical measure so that facilities that meet previously finalized minimum data and eligibility requirements would receive a score on the STrR clinical measure based on the actual clinical values reported by the facility. We are also finalizing our proposal to express the STrR clinical measure results as a rate.

c. Conversion of the Hypercalcemia Clinical Measure to a Reporting Measure Beginning With PY 2025

Section 1881(h)(2)(A)(iv)(II) of the Act states that the measures specified for the ESRD QIP must include, to the extent feasible, measures of bone mineral metabolism. Abnormalities of bone mineral metabolism are exceedingly common and contribute significantly to morbidity and mortality in patients with advanced Chronic Kidney Disease (CKD). Many studies have associated disorders of mineral metabolism with mortality, fractures, cardiovascular disease, and other morbidities. Therefore, in the CY 2014 ESRD PPS final rule (78 FR 72200 through 72203), we adopted the Hypercalcemia clinical measure as part of the ESRD QIP measure set, which we believed would encourage adequate management of bone mineral metabolism and disease in patients with ESRD.

In the CY 2023 ESRD PPS proposed rule, we noted that in recent years, we have received numerous public comments expressing concern about the role and weight of the Hypercalcemia clinical measure in the ESRD QIP (87 FR 38545). We noted that many interested parties have indicated that they believe the measure is topped out, pointing out that the NQF has placed the measure in Reserve Status because of high facility performance and minimal room for improvement. As a result, the ability to distinguish meaningful differences in performance between facilities is substantially reduced because small random variations in measure rates can result in different scores. Others have expressed concern about whether the Hypercalcemia clinical measure is the best measure in the bone mineral metabolism domain to impact patient outcomes.

Considering these persistent concerns expressed by interested parties, we stated in the proposed rule that we are currently examining the continued viability of the Hypercalcemia clinical measure as part of the ESRD QIP measure set. We also acknowledged that there may be other measures of bone mineral metabolism that are more informative or effective than the Hypercalcemia clinical measure, such as the serum phosphorus measure.[278]

In the proposed rule, we stated that although recent annual measure analyses have indicated that the Hypercalcemia clinical measure may not be fully topped out based on the statistical criteria that we adopted in the CY 2015 ESRD PPS final rule (79 FR 66174), they also indicate that the measure is very close to being topped out (87 FR 38545). We noted that, under our previously adopted methodology, a clinical measure is considered to be topped out if national measure data show (1) statistically indistinguishable performance levels at the 75th and 90th percentiles; and (2) a truncated coefficient of variation (TCV) of less than or equal to 0.1. To determine whether a clinical measure is topped out, we initially focus on the top distribution of facility performance on each measure and note if their 75th and 90th percentiles are statistically indistinguishable. Then, to ensure that we properly account for the entire distribution of scores, we analyze the truncated coefficient of variation (TCV) for the measure. Based on a 2017 analysis using CY 2015 CROWNWeb measure data, the Hypercalcemia clinical measure did not meet both conditions. Although the TCV was less than 1 percent, the difference between the 75th percentile (0.91) was statistically distinguishable from the 90th percentile (0.32). However, given that the TCV was so low and was calculated by removing the lower and upper 5th percentiles, we stated our belief that it was possible that certain outliers in the 90th percentile could have skewed the statistically distinguishable part of the topped out analysis. In other words, although the Hypercalcemia clinical measure was not considered topped out based on our previously adopted methodology, we believed that it was very close to being topped out based on the available data and were concerned that small differences in measure performance may disproportionately impact a facility's score on the measure.

Therefore, we proposed to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025 while we explore possible replacement measures that would be more clinically meaningful for purposes of quality improvement. We also proposed to update the scoring methodology so that facilities that meet previously finalized minimum data and eligibility requirements would receive a score on the Hypercalcemia reporting measure based on the successful reporting of the data, rather than the actual clinical values reported by the facility. Facilities would be scored using the following equation, beginning in PY 2025:

[278] CMS ESRD QIP PY 2020 Final Measure Technical Specifications. Accessed May 18, 2022 at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/PY-2020-Technical-Specification.pdf.*

$$\left(\frac{\text{number of patient-months successfully reporting data}}{\text{number of eligible patient-months}} \times 12\right) - 2$$

If finalized, we stated that the Hypercalcemia reporting measure would be in our Reporting Measure Domain, which we discussed in section IV.E.2 of the proposed rule.

We welcomed public comments on our proposal to convert the Hypercalcemia clinical measure to a reporting measure, beginning in PY 2025. The comments we received and our responses are set forth below.

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Comment: Several commenters expressed support for the proposal to convert the Hypercalcemia measure to a reporting measure, noting that the measure is topped out and does not provide meaningful information to patients or care providers. One commenter supported the proposal to convert the Hypercalcemia clinical measure into a reporting measure, noting that this measure is important for monitoring but that facilities cannot control their performance on the measure. One commenter supported conversion of the Hypercalcemia clinical measure to a reporting measure because it will reduce burden for a condition in which interventions are beyond providers' control.

Response: We thank the commenters for their support.

Comment: Several commenters recommended that CMS replace the hypercalcemia measure with the Serum Phosphorus measure, noting that it is a more informative and effective measure of bone mineral metabolism and that physicians rely on the serum phosphorus measure to make clinical decisions. One commenter recommended replacing the Hypercalcemia measure with the Serum Phosphorus measure in ESRD QIP because it better aligns with the requirements of the Protecting Access to Medicare Act of 2014 (PAMA) for CMS to include measures of relevance for oral-only drugs in the ESRD QIP, and it encourages coordination of care among an ESRD patient's providers to ensure that phosphorus levels are regularly assessed for purposes of phosphorus management. One commenter recommended that CMS replace the hypercalcemia measure with a new measure of appropriate use of secondary hyperparathyroidism (SHPT) medications to reduce excessive PTH levels according to current clinical guidelines. A few commenters recommended that CMS consider only feasible measures that are more clinically meaningful for purposes of quality improvement.

Response: We thank the commenters for their recommendations and will take them under consideration. As noted in the proposed rule, we are currently examining the continued viability of the Hypercalcemia clinical measure as part of the ESRD QIP measure set and acknowledge that there may be other measures of bone mineral metabolism that are more informative or effective than the Hypercalcemia clinical measure, such as the Serum Phosphorus measure.

Comment: A few commenters recommended that CMS remove the Hypercalcemia measure from the ESRD QIP measure set entirely. One commenter recommended that the hypercalcemia measure should be suppressed in the interim while CMS finds a more appropriate measure of bone mineral metabolism. This commenter stated that, although converting Hypercalcemia to a reporting measure would alleviate the measure's impact on a facility's score, a facility should not have to report on a measure that lacks significance.

Response: We are considering the long-term viability of the Hypercalcemia measure and examining possible alternative measures to replace the Hypercalcemia measure in the ESRD QIP. If we do propose to remove the Hypercalcemia measure from the ESRD QIP measure set in future rulemaking, we will also propose to replace it with a different bone mineral metabolism measure. We disagree with the commenter's recommendation to suppress the Hypercalcemia measure in the interim, and note that our measure suppression policy only enables us to suppress the use of measure data for scoring and payment adjustments if we determine that circumstances caused by the COVID–19 PHE have affected the measures and the resulting Total Performance Scores (TPSs) significantly, as guided by the measure suppression factors we have finalized. Our analyses indicate that facility performance on the Hypercalcemia clinical measure was not significantly impacted by the COVID–19 PHE in CY 2021, as the scoring simulations for the Hypercalcemia clinical measure showed that measure performance was consistent with performance from previous years. Our analyses also did not show that there were significant changes in measure performance on the Hypercalcemia clinical measure, proximity between the measure's focus to the health impacts of the COVID–19 PHE, rapid or unprecedented changes in clinical guidelines or care delivery or practice, or significant national shortages or rapid or unprecedented changes in patient-case volumes or facility-level case mix. Therefore, we concluded that suppression of the Hypercalcemia clinical measure is not warranted under any of our previously finalized Measure Suppression Factors. We also disagree that the Hypercalcemia measure lacks significance. Although the Hypercalcemia clinical measure may be close to being topped out, we believe the measure still encourages adequate management of bone mineral metabolism and disease in patients with ESRD and thus is appropriately included in the ESRD QIP measure set at this time.

Final Rule Action: After considering public comments, we are finalizing our proposal to convert the Hypercalcemia clinical measure to a reporting measure, beginning with the PY 2025 ESRD QIP.

2. Revisions To Measure Domains and to the Domain and Measure Weights Used To Calculate the Total Performance Score (TPS) Beginning With the PY 2025 ESRD QIP

In the CY 2019 ESRD PPS final rule (83 FR 56991 through 56992), we finalized revisions to the ESRD QIP measure domains. Specifically, we eliminated the Reporting Domain and reorganized the Clinical Domain into three distinct domains: Patient & Family Engagement Domain, Care Coordination Domain, and Clinical Care Domain. We stated that adopting these topics as separate domains would result in a measure set that is more closely aligned with the priority areas in the Meaningful Measures Framework.[279] We also continued use of the Patient Safety Domain, which aligns with the Meaningful Measures Framework priority to make care safer by reducing harm caused in the delivery of care. In that rule, we finalized our proposal to eliminate the Reporting Measure Domain from the ESRD QIP scoring methodology, beginning in PY 2021, because there would no longer be any measures in that domain as a result of

[279] CMS website, Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*.

our finalized proposals to reassign the Ultrafiltration Rate and Clinical Depression Screening and Follow-Up Reporting measures to the Clinical Care Measure Domain and the Care Coordination Measure Domain, respectively (83 FR 56991 through 56997).

In the CY 2019 ESRD PPS final rule, we also stated our intent to reassess how the finalized ESRD QIP measure domains and domain weights affect TPSs awarded under the Program in the future (83 FR 56995). We take numerous factors into account when determining appropriate domain and measure weights, including clinical evidence, opportunity for improvement, clinical significance, and patient and provider burden. We also consider criteria previously used to determine appropriate domain and measures weights, including: (1) The number of measures and measure topics in a proposed domain; (2) how much experience facilities have had with the measures and measure topics in a proposed domain; and (3) how well the measures align with CMS's highest priorities for quality improvement for patients with ESRD (79 FR 66214) (that is, the Meaningful Measures Framework priorities, which includes our preferred emphasis on patient outcomes).

In the CY 2023 ESRD PPS proposed rule, we stated that currently, ESRD QIP measures are weighted and distributed across four measure domains: Patient & Family Engagement, Care Coordination, Clinical Care, and Safety (87 FR 38546). Based on changes to the measure set since PY 2021, including adoption of the Medication Reconciliation (MedRec) reporting measure, the PPPW clinical measure, and the measure-related proposals we are finalizing in this final rule, we have reassessed the impact of the ESRD QIP measure domains and domain weights on TPSs, and we believe it is necessary to increase incentives for improving performance by increasing the weights on measures where there is the most room for improvement, especially on patient clinical outcomes. Therefore, we proposed to create a new Reporting Measure Domain which would include the four current reporting measures in the ESRD QIP measure set, as well as the proposed COVID–19 HCP Vaccination reporting measure and the proposed Hypercalcemia reporting measure. We noted that we proposed to convert the STrR reporting measure to a clinical measure, as discussed in section IV.E.1.b of the proposed rule, and as a result, we proposed that the proposed STrR clinical measure would be placed in the Clinical Care Measure Domain (87 FR 38546).

We also proposed to update the domain weights and individual measure weights in the Care Coordination Domain, Clinical Care Domain, and Safety Domain accordingly to accommodate the new Reporting Measure Domain and individual reporting measures therein. As the ESRD QIP measure set has evolved over the years, we stated our belief that this would help to address concerns regarding the impact of individual measure performance on a facility's TPS, while also further incentivizing improvement on clinical measures. For a comparison of current and proposed measure domains and weighting, please see Table 19 and Table 20 in the CY 2023 ESRD PPS proposed rule (87 FR 38547), which we include in this final rule as Table 23 and Table 24.

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TABLE 23: Current ESRD QIP Measure Domains and Weights

Measure/Measure Topics by Subdomain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	**15.00**
ICH CAHPS measure	15.00
Care Coordination Measure Domain	**30.00**
SHR clinical measure	12.00
SRR clinical measure	12.00
PPPW measure	4.00
Clinical Depression and Follow-Up reporting measure	2.00
Clinical Care Measure Domain	**40.00**
Kt/V Dialysis Adequacy Comprehensive Measure	9.00
Vascular Access Type Measure Topic	12.00
STrR measure	10.00
Hypercalcemia measure	3.00
Ultrafiltration Rate measure	6.00
Safety Measure Domain	**15.00**
NHSN BSI clinical measure	8.00
MedRec measure	4.00
NHSN Dialysis Event reporting measure	3.00

TABLE 24: Proposed ESRD QIP Measure Domains and Weights

Measure/Measure Topics by Subdomain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	**15.00**
ICH CAHPS measure	15.00
Care Coordination Measure Domain	**30.00**
SHR clinical measure	12.00
SRR clinical measure	12.00
PPPW measure	6.00
Clinical Care Measure Domain	**35.00**
Kt/V Dialysis Adequacy Comprehensive Measure	11.00
Vascular Access Type Measure Topic	12.00
STrR clinical measure*	12.00
Safety Measure Domain	**10.00**
NHSN BSI clinical measure	10.00
Reporting Measure Domain	**10.00**
Clinical Depression and Follow-Up reporting measure	1.67
Hypercalcemia reporting measure**	1.67
Ultrafiltration Rate reporting measure	1.67
MedRec reporting measure	1.67
NHSN Dialysis Event reporting measure	1.67
COVID-19 HCP Vaccination reporting measure***	1.67

* We are finalizing our proposal to convert the STrR reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this final rule.

**We are finalizing our proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this final rule.

***We are finalizing our proposal to adopt the COVID-19 HCP Vaccination measure beginning in PY 2025, as discussed in section IV.E.1.a of this final rule.

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We welcomed public comment on our proposal to create a new Reporting Domain and to update the existing domains and measure weights used to calculate the TPS, beginning with PY 2025. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for our proposal to create a reporting measure domain and reweight measures and measure domains.

Response: We thank commenters for their support.

Comment: A few commenters expressed concern with our proposal to create a new reporting measure domain and re-weight existing measure domains, stating that CMS should instead aim to reduce the number of measures in the ESRD QIP and weight the remaining measures to align with clinical value and importance to patients so that they are meaningful.

Response: We agree with commenters that the weights should reflect clinical value and meaningfulness to patients, which we took into account in developing our proposal. We believe that the proposed measure domains and weights will provide facilities with more meaningful incentives to improve performance on measures that align with clinical value and importance to patients. Although we aim to minimize facility burden as much as feasible, we disagree that reducing the number of measures in the ESRD QIP should be a goal, absent justification under our previously finalized measure removal policy (83 FR 56983 through 56985). We note that we have developed the ESRD QIP measure set specifically to ensure that facilities focus on the most relevant clinical topics that will lead to improved quality of care and better outcomes for patients.

Comment: A few commenters expressed concern regarding our proposal to update domain weights and our proposal to update individual weights within those domains. One commenter expressed concern with our proposal to weight the reporting measure domain at 10 percent, noting that reporting measures currently account for 18 percent of a facility's TPS. This commenter recommended that the reporting measure domain should be worth at least 18 percent of a facility's total score, emphasizing the critical role of reporting measures in a facility's quality of care provided to patients. One commenter recommended that each measure domain should have equal weight because it would support the CMS National Quality Strategy goal of alignment among value-based purchasing programs and would further highlight the importance of patient experience and person-centered care. One commenter was particularly concerned with the weight of the ICH CAHPS and the STrR, believing that the measures were too heavily weighted and that the resulting TPS would not accurately reflect a facility's performance. One commenter recommended that CMS weight the Long-Term Catheter Rate measure greater than the Standardized Fistula Rate measure to support a ''catheters last'' approach to improve patient outcomes. This commenter also recommended that CMS work with the kidney care community to develop more appropriate weights. One commenter expressed support for increasing the PPPW measure weight, but noted that dialysis facilities should be more strongly encouraged to refer clinically appropriate patients for transplant evaluation by strengthening regulatory incentives for the referral source.

Response: Although we will take these recommendations into consideration for future rulemaking, we believe that the proposed Reporting Measure Domain weights are appropriate to support high quality health care on all ESRD QIP measures. We will also take commenters'

recommendations regarding specific measure weights into consideration for future rulemaking, but believe that the proposed weights are appropriate at this time to incentivize quality improvement in more actionable clinical measures. That is, we believe it is appropriate to assign greater weights to those clinical measures that have more room for quality improvement and therefore may help to ensure better patient outcomes. We note the ICH CAHPS measure weight will remain the same at 15 percent, which we continue to believe is an appropriate weight for incentivizing facility performance on a measure of a patient's experience of care. Although the STrR clinical measure weight will increase from 10 percent to 12 percent, we believe this incremental increase appropriately reflects the importance of anemia management in the ESRD QIP. We believe a combined vascular access type measure topic, weighted at 12 percent, makes sense to accommodate the different vascular access needs of patients. We appreciate commenter's support for increasing the weight of the PPPW clinical measure and will continue to consider ways to further incentivize transplant referrals where clinically appropriate.

Comment: One commenter expressed concern that changing the weight of ESRD QIP measures may increase burden and confusion among facilities and providers.

Response: We appreciate commenter's feedback, but we disagree that changing the weight would increase burden or confusion among facilities and providers. We believe that changing the weights of ESRD QIP measures as proposed will better inform facilities' ability to improve performance on more actionable clinical measures and will result in more meaningful patient outcomes. In addition, we will engage in education and outreach activities to communicate information about the updated weights as well as other measure and program changes being finalized in this rule.

Comment: One commenter urged CMS to re-base performance for the first year after the COVID–19 PHE to ensure the impact of the PHE is accurately accounted for and that measure performance is accurately assessed going forward. One commenter recommended that CMS should have a reassessment plan for all measures and that home dialysis-only programs be reassessed for measure weights because some current domains would no longer be applicable.

Response: We thank commenters for their suggestions and will take them into consideration for future rulemaking.

Final Rule Action: After considering public comments, we are finalizing our proposal to create a new Reporting Domain and to update the domains and measure weights used to calculate the TPS, beginning with PY 2025. We are finalizing the proposed domain and measure weights described in Table 24 of this final rule.

3. Performance Standards for the PY 2025 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at 42 CFR 413.178(a)(1), (3), (7), and (12), respectively.

In the CY 2022 ESRD PPS final rule (86 FR 61927), we set the performance period for the PY 2025 ESRD QIP as CY 2023 and the baseline period as CY 2021. We note that, for the seven measures we are suppressing for the PY 2023 ESRD QIP, we would continue to use CY 2019 data as the baseline period for those measures. We believe that this is consistent with our established policy to use the prior year's numerical values for the performance standards if the most recent full CY's final numerical values are worse. In the proposed rule, we estimated the performance standards for the PY 2025 clinical measures in Table 21 using data from CY 2019, which was the most recent data available (87 FR 38548). We are updating these standards for the non-suppressed measures, using CY 2021 data, in this final rule, in Table 25 below.

TABLE 25: Performance Standards for the PY 2025 ESRD QIP Clinical Measures

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Vascular Access Type (VAT)			
Standardized Fistula Rate	53.29%	64.36%	76.77%
Catheter Rate	18.35%	11.04%	4.69%
Kt/V Comprehensive	94.33%	97.61%	99.42%
Standardized Readmission Ratio[a]	34.27	26.97	17.02
NHSN BSI	0.833	0.290	0
Standardized Hospitalization Ratio[b]	187.80	148.33	105.54
Standardized Transfusion Ratio[b]	53.46	29.78	10.75
PPPW	8.12%*	16.73%*	33.90%*
ICH CAHPS: Nephrologists' Communication and Caring	58.20%	67.90%	79.15%
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.64%	63.08%	72.66%
ICH CAHPS: Providing Information to Patients	74.49%	81.09%	87.80%
ICH CAHPS: Overall Rating of Nephrologists	49.33%*	62.22%*	76.57%*
ICH CAHPS: Overall Rating of Dialysis Center Staff	50.02%	63.37%	78.30%
ICH CAHPS: Overall Rating of the Dialysis Facility	54.51%	69.04%	83.72%

*Values are the same final performance standards for those measures for PY 2024. In accordance with our longstanding policy, we are using those numerical values for those measures for PY 2025 because they are higher standards than the PY 2025 numerical values for those measures.

**We are finalizing our proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this final rule, and have updated the table accordingly in this final rule.

[a]Rate calculated as a percentage of hospital discharges

[b]Rate per 100 patient-years

Data sources: VAT measures: 2019 EQRS; SRR, SHR: 2019 Medicare claims; STrR: 2021 Medicare claims; Kt/V: 2019 EQRS; Hypercalcemia: 2019 EQRS; NHSN: 2021 CDC; ICH CAHPS: CMS 2019; PPPW: 2019 EQRS and 2019 Organ Procurement and Transplantation Network (OPTN).

In addition, we summarize in Table 26 existing requirements for successful reporting on reporting measures in the PY 2025 ESRD QIP.

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TABLE 26: Requirements for Successful Reporting on the PY 2025 ESRD QIP Reporting Measures

Measure	Reporting Frequency	Data Elements
Ultrafiltration	4 data elements are reported for every hemodialysis (HD) Kt/V session during the week of the monthly Kt/V draw, and the number of sessions of dialysis is reported monthly	• In-Center Hemodialysis (ICHD) Kt/V Date • Post-Dialysis Weight • Pre-Dialysis Weight • Delivered Minutes of blood urea nitrogen (BUN) Hemodialysis • Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting Month
MedRec	Monthly	• Date of the medication reconciliation. • Type of eligible professional who completed the medication reconciliation: o physician, o nurse, o advanced registered nurse practitioner (ARNP), o physician assistant (PA), o pharmacist, or o pharmacy technician personnel • Name of eligible professional
Clinical Depression Screening and Follow-Up	1 of 6 conditions reported annually	• Screening for clinical depression is documented as being positive and a follow-up plan is documented. • Screening for clinical depression documented as positive, a follow-up plan is not documented, and the facility possesses documentation that the patient is not eligible. • Screening for clinical depression documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given. • Screening for clinical depression documented as negative and no follow-up plan required. • Screening for clinical depression not documented, but the facility possesses documentation stating the patient is not eligible. • Clinical depression screening not documented, and no reason is given.
NHSN Dialysis Event	Monthly	Three types of dialysis events reported: • IV antimicrobial start; • positive blood culture; and • pus, redness, or increased swelling at the vascular access site.
Hypercalcemia**	Monthly	Total uncorrected serum or plasma calcium lab values
COVID-19 Vaccination Coverage among HCP***	At least one week of data each month, submitted quarterly	Cumulative number of HCP eligible to work in the facility for at least one day during the reporting period and who received a complete vaccination course against SARS-CoV-2.

*We are finalizing our proposal to convert the STrR reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this final rule, and have updated this table accordingly.

**We are finalizing our proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this final rule.

***We are finalizing our proposal to adopt the COVID-19 Coverage among HCP reporting measure beginning in PY 2025, as discussed in section IV.E.1.a of this final rule.

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4. Eligibility Requirements for the PY 2025 ESRD QIP

Our current minimum eligibility requirements for scoring the ESRD QIP measures are described in Table 27. We did not propose any changes to these eligibility requirements for the PY 2025 ESRD QIP in the proposed rule.

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TABLE 27: Eligibility Requirements for Scoring on ESRD QIP Measures

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Standardized Fistula Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Hypercalcemia (Reporting)*	11 qualifying patients	N/A	N/A
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11-25 qualifying patients
NHSN Dialysis Event (Reporting)	11 qualifying patients	N/A	N/A
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Clinical)**	10 patient-years at risk	N/A	10-21 patient-years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities would not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A
Ultrafiltration (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	N/A
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
COVID-19 Vaccination Coverage among HCP (Reporting)***	11 qualifying healthcare personnel	N/A	N/A

* We are finalizing our proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this final rule.

**We are finalizing our proposal to convert the STrR reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this final rule, and have updated this table accordingly in this final rule.

***We are finalizing our proposal to adopt the COVID-19 Vaccination Coverage among HCP measure beginning in PY 2025, as discussed in section IV.E.1.a of this final rule.

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5. Payment Reduction Scale for the PY 2025 ESRD QIP

Under our current policy, a facility does not receive a payment reduction for a payment year in connection with its performance under the ESRD QIP if it achieves a TPS that is at or above the minimum TPS (mTPS) that we establish for the payment year. We have defined the mTPS in our regulations at 42 CFR 413.178(a)(8) as, with respect to a payment year, the TPS that an ESRD facility would receive if, during the baseline period it performed at the 50th percentile of national performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.

Our current policy, which is codified at 42 CFR 413.177 of our regulations, also implements the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the mTPS (76 FR 634 through 635).

In the proposed rule, we stated that for PY 2025, based on available data, a facility must meet or exceed a mTPS of 55 to avoid a payment reduction (87 FR 38552). We noted that the mTPS estimated in the proposed rule is based on data from CY 2019 instead of the PY 2025 baseline period (CY 2021) because CY 2021 data were not yet available.

We refer readers to Table 25 of this final rule for the PY 2025 finalized performance standards for each clinical measure. We stated in the CY 2023 ESRD PPS proposed rule that under our current policy, a facility that achieves a TPS below 55 would receive a payment reduction based on the TPS ranges indicated in Table 24 of the proposed rule (87 FR 38552).

Table 28 of this final rule is a reproduction of Table 24 from the CY 2023 ESRD PPS proposed rule.

We stated our intention to update the mTPS for PY 2025, as well as the payment reduction ranges for that payment year, in this CY 2023 ESRD PPS final rule.

We have now finalized the payment reductions that will apply to the PY 2025 ESRD QIP using updated CY 2021 data. The mTPS for PY 2025 will be 55, and the finalized payment reduction scale is shown in Table 29.

F. Updates for the PY 2026 ESRD QIP

1. Continuing Measures for the PY 2026 ESRD QIP

TABLE 28: Estimated Payment Reduction Scale for PY 2025 Based on the Most Recently Available Data

Total performance score	Reduction (%)
100-55	0%
54-45	0.5%
44-35	1.0%
34-25	1.5%
24-0	2.0%

TABLE 29: Finalized Payment Reduction Scale for PY 2025 Based on the Most Recently Available Data

Total performance score	Reduction (%)
100-55	0%
54-45	0.5%
44-35	1.0%
34-25	1.5%
24-0	2.0%

In the CY 2023 ESRD PPS proposed rule, we stated that, under our previously adopted policy, the PY 2025 ESRD QIP measure set would also be used for PY 2026 (87 FR 38552). We did not propose to adopt any new measures beginning with the PY 2026 ESRD QIP.

2. Performance Period for the PY 2026 ESRD QIP

In the CY 2023 ESRD PPS proposed rule, we stated our continued belief that 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP (87 FR 38552). Under this policy, we would adopt CY 2024 as the performance period and CY 2022 as the baseline period for the PY 2026 ESRD QIP.

We did not propose any changes to this policy.

3. Performance Standards for the PY 2026 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2012 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at 42 CFR 413.178(a)(1), (3), (7), and (12), respectively.

A. Performance Standards for Clinical Measures in the PY 2026 ESRD QIP

In the CY 2023 ESRD PPS proposed rule, we stated that at the time, we did not have the necessary data to assign numerical values to the achievement thresholds, benchmarks, and 50th percentiles of national performance for the clinical measures because we did not have CY 2021 data (87 FR 38552). We stated our intent to publish these numerical values, using CY 2021 data, in this CY 2023 ESRD PPS final rule. We provide the estimated performance standards for the PY 2026 ESRD QIP clinical measures, using applicable CY 2021 data, in Table 30 of this final rule.

We note that these performance standards may be updated in the CY 2024 ESRD PPS final rule based on CY 2022 data.

TABLE 30: Estimated Performance Standards for the PY 2026 ESRD QIP Clinical Measures Using the Most Recently Available Data

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Vascular Access Type (VAT)			
Standardized Fistula Rate	53.29%	64.36%	76.77%
Catheter Rate	18.35%	11.04%	4.69%
Kt/V Comprehensive	94.33%	97.61%	99.42%
Standardized Readmission Ratio[a]	34.27	26.97	17.02
NHSN BSI	0.833	0.290	0
Standardized Hospitalization Ratio[b]	187.80	148.33	105.54
Standardized Transfusion Ratio[b]	53.46	29.78	10.75
PPPW	8.12%*	16.73%*	33.90%*
ICH CAHPS: Nephrologists' Communication and Caring	58.20%	67.90%	79.15%
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.64%	63.08%	72.66%
ICH CAHPS: Providing Information to Patients	74.49%	81.09%	87.80%
ICH CAHPS: Overall Rating of Nephrologists	49.33%*	62.22%*	76.57%*
ICH CAHPS: Overall Rating of Dialysis Center Staff	50.02%	63.37%	78.30%
ICH CAHPS: Overall Rating of the Dialysis Facility	54.51%	69.04%	83.72%

*Values are the same final performance standards for those measures for PY 2024. In accordance with our longstanding policy, we are using those numerical values for those measures for PY 2025 because they are higher standards than the PY 2025 numerical values for those measures.

**We are finalizing our proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this final rule, and have updated the table accordingly in this final rule.

[a]Rate calculated as a percentage of hospital discharges

[b]Rate per 100 patient-years

Data sources: VAT measures: 2019 EQRS; SRR, SHR: 2019 Medicare claims; STrR: 2021 Medicare claims; Kt/V: 2019 EQRS; Hypercalcemia: 2019 EQRS; NHSN: 2021 CDC; ICH CAHPS: CMS 2019; PPPW: 2019 EQRS and 2019 Organ Procurement and Transplantation Network (OPTN).

b. Performance Standards for the Reporting Measures in the PY 2026 ESRD QIP

In the CY 2019 ESRD PPS final rule, we finalized the continued use of existing performance standards for the Screening for Clinical Depression and Follow-Up reporting measure, the Ultrafiltration Rate reporting measure, the NHSN Dialysis Event reporting measure, and the MedRec reporting measure (83 FR 57010 through 57011). We would continue use of these performance standards in PY 2026. In sections IV.E.1.c and IV.E.1.a of this final rule, we are finalizing our proposals to convert the Hypercalcemia clinical measure to a reporting measure and to add the COVID–19 Vaccination Coverage among HCP reporting measure to the ESRD QIP measure set beginning with PY 2025, and will include these in the performance standards for reporting measures in the PY 2026 ESRD QIP.

4. Scoring the PY 2026 ESRD QIP

a. Scoring Facility Performance on Clinical Measures

In the CY 2014 ESRD PPS final rule, we finalized policies for scoring performance on clinical measures based on achievement and improvement (78 FR 72215 through 72216). In the CY 2019 ESRD PPS final rule, we finalized a policy to continue use of this methodology for future payment years (83 FR 57011) and we codified these

scoring policies at 42 CFR 413.178(e). In section IV.E.1.b of this final rule, we are finalizing our proposal to update our scoring methodology beginning with PY 2025.

b. Scoring Facility Performance on Reporting Measures

Our policy for scoring performance on reporting measures is codified at 42 CFR 413.178(e), and more information on our scoring policy for reporting measures can be found in the CY 2020 ESRD PPS final rule (84 FR 60728). We previously finalized policies for scoring performance on the NHSN Dialysis Event reporting measure in the CY 2018 ESRD PPS final rule (82 FR 50780 through 50781), as well as policies for scoring the MedRec reporting measure and Clinical Depression Screening and Follow-up reporting measure in the CY 2019 ESRD PPS final rule (83 FR 57011). We also previously finalized the scoring policy for the STrR reporting measure in the CY 2020 ESRD PPS final rule (84 FR 60721 through 60723). In the CY 2021 ESRD PPS final rule, we finalized our updated scoring methodology for the Ultrafiltration Rate reporting measure (85 FR 71468 through 71470). In section IV.E.1.c of this final rule, we are finalizing our proposal to update our scoring methodology as part of our policy to convert the Hypercalcemia clinical measure to a reporting measure beginning with PY 2025. We are also finalizing our proposal to adopt a scoring methodology as part of our policy to add the COVID–19 Vaccination Coverage among HCP reporting measure to the ESRD QIP measure set beginning with PY 2025, as discussed in section IV.E.1.a of this final rule.

5. Weighting the Measure Domains and the TPS for PY 2026

Under our current policy, we assign the Patient & Family Engagement Measure Domain a weight of 15 percent of the TPS, the Care Coordination Measure Domain a weight of 30 percent of the TPS, the Clinical Care Measure Domain a weight of 40 percent of the TPS, and the Safety Measure domain a weight of 15 percent of the TPS.

In the CY 2019 ESRD PPS final rule, we finalized a policy to assign weights to individual measures and a policy to redistribute the weight of unscored measures (83 FR 57011 through 57012). In the CY 2020 ESRD PPS final rule, we finalized a policy to use the measure weights we finalized for PY 2022 for the PY 2023 ESRD QIP and subsequent payment years, and also to use the PY 2022 measure weight redistribution policy for the PY 2023 ESRD QIP and subsequent payment years (84 FR 60728 through 60729).

In section IV.E.2 of this final rule, we are finalizing our proposal to add a new Reporting Measure Domain, and we are finalizing our proposed new weights for the four existing measure domains, beginning in PY 2025. We provide the updated measure weights and domains and the TPS for PY 2026 in this final rule in Table 24.

G. Requests for Information (RFI) on Topics Relevant to ESRD QIP

1. Request for Information on Quality Indicators for Home Dialysis Patients

In the proposed rule, we sought public comments on potential indicators of quality for patients who receive dialysis at home to support the use of home dialysis for ESRD patients where it is appropriate (87 FR 38553 through 38554). While home-based dialysis may not meet the needs of every patient, we stated that home dialysis has clear benefits for those who are suitable candidates. Often, it may be more convenient for many ESRD patients, and survivability rates for home dialysis are comparable to those of transplant recipients and in-center hemodialysis.[280]

There are two general types of dialysis: hemodialysis (HD), in which an artificial filter outside of the body is used to clean the blood; and peritoneal dialysis (PD), in which the patient's peritoneum, covering the abdominal organs, is used as the dialysis membrane. HD is conducted at an ESRD facility, usually three times a week, or at a patient's home, often at a greater frequency. PD most commonly occurs at the patient's home. (Although PD can be furnished within an ESRD facility, it is very rare. For purposes of this RFI, we consider PD to be exclusively a home modality.) Assuming that either modality would be clinically appropriate, whether a patient selects HD or PD may depend on a number of factors, such as patient education before dialysis initiation, social and care partner support, socioeconomic factors, and patient perceptions and preference.[281] [282]

When Medicare began coverage for individuals with ESRD in 1973, more than 40 percent of dialysis patients in the U.S. were on home hemodialysis (HHD). More favorable reimbursement for outpatient dialysis and the introduction in the 1970s of continuous ambulatory peritoneal dialysis, which required less intensive training, contributed to a relative decline in HHD utilization.[283] Overall, the proportion of home dialysis patients in the U.S. declined from 1988 to 2012, with the number of home dialysis patients increasing at a slower rate relative to the total number of all dialysis patients. As cited in a U.S. Government Accountability Office (GAO) report, according to U.S. Renal Data System (USRDS) data, approximately 16 percent of the 104,000 dialysis patients in the U.S. received home dialysis in 1988; however, by 2012, the rates of HHD and PD utilization were 2 and 9 percent, respectively.[284]

Currently, the majority of ESRD patients receiving dialysis receive HD in an ESRD facility. At the end of 2016, 63.1 percent of all prevalent ESRD patients—meaning patients already diagnosed with ESRD—in the U.S. were receiving HD, 7.0 percent were being treated with PD, and 29.6 percent had a functioning kidney transplant.[285] Among HD cases, 98.0 percent used in-center HD, and 2.0 percent used HHD.[286] In the proposed rule, we noted that once they are stable on a specific modality, patients are infrequently aware that they are able to change modalities. In 2018, 72 percent of Black ESRD patients received in-center hemodialysis versus only 57 percent of White patients. This data point may indicate that a greater number of white ESRD patients receive home dialysis than Black patients.[287]

Research suggests that dialyzing at home is associated with lower overall medical expenditures than dialyzing in-center. Key factors that may be related

[280] ASPE Report, Advancing American Kidney Health, p. 24. Available at *https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf*.

[281] Stack AG. Determinants of Modality Selection among Incident US Dialysis Patients: Results from a National Study. Journal of the American Society of Nephrology. 2002; 13: 1279–1287. Doi 1046–6673/1305–1279.

[282] Miskulin DC, et al. Comorbidity and Other Factors Associated With Modality Selection in Incident Dialysis Patients: The CHOICE Study. American Journal of Kidney Diseases. 2002; 39(2): 324–336. Doi 10.1053/ajkd.2002.30552.

[283] Blagg CR. A Brief History of Home Hemodialysis. Annals in Renal Replacement Therapy. 1996; 3: 99–105.

[284] United States Government Accountability Office. End Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis (GAO–16–125). October 2015.

[285] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. *https://www.usrds.org/2018/view/v2_01.aspx*.

[286] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. *https://www.usrds.org/2018/view/v2_01.aspx*.

[287] National Kidney Foundation. *https://www.kidney.org/news/newsroom/fsindex*. Accessed 11/15/2021.

to lower expenditures include potentially lower rates of infection associated with dialysis treatment, fewer hospitalizations, cost differentials between PD and HD services and supplies, and lower operating costs for dialysis providers for providing home dialysis.[288] [289] [290] [291] [292]

In the proposed rule, we stated our belief that increasing rates of home dialysis has the potential to not only reduce Medicare expenditures, but also to preserve or enhance the quality of care for ESRD beneficiaries. In fact, recent studies show substantial support among nephrologists and patients for dialysis treatment at home.[293] [294] [295] [296] [297] Although some measures in the ESRD QIP apply to home dialysis facilities, certain measures do not apply to facilities that have high rates of home dialysis. For example, home dialysis facilities are generally not eligible for scoring on the ICH–CAHPS measure, the Long-Term Catheter Rate clinical measure, the Standardized Fistula Rate measure, and the NHSN BSI clinical measure. Therefore, many of these facilities are eligible for fewer measures than facilities that provide in-center hemodialysis only. As increasing numbers of ESRD patients use home dialysis therapies,[298] we stated our interest in learning more about potential indicators of quality of care for home dialysis patients that are not currently being captured by the ESRD QIP. Therefore, we sought comments on strategies to monitor and assess the quality of care delivered to patients who receive dialysis at home. We also sought comments on how to support more equitable access to home dialysis across different ESRD patient populations.

We received comments in response to this request for information and have summarized them here.

Comment: Many commenters expressed strong support for our efforts to support home dialysis through the ESRD QIP, noting that home dialysis can be medically effective and provide a potentially higher quality of life for ESRD patients and that monitoring the quality of care for home dialysis patients will have a meaningful impact on increasing utilization of home dialysis.

Several commenters recommended CMS develop a home dialysis patient experience of care survey that would capture feedback from patients on home dialysis. A few commenters noted the importance of a quality-of-life measure that accounts for the unique issues that are associated with dialyzing at home. One commenter recommended that CMS develop a new instrument to develop a patient experience survey which would include questions that specifically measure patient experience of home dialysis care, including components of in-center dialysis, patient training on home medical equipment, supplies, and safety, as well as communication with and access to health care providers. One commenter noted that any potential survey should be rigorously tested to ensure validity and reliability. One commenter further recommended that as a preliminary step, CMS could report a measure of Activities of Daily Living, which is closely linked to quality of life.

A few commenters observed the importance of comparing home dialysis patient experiences to in-center patient experiences because measuring home dialysis patient experiences and comparing those experiences to those of in-center patients will become increasingly important as the home dialysis patient population grows, and as results and familiarity with the survey tool are gained. One commenter recommended that CMS pursue and incorporate patient-reported home dialysis experiences into a QIP measure because measuring patients' experiences and being able to compare those experiences to those of in-center patients will become increasingly important and because tracking retention on home dialysis including transferring from one home modality to another is critical to understanding shifts in home dialysis care. One commenter recommended that CMS use distinct hemodialysis and peritoneal dialysis adequacy measures endorsed by the NQF so that patients, caregivers, and care providers can access performance on specific dialysis modality types to make informed decisions about modality choice.

Several commenters supported a home dialysis rate measure, which commenters believe will help encourage facilities to place patients suitable for home dialysis on this modality. A few commenters recommended that CMS adopt a home dialysis retention rate measure (excluding transplant and mortality) to ensure that facilities are incentivized to support home dialysis patients and proactively address barriers such as patient comfort with dialysis technology and supply management.

Several commenters supported a home dialysis retention measure because it is important to maintaining existing home patients on home therapy. A few commenters stated that home dialysis patient retention measures are helpful quality indicators and can help facilities identify how to better support their home dialysis patients. One commenter recommended that CMS capture home dialysis retention by modality because this focus would create improvement in addressing transition management, which is a significant challenge to home dialysis utilization. This commenter recommended that CMS consider transition to in-center HD, transplant, and mortality as the three components of measuring home dialysis retention by modality. A few commenters recommended a retention measure that could help assess the quality of home training and help incentivize facilities to take steps to manage patient and care partner burnout. One commenter recommended CMS include routine assessment of family caregivers involved in dialysis patients' care as a

[288] Walker R, Marshall MR, Morton RL, McFarlane P, Howard K. The cost-effectiveness of contemporary home hemodialysis modalities compared with facility hemodialysis: A systematic review of full economic evaluations. Nephrology. 2014; 19: 459–470 doi: 10.1111/nep.12269.

[289] Walker R, Howard K, Morton R. Home hemodialysis: A comprehensive review of patient-centered and economic considerations. ClinicoEconomics and Outcomes Research. 2017; 9: 149–161.

[290] Howard K, Salkeld G, White S, McDonald S, Chadban S, Craig J, Cass A. The cost effectiveness of increasing kidney transplantation and home-based dialysis. Nephrology. 2009; 14: 123–132 doi: 10.1111/j.1440–1797.2008.01073.x.

[291] Quinn R, Ravani P, Zhang X, Garg A, Blake P, Austin P, Zacharias JM, Johnson JF, Padeya S, Verreli M, Oliver M. Impact of Modality Choice on Rates of Hospitalization in Patients Eligible for Both Peritoneal Dialysis and Hemodialysis. Peritoneal Dialysis International. 2014; 34(1): 41–48 doi: 10.3447/pdi.2012.00257.

[292] Sinnakirouchenan R, Holley, J. Peritoneal Dialysis Versus Hemodialysis: Risks, Benefits, and Access Issues. Advances in Chronic Kidney Disease. 2011; 18(6): 428–432. doi: 10.1053/j.ackd.2011.09.001.

[293] Rivara MB, Mehrotra R. The Changing Landscape of Home Dialysis in the United States. Current Opinion in Nephrology and Hypertension.2014; 23(6):586–591.doi:10.1097/MNH0000000000000066.

[294] Mehrotra R, Chiu YW, Kalantar-Zadeh K, Bargman J, Vonesh E. Similar Outcomes With Hemodialysis and Peritoneal Dialysis in Patients With End-Stage Renal Disease. Archives of Internal Medicine. 2011; 171(2): 110–118. Doi:10.1001/archinternmed.2010.352.

[295] Ghaffarri A, Kalantar-Zadeh K, Lee J, Maddux F, Moran J, Nissenson A. PD First: Peritoneal Dialysis as the Default Transition to Dialysis Therapy. Seminars in Dialysis. 2013; 26(6): 706–713. doi: 10.1111/sdi.12125.

[296] Ledebo I, Ronco C. The best dialysis therapy? Results from an international survey among nephrology professionals. Nephrology Dialysis Transplantation.2008;6:403–408.doi:10.1093/ndtplus/sfn148.

[297] Schiller B, Neitzer A, Doss S. Perceptions about renal replacement therapy among nephrology professionals. Nephrology News & Issues. September 2010; 36–44.

[298] United States Renal Data System, 2018 Annual Data Report. Available at *https://www.usrds.org/2018/view/v2_01.aspx*.

quality indicator. One commenter recommended that CMS should measure home dialysis retention and home patients' experiences in the ESRD QIP because a critical measure of success for home dialysis is avoiding ''drop-out'' or permanent conversion to in-center dialysis.

A few commenters recommended that CMS adopt the home dialysis rate and home dialysis retention measures developed by the Kidney Care Quality Alliance (KCQA). One commenter expressed caution that the current health care system is not adequately prepared for an influx in home dialysis treatment, which may lead to negative patient impacts and technique failure rates. This commenter stated that the home dialysis rate and retention measures have been developed to promote steady growth in home dialysis uptake and retention to minimize potential unintended or adverse consequences that may occur with unchecked, rapid growth in home dialysis without proper monitoring and assessment of the quality of care. One commenter requested that CMS examine home dialysis retention through adopting measures such as CMS's Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR). This commenter recommended that these measures exclude facilities with fewer than 11 eligible patients to ensure an adequate sample size.

A few commenters recommended that CMS adopt the Home Dialysis Care Experience instrument as a patient-reported experience of care measure to measure home dialysis patient experience. One commenter recommended a measure of home dialysis patient satisfaction, but expressed concern that the Home Dialysis Care Experience measure does not capture outcomes or the patient experience.

A few commenters recommended that CMS further explore the role of telehealth in providing care to home dialysis patients, noting that telehealth and in-home training may help support prospective home dialysis patients who may not have reliable access to transportation. A few commenters recommended that CMS consider the benefits associated with remote monitoring, including patient engagement and outcomes, as well as caregiver experience. One commenter also recommended that quality indicators for home dialysis should account for the benefits of ongoing remote monitoring and its enablement of real-time trending and interventions.

A few commenters observed that lower levels of health literacy are barriers to equitable access to home dialysis. A few commenters recommended that CMS consider efforts aimed at timely CKD screening and education for patients, particularly those in communities of color, to promote more equitable access to home dialysis across different patient populations. A few commenters recommended that CMS establish standard requirements for care providers to discuss dialysis modality options with patients early on, preferably prior to beginning dialysis, so that patients have sufficient time and resources to make an informed decision about their treatment options. A few commenters recommended that the KDE benefit be expanded to allow more patients to access KDE services and permit more providers to provide the services. One commenter suggested that such services could be provided through telehealth platforms, and encouraged the passage of ''The Chronic Kidney Disease Improvement in Research and Treatment Act of 2021'' to further such efforts. One commenter recommended including kidney disease screening in the ''Welcome to Medicare'' preventive visit as it would help with early detection of CKD and allow patients and providers to slow progression and discuss treatment modalities.

Several commenters noted that many barriers exist to equitable access to home dialysis, including social determinants of health-related challenges such as lack of support, space, transportation, and access to facilities providing home dialysis as an option. A few commenters made suggestions aimed at supporting home dialysis patients so they feel comfortable with the process of doing dialysis at home. One commenter recommended that patients should be trained to do their own home dialysis treatments in an in-center setting before going home so that they feel comfortable with that additional responsibility and can be more self-sufficient, which would also reduce the burden on dialysis staff. One commenter recommended that CMS stipulate specific guidance in providing clinician support to patients during their first year of home dialysis because that support is critical to the overall success of the home dialyzer. One commenter recommended that CMS bring back staff-assisted home dialysis with clear parameters and guidelines because it has been shown to achieve higher rates of home dialysis and has the highest rate of retention.

A few commenters stated that financial barriers exist to equitable access to home dialysis, including the inability to afford costs associated with home dialysis. A few commenters recommended that, to address barriers to health equity and broaden access to home dialysis, CMS offer payment options for modifications a patient may need to make to their home environment to support home dialysis care. A few commenters also suggested that CMS remove financial barriers to home dialysis, such as eliminating copays for home dialysis training or exploring opportunities to provide financial support for staff-assisted home dialysis. One commenter recommended that CMS work with community and patient advocates to address financial concerns faced by patients so that patients understand their rights. One commenter noted the financial burden associated with home dialysis, such as increased water bills due to the use of a reverse osmosis machine, and the need for additional supplies to handle associated medical waste.

A few commenters noted that, to address existing barriers to equitable access to home dialysis, the government must expand access to CKD screening, incentivize specialization in nephrology, treat and educate patients on CKD earlier on, and address a patient's specific concerns regarding home dialysis that may impact a patient's decision-making. One commenter recommended that CMS provide coverage for nurse or caregiver services to support home dialysis patients. One commenter requested that CMS allow more flexibility in Medicare program rules to enable providers to work more closely with patients to overcome barriers to home dialysis, many of which result from factors related to social determinants of health.

One commenter recommended that home dialysis quality measures should include stratification by race and ethnicity to ensure home dialysis is being offered equitably. One commenter recommended that CMS add a measure to determine equal access to home dialysis that includes patient demographics and reason(s) why the patient did not choose a home dialysis option or was not suitable because USRDS data show Black and Hispanic patients are vastly underrepresented among those on home dialysis and without more data it is impossible to know and address why this occurs.

A few commenters suggested that CMS broaden the applicability of current ESRD QIP measures to include home dialysis patients, noting that home dialysis is underrepresented in the current ESRD QIP measure set. A few commenters recommended a measure that surveils bloodstream

infection in home hemodialysis patients. One commenter recommended revising the ICH CAHPS to include home dialysis. One commenter recommended CMS consider a Technical Expert Panel (TEP) to determine the most appropriate survey questions and prioritize either new development of a measure or validation and refinement of existing tools to capture the experiences of patients receiving home-based dialysis, noting that the current ICH CAHPS survey focuses on HD, whereas most home dialysis patients are on PD. One commenter recommended expanding the Kt/V Dialysis Adequacy measure. One commenter recommended prioritization of outcome measures that focus on relevant outcomes such as reporting peritonitis rate, inpatient readmission rates, and mortality. One commenter recommended that CMS explore hospitalization as an indicator of quality care for home dialysis patients, noting that the hospitalization rate is the biggest factor in reducing the total cost of care for home dialysis. One commenter recommended that CMS tailor measure performance standards within the ESRD QIP separately for in-center dialysis and home dialysis. This commenter also recommended that performance on a dialysis adequacy measure could be assessed separately within modality and then reaggregated at the facility level, which commenter believes would maintain a comprehensive dialysis adequacy measure while further promoting the uptake of home dialysis.

A few commenters expressed concern with our efforts to expand the ESRD QIP to include more home dialysis measures. One commenter expressed concern that scoring home dialysis programs on only a few measures is a barrier to home dialysis uptake due to the risk for an ESRD QIP payment reduction. One commenter noted that home dialysis programs are negatively impacted by current ESRD QIP scoring and recommended that CMS revise the scoring methodology for home dialysis programs, to reweight measures, establish appropriate benchmarks, and create reporting minimums for the home dialysis programs. Although the commenter expressed support for additional opportunities to monitor the quality of care for home dialysis patients, the commenter did not support the inclusion of additional measures aimed at home dialysis in the ESRD QIP. This commenter recommended that if any home dialysis measure is included in the ESRD QIP, that such measure be a reporting measure and exclude nursing home patients due to unique nature of their care needs. One commenter did not support the RFIs on ESRD QIP because they believe there is inadequate adjustment for or inclusion or pediatric patients within the RFI which results in financial penalization exacerbating inequities in provision of ESRD care to pediatric patients.

Response: We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of our efforts to support home dialysis. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our home dialysis-related efforts.

2. Request for Information on Potential Future Inclusion of Two Social Drivers of Health Measures

(1) Background

Our commitment to supporting facilities in building equity into their health care delivery practices centers on empowering their workforce to recognize and eliminate health disparities that disproportionately impact people with ESRD, such as, individuals who are members of racial and ethnic minority groups, have low incomes, and/or reside in rural areas. In the CY 2022 ESRD PPS final rule, we noted our intention to initiate additional request(s) for information (RFIs) on closing the health equity gap, including identification of the most relevant social risk factors for people with ESRD (86 FR 61930). Health-related social needs (HRSNs), defined as individual-level, adverse social conditions that negatively impact a person's health or health care, are significant risk factors associated with worse health outcomes as well as increased health care utilization.[299] In the CY 2023 ESRD PPS proposed rule, we stated our belief that consistently pursuing identification of HRSNs would have two significant benefits (87 FR 38554). First, because social risk factors disproportionately impact underserved communities, promoting screening for these factors could serve as evidence-based building blocks for supporting facilities and health systems in actualizing commitment to address disparities, improve health equity, and implement associated equity measures to track progress.[300] Second, these measures could support ongoing quality improvement initiatives by providing data with which dialysis providers would be able to stratify patient risk and organizational performance.

In the proposed rule, we stated that we are investigating potential integration of screening for health-related social needs into the ESRD QIP measure set (87 FR 38554). This type of screening was the subject of the recently ended Accountable Health Communities (AHC) Model, which was implemented by the CMS Innovation Center.[301] The CMS Innovation Center developed the AHC Model based on evidence that addressing health-related social needs (HRSNs) through enhanced linkages between health systems and community-based organizations can improve health outcomes and reduce costs.[302] HRSNs are significant risk factors associated with adverse health outcomes and increased health care utilization, including excessive emergency department (ED) visits and avoidable hospitalizations.[303] [304] Unmet HRSNs, such as food insecurity, inadequate or unstable housing, and inadequate transportation may increase risk for onset of chronic conditions, such as ESRD, and accelerate exacerbation of related adverse health outcomes.[305] [306] [307]

[299] 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.

[300] 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.*

[301] Additional information about the Accountable Health Communities Model is available at: *https://innovation.cms.gov/innovation-models/ahcm.*

[302] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

[303] 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.*

[304] 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.*

[305] 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.*

[306] 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.*

[307] Laraia, B.A. (2013). Food Insecurity and Chronic Disease. Advances in Nutrition, 4: 203–212, doi: 10.3945/an.112.003277.

We stated our belief that consistent identification of HRSNs among people with ESRD would have two significant benefits that would contribute to reduction in health disparities and improvements in quality and efficiency of dialysis care delivery. First, due to the association between chronic condition risk and HRSNs, screening for these needs could serve as evidence-based building blocks for supporting ESRD facilities and health systems in addressing persistent disparities and tracking progress towards closing the health equity gap in the ESRD population. Second, these measures would support ongoing quality improvement initiatives, specifically, care coordination for ESRD patients, by providing data with which to potentially stratify quality performance in dialysis providers. This is especially relevant in settings where a disproportionate number of patients have HRSNs and adverse health care outcomes, including hospital readmissions, that result in higher penalties related to diminished quality performance.[308] [309] We stated our belief that these measures align with *The CMS Quality Strategy Goals* around effective care coordination and prevention and treatment of chronic conditions.[310] We noted that advancing health equity by addressing the health disparities that underlie the country's health system is one of our strategic pillars and a Biden-Harris Administration priority.[311] In the proposed rule, we sought public comment on the potential future inclusion of two related measures discussed later in this section.

(2) Screening for Social Drivers of Health Measure

Significant and persistent health disparities in the United States result in adverse health outcomes for people with ESRD.[312] [313] The COVID–19 pandemic has illuminated the detrimental interaction between HRSNs, adverse health outcomes, and health care utilization in the United States.[314] [315] Individuals from racial and ethnic minority groups and with lower incomes are less likely to receive recommended care for CKD risk factors and are also less likely to reduce CKD risk through recommended treatment goals.[316] [317] [318] [319] Consequently, some groups are more likely to progress from CKD to ESRD and less likely to be under the care of a nephrologist before starting dialysis.[320] Individuals from racial and ethnic minority groups with ESRD are more likely to have 30-day hospital readmissions when compared to non-Hispanic White patients.[321] Emerging evidence has shown that specific social risk factors are directly associated with health outcomes and health care utilization and costs.[322] [323] [324] [325] Of particular concern among people with ESRD are barriers to treatment prior to and after diagnosis, including inadequate access to healthy foods, unstable housing, limited transportation, and community safety concerns.[326] [327]

In the proposed rule, we stated our belief that improvement in care coordination between ESRD facilities, hospitals, and community-based organizations would yield better health outcomes for people with ESRD and quality performance for dialysis and other health care providers. Recognizing the importance of social drivers of health, this year we have finalized proposals to include social drivers of health screening measures in the Hospital Inpatient Quality Reporting Program (87 FR 49202 through 49220). In the CY 2023 ESRD PPS proposed rule, we stated our belief that screening for social drivers of health would similarly help inform facilities and other health care providers of the impact of HRSNs in people with ESRD, including their health outcomes and health care utilization (87 FR 38555). The Screening for Social Drivers of Health measure would assess the proportion of adult patients who are screened for social drivers of health in five core domains, including food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

In the CY 2023 ESRD PPS proposed rule, we stated that CMS's goal is to lay the groundwork for potential future measures that focus on the development of an action plan to address these HRSNs, including efficiently navigating patients to available resources and strengthening the system of community-based supports where resources are

[308] National Academies of Sciences, Engineering, and Medicine.2017. *Accounting for social risk factors in Medicare payment.* Washington, DC: The National Academies Press. doi: 10.17226/23635.

[309] 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.*

[310] Centers for Medicare & Medicaid Services. (2021) CMS' Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

[311] 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.*

[312] United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021.

[313] Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et.al., (2021). Initial Effects of COVID–19 on Patient with ESKD. Journal of the American Society of Nephrology 32: 1444–1453. doi: *https://doi.org/10.1681/ASN.2021010009.*

[314] Centers for Disease Control. 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.

[315] Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et.al., (2021). Initial Effects of COVID–19 on Patient with ESKD. Journal of the American Society of Nephrology 32: 1444–1453. doi: *https://doi.org/10.1681/ASN.2021010009.*

[316] United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021.

[317] Benjamin O, Lappin SL. End-Stage Renal Disease. [Updated 2021 Sep 16]. In: Stat Pearls [internet]. Treasure Island (FL): StatPearls Publishing; 2022. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK499861/.*

[318] Norris, K.C., Williams, S.F., Rhee, C.M., Nicholas, S.B., Kovesdy, C.P., et.al. (2017). Hemodialysis Disparities in African Americans: The Deeply Integrated Concept of Race in the Social Fabric of Our Society. Seminars in Dialysis 30(3):213–223. doi:10.1111/sdi.12589.

[319] CMS (2021). Chronic Kidney Disease Disparities: Educational Guide for Primary Care. Available at: *https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf.*

[320] Norton, J. M., Moxey-Mims, M. M., Eggers, P. W., Narva, A. S., Star, R. A., Kimmel, P. L., & Rodgers, G. P. (2016). Social Determinants of Racial Disparities in CKD. Journal of the American Society of Nephrology: JASN, 27(9), 2576–2595. *https://doi.org/10.1681/ASN.2016010027.*

[321] CMS (2014). Health Disparities Among Aged ESRD Beneficiaries, 2014. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/ESRD-Infographic.pdf.*

[322] 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.*

[323] Dean, E.B., French, M.T., Mortensen, K. (2020). Health Services Research 55 (Supplement 2): 883–893. doi: 10.1111/1475–6773.13283.

[324] Berkowitz, S.A., Kalkhoran, S., Edwards, S.T., Essien, U.R., Baggett, T.P. (2018). Unstable Housing and Diabetes-Related Emergency Department Visits and Hospitalization: A Nationally Representative Study of Safety-Net Clinic Patients. Diabetes Care 41: 933–939. *https://doi.org/10.2337/dc17-1812.*

[325] National Academies of Sciences, Engineering, and Medicine 2019. *Dialysis Transportation: The Intersection of Transportation and Healthcare.* Washington, DC: The National Academies Press. *https://doi.org/10.17226/25385.*

[326] *Ibid.*

[327] CMS (2021). Chronic Kidney Disease Disparities: Educational Guide for Primary Care. Available at: *https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf.*

lacking. Collecting baseline data via this measure would be crucial in informing design of future measures that could enable us to set appropriate performance targets. While widespread interest in addressing HRSNs exists, action is inconsistent, specifically in ESRD facilities. In the proposed rule, we noted that we are exploring potential future inclusion of social drivers of health screening measures to the ESRD QIP. Therefore, we sought public comment on adding a new measure, Screening for Social Drivers of Health, to the ESRD QIP measure set in the next rulemaking cycle. We stated that the measure would assess the proportion of a facility's patients that are screened for one or more social drivers of health in the five core domains.

In the proposed rule, we stated our belief that facilities should screen for HRSNs among their patients to assess and increase the effectiveness of care coordination. Referral to community-based organizations can potentially reduce avoidable hospitalizations and disruptions to dialysis care. Data demonstrate that an overwhelming majority of people with ESRD travel outside their homes for dialysis three times per week, round trip, and that transportation challenges contribute to shortened treatment episodes and adverse health outcomes.[328] [329] We stated our belief that screening for HRSNs like transportation in people with ESRD and targeted care coordination that links them to community-based services could improve health outcomes in this population. We also noted our belief that publishing social drivers of health screening rates would be helpful to many patients who need additional care coordination but may experience reluctance in seeking assistance due to concerns for personal stigmatization. Under our Meaningful Measures Framework, the Screening for Social Drivers of Health measure would address the quality priority ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area ''Management of Chronic Conditions.''

(3) Screen Positive Rate for Social Drivers of Health Measure

In the CY 2023 ESRD PPS proposed rule, we stated our belief that it is important to screen patients with ESRD for HRSNs that can negatively impact health outcomes and contribute to avoidable hospitalizations (87 FR 38556). Unmet HRSNs can interrupt dialysis treatment and other routine care, including preventive health screenings, that is essential for ESRD-related conditions. Many patients treated in ESRD facilities have other chronic conditions that require consistent, multidisciplinary care to maintain their health.[330] [331] Household food insecurity has been associated with reliance on energy-dense foods which increase risks for onset of diabetes and hypertension, the leading causes of ESRD.[332] Housing instability and transportation difficulties both contribute to interruptions in dialysis care which leads to avoidable hospitalizations.[333] [334] Additionally, the COVID–19 pandemic has highlighted associations between disproportionate health risk, hospitalization, and adverse health outcomes.[335] [336] Capturing HRSN data may facilitate strengthening of linkages between facilities, medical providers (inpatient and outpatient), and community-based organizations which potentially could enhance care coordination for this group. Therefore, we sought public comment on the possible addition of a new measure, Screen Positive Rate for Social Drivers of Health, to the ESRD QIP measure set in future rulemaking. The measure would assess the proportion of patients who screen positive for HRSNs in five core domains, including food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. In the CY 2023 ESRD PPS proposed rule, we also stated our belief that publishing screen positive rates for social drivers of health would be helpful to many patients who need additional care coordination but may experience reluctance in seeking assistance due to concerns for personal stigmatization (87 FR 38556). Under our Meaningful Measures Framework, the Screening for Social Drivers of Health measure would address the quality priority ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area ''Management of Chronic Conditions.''

We welcomed public comment on potentially adding these two related Social Drivers of Health measures to the ESRD QIP measure set. We also welcomed public comment on data collection, submission, and reporting for these two measures. We received comments in response to this request for information and have summarized them here. We also note that since publication of the CY 2023 ESRD PPS proposed rule, we finalized the adoption of these two measures for the Hospital Inpatient Quality Reporting Program (87 FR 49201 through 49220).

Comment: Many commenters supported addition of the Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures to the ESRD QIP measure set as part of future rulemaking efforts. Commenters supported these two measures as important steps towards meaningful measurement of unique challenges affecting dialysis patients and their health outcomes. Commenters believed the two measures will align well with CMS' commitment to health equity because they will enable identification of health disparities in dialysis patients. Additionally, commenters believed the measures will clarify understanding of the overall impact of HRSNs in dialysis patients at the facility level by capturing relevant data for diverse patient cohorts. Several commenters highlighted the potential for these measures to inform actionable planning at the facility level and for resource allocation with the ESRD QIP. A few commenters noted the measures will improve understanding of access to appropriate care continuity for patients from under-resourced communities and consequently, provide evidence of health disparities in the management of specific disease and associated outcomes that disproportionately affect these groups. One commenter noted that dialysis providers are in a unique position

[328] *Ibid.*

[329] United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021.

[330] Benjamin O, Lappin SL. End-Stage Renal Disease. [Updated 2021 Sep 16]. In: Stat Pearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK499861/.*

[331] Norris, K.C., Williams, S.F., Rhee, C.M., Nicholas, S.B., Kovesdy, C.P., et al. (2017). Hemodialysis Disparities in African Americans: The Deeply Integrated Concept of Race in the Social Fabric of Our Society. Seminars in Dialysis 30(3):213–223. doi:10.1111/sdi.12589.

[332] Laraia, B.A. (2013). Food Insecurity and Chronic Disease. Advances in Nutrition, 4: 203–212, doi: 10.3945/an.112.003277.

[333] United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021.

[334] National Academies of Sciences, Engineering, and Medicine 2019. *Dialysis Transportation: The Intersection of Transportation and Healthcare.* Washington, DC: The National Academies Press. *https://doi.org/10.17226/25385.*

[335] Centers for Disease Control. 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.

[336] Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et.al., (2021). Initial Effects of COVID–19 on Patient with ESKD. Journal of the American Society of Nephrology 32: 1444–1453. doi: *https://doi.org/10.1681/ASN.2021010009.*

because they see most of their patients three times per week and often form trusting relationships, which provide opportunities for screening for social drivers of health. One commenter cited opportunities to promote whole-person care, particularly in CKD and ESRD patients from communities that have been underserved and/or historically marginalized by the health care system, as the rationale for their support for adding the two Social Drivers of Health measures to the ESRD QIP measure set.

Several commenters provided specific and related reasons for supporting the two Social Drivers of Health measures, including valuable data capture of HRSNs affecting dialysis patients which they believe would inform quality improvement strategies to help advance health equity. One commenter noted the two measures could help inform actionable planning at the facility level and overall resource allocation within the ESRD QIP. Another commenter believes the measures will improve understanding of access to appropriate care continuity for dialysis patients from communities that are under-resourced and allow evaluation of health disparities in the management of specific diseases that disproportionately impact patient outcomes in this population.

Several commenters expressed support for the addition of the two Social Drivers of Health measures to the ESRD QIP measure set and offered specific recommendations for their implementation. A few commenters recommended CMS consider the use of Z codes to document patients' HRSNs, with a focus on the most common non-clinical barriers to home dialysis, including housing instability, financial insecurity, inadequate caregiver support, and advanced age. A few commenters recommended CMS address how the measures will be implemented, specifically how the Social Drivers of Health data would be used to link patients to follow-on community-based services to address HRSNs. One commenter recommended the measures be classified as reporting measures, not performance measures, while another recommended voluntary reporting for the measures with patients being able to opt-out to prevent penalization for patients who refuse to participate in Social Drivers of Health screening. A commenter recommended CMS consider a trial period to test the feasibility of Social Drivers of Health screening process in dialysis patients. One commenter recommended CMS submit the two Social Drivers of Health measures for NQF review and approval prior to adding them to the ESRD QIP measure set. A commenter recommended screening be comprehensive to include the needs of family caregivers, since caregiver burden can prompt an emergency department visit or hospitalization. One commenter noted the important role that social workers in dialysis facilities can play in assessing HRSNs and connecting patients to available resources. A commenter recommended selection of The Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) developed by the National Association of Community Health Centers, Inc (NACHC) as the screening instrument for the HRSN screening measure because it will address the five core HRSN domains noted in the RFI. One commenter recommended CMS consider how pediatric ESRD patients are impacted by issues such as housing instability, food insecurity, and transportation needs. A commenter recommended that CMS require dialysis facilities to report Social Drivers of Health data in EQRS and encourage them to address patient-level HRSNs in individual care planning and at the facility-level in Quality Assessment and Performance Improvement meetings.

A few commenters expressed support for the addition of the two Social Drivers of Health measures to the ESRD QIP measure set but expressed concerns about their implementation. A few commenters expressed concerns about the limited availability of community-based resources to address dialysis patients' HRSNs. A few commenters did not believe that quality measurement is the appropriate approach for addressing patients' social needs. A few commenters expressed concern about documentation burden for providers and patients if the screening tool would be self-administered.

Several commenters expressed concerns and noted questions related to the actual screening process for the Social Drivers of Health measures. A few commenters were specifically concerned about potential use of the Accountable Health Communities Model (AHC) Screening Tool for capturing Social Drivers of Health data in the ESRD QIP. One commenter noted the tool has not been reviewed by NQF for appropriate utilization in a penalty-based accountability program. Another commenter noted the AHC Model Screening Tool has not been validated in ESRD patients. One commenter recommended use of The Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) developed by the National Association of Community Health Centers, Inc (NACHC) as the instrument for Social Drivers of Health screening in the ESRD QIP because it is national standardized patient risk assessment protocol designed to engage patients in assessing and addressing social drivers of health because it is paired with an Implementation and Action Toolkit, and standardized across ICD-10, LOINC, and SNOMED. A commenter recommended CMS consider a focused question set to eliminate the need for annual screening. One commenter recommended testing the AHC Screening Tool for feasibility, accuracy, and validity before introducing it to existing data collection requirements for the ESRD QIP.

Several commenters supported the Screening for Social Drivers of Health measure in particular, noting the ability of that measure to capture HRSN data that inhibits dialysis patients' ability to access and participate in appropriate care and treatment, and increased availability of essential data to support health care professionals, including registered dietitian nutritionists and community and social services providers. One commenter recommended CMS provide guidance on addressing ERSD patients' HRSNs. A commenter recommended CMS establish universal standards for screening to address timeframe, data collection and use. A commenter recommended an incremental approach to adding the Screening for Social Drivers of Health measure to the ESRD QIP measure set to start with voluntary reporting on one HRSN with subsequent introduction of additional domains over time and mandatory reporting to start the second year because it would allow dialysis facilities to become more familiar with HRSNs and screening process logistics.

One commenter specifically supported the Screen Positive Rate for Social Drivers of Health measure because it believes the measure is the next logical step after screening for drivers of health. Another commenter agreed that the measure has the potential to enable development of action plans to address the HRSNs for which dialysis facilities would screen.

A few commenters expressed concerns about adding the Screen Positive Rate for Social Drivers of Health measure to the ESRD QIP measure set. One commenter was concerned about potential penalization for facilities providing care for more patients from communities that are historically underserved. Another commenter stated it is essential that a higher screen positive rate is not used to reduce quality standards or expected outcomes for a given facility. One

commenter expressed similar concerns about availability of the measure specification similar to the Screening for Social Drivers of Health measure and asked that CMS provide additional information on screening requirements in the context of the ESRD QIP.

A few commenters provided recommendations for implementing the Screen Positive Rate for Social Drivers of Health measure. One commenter recommended that CMS provide requirements for action plans to address HRSNs when patients screen positive, either within the measure itself or through patient follow-up requirements, to make the measure meaningful to patients. A commenter suggested that CMS eventually require referrals that link patients to services to address their HRSNs after screening. One commenter recommended that CMS consider other opportunities to leverage existing data sources to capture HRSN data.

Response: We thank the commenters for their feedback. We agree that screening for social drivers of health has potential to support meaningful measurement of unique challenges affecting dialysis patients and their health outcomes. We anticipate that such screening will align well with CMS's commitment to health equity because the measures will clarify understanding of the overall impact of HRSNs in dialysis patients. We also acknowledge the potential implementation issues and appreciate commenters' suggestions for mitigation strategies. We are committed to collecting and reporting data—including related to drivers of health—that will be relevant to the unique challenges facing the ESRD QIP patient population, and will take commenters' feedback into consideration in future policy development.

3. Request for Information on Overarching Principles for Measuring Health Care Quality Disparities Across CMS Quality Programs

a. Background

Significant and persistent inequities in health care outcomes exist in the United States. Belonging to a racial or ethnic minority group; being a member of a religious minority; living with a disability; being a member of the LGBTQ+ community; living in a rural area; or being near or below the poverty level, are often associated with worse health outcomes.[337] [338] [339] [340] [341] [342] [343] [344] [345] In the CY 2023 ESRD PPS proposed rule, we stated that we are committed to achieving equity in health care outcomes for our beneficiaries by supporting health care providers' quality improvement activities to reduce health disparities, enabling beneficiaries to make more informed decisions, and promoting health care provider accountability for health care disparities (87 FR 38556 through 38557).[346]

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; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [347]

In the CY 2023 ESRD PPS proposed rule, we stated that 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 (87 FR 38557). We noted that 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.[348]

Such disparities in health outcomes and health care access are the result of multiple factors including differences in access to routine dialysis and primary care which contribute to health disparities among patients with ESRD. We discussed the impact of these disparities on patients with ESRD in our request for information on closing the health equity gap in the CY 2022 ESRD PPS proposed rule (86 FR 36362). Because we are working toward the goal of all ESRD patients receiving high quality dialysis treatment and other health care, irrespective of individual characteristics, in the CY 2023 ESRD PPS proposed rule we stated that we are committed to supporting dialysis providers and health systems in building a culture of equity that focuses on educating and empowering the health care workforce to recognize and eliminate health disparities in ESRD patients (87 FR 38557).[349]

Closing the health equity gap would require multipronged approaches that effectively address the many drivers of health disparities. As summarized in the CY 2022 ESRD PPS final rule request for information, we noted our intention to initiate additional request(s) for information (RFIs) on closing the health equity gap, including identification of

[337] 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.

[338] 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.

[339] 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.

[340] 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.

[341] 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.

[342] 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-incomehealth-status-recap.pdf*.

[343] 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/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf*.

[344] 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 2021;70:149–154. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm*.

[345] 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.

[346] 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*.

[347] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government*.

[348] Centers for Medicare & Medicaid Services. (2022). Health Equity. Available at: *https://www.cms.gov/pillar/health-equity*.

[349] 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*.

the most relevant social risk factors for people with ESRD (86 FR 61930). Advancing health equity would require a variety of efforts across the health care system. The reduction in health care disparities is one aspect of improving equity that we have prioritized. In the CY 2022 ESRD PPS final rule request for information, ''Closing the Health Equity Gap in CMS Hospital Quality Programs'' (86 FR 61928 through 61937), we described programs and policies we have implemented over the past decade with the aim of identifying and reducing health care disparities, including: the CMS Mapping Medicare Disparities Tool [350] and the CMS Disparity Methods stratified reporting.[351] CMS has also begun efforts supporting implementation of the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (78 FR 58539); [352] 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 CMMI Accountable Health Communities Model.[353] [354] [355]

Measuring health care disparities and reporting these results to health care providers is a cornerstone of our approach to advancing health 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 health care disparities through stratification is only one method for using health care quality measurement to address health equity, but it is an important approach that allows health care 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 CMS Office of Minority Health (CMS OMH) as well as by external organizations such as the American Hospital Association as a critical component of an organized response to health disparities.[356] [357] 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.

As efforts to improve methods and sources of social determinant and demographic data collection mentioned previously are ongoing, we would continue to evaluate opportunities to expand these current measure stratification reporting initiatives with existing sources of data. We aim to provide comprehensive and actionable information on health disparities to health care providers participating in our quality programs, in part, by starting with confidential reporting of stratified measure results that highlight potential gaps in care between groups of patients using existing data sources. This includes examining and reporting disparities in care across additional social risk factors and demographic variables associated with historic disadvantage in the health care system, and examining disparities across additional health care quality measures, and in new care settings. As disparity measurement initiatives expand through the use of measure stratification, it is important to model efforts off of existing best practices by continuing to gather feedback from interested parties and to make use of lessons learned in the development of existing disparity reporting efforts.

Specific efforts aimed at closing the health equity gap in ESRD patients include the *Chronic Kidney Disease Disparities: Educational Guide for Primary Care,* which is intended to foster the development of primary care practice teams to enhance care for medically underserved patients with CKD and are at risk of progression of disease or complications,[358] and the CMS ETC Model, which aims to test the effectiveness of adjusting certain Medicare payments to encourage more home dialysis and kidney transplants, support beneficiary modality choice, and preserve or improve quality of care provided to ESRD beneficiaries while reducing Medicare expenditures.[359]

In the CY 2023 ESRD PPS proposed rule, we noted that measuring health care disparities and reporting the results to dialysis providers is under consideration as a central component of our approach to closing the health equity gap in patients with ESRD (87 FR 38558). Stratification of quality measures would facilitate consistent measurement of differences in care received and subsequent outcomes by different groups of patients. Stratification is one of several methodological approaches to estimating health disparities that would support facilities in tailoring quality improvement initiatives to reduce disparities and track improvement over time. We have identified stratification as a critical component of an organized response to health disparities.[360] [361] To date, we have employed stratification techniques in a few programs to evaluate quality of care for patients with disproportionate social risk burden and demographic characteristics associated with adverse health outcomes. For example, in the FY 2018 IPPS/LTCH PPS final rule, the Hospital Inpatient Quality Reporting Program introduced confidential reporting of hospital quality measure data stratified by dual eligibility (82 FR 38403 through 38409).

As efforts to improve methods and sources of social determinant and demographic data collection are ongoing, in the CY 2023 ESRD PPS proposed rule we stated our intent to continue to evaluate opportunities to expand these current measure stratification reporting initiatives with existing sources of data (87 FR 38558). We noted that we anticipate expanding our efforts to provide comprehensive

[350] 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.*

[351] Centers for Medicare and Medicaid Services. Disparity Methods Confidential Reporting. Available at: *https://qualitynet.cms.gov/inpatient/measures/disparity-methods.*

[352] *https://www.federalregister.gov/documents/2013/09/24/2013-23164/national-standards-for-culturally-and-linguistically-appropriate-services-clas-in-health-and-health.*

[353] Centers for Medicare and Medicaid Services. (2021). Accountable Health Communities Model. Available at: *https://innovation.cms.gov/innovation-models/ahcm.*

[354] *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.*

[355] 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.*

[356] 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.*

[357] Improving Health Equity Through Data Collection and Use: A Guide for Hospital Leaders. (2011). Available at: *http://www.hpoe.org/Reports-HPOE/improvinghealthequity3.2011.pdf.*

[358] CMS (2021). Chronic Kidney Disease Disparities: Educational Guide for Primary Care. Available at: *https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf.*

[359] CMS (2021). ESRD Treatment Choices (ETC) Model. Available at: *https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model.*

[360] *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf.*

[361] *http://www.hpoe.org/Reports-HPOE/improvinghealthequity3.2011.pdf.*

and actionable information on health disparities to dialysis providers participating in the ESRD QIP by providing measure stratification results to highlight potential gaps in care among patient groups. This includes examining and reporting disparities in care across specific social risk factors and demographic variables associated with historic disadvantage in ESRD care in particular and examining disparities across ESRD QIP measures. We stated that we aim to gather feedback from technical experts and dialysis providers as we evaluate existing best practices for measure stratification methods and reporting approaches applied to health disparity evaluation. As disparity measurement initiatives expand through the use of measure stratification, it is important to model efforts off of existing best practices by continuing to gather feedback from interested parties and to make use of lessons learned in the development of existing disparity reporting efforts.

There are several key considerations that we intend to consider when advancing the use of measurement and stratification as tools to address health care disparities and advance health equity. In the CY 2023 ESRD PPS proposed rule, we sought input on key considerations in five specific areas that could inform our approach (87 FR 38558). Each is described in more detail later in this section:

- *Identification of Goals and Approaches for Measuring Health Care Disparities and Using Measure Stratification in ESRD QIP*—This section identifies the approaches for measuring health care disparities through measure stratification in CMS quality reporting programs.
- *Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting*—This section describes considerations that could inform the selection of ESRD QIP measures to prioritize for stratification.
- *Principles for Social Risk Factor and Demographic Data Selection and Use*—This section describes social risk factor and demographic data that we would consider investigating for use in stratifying ESRD QIP measures for health care disparity measurement. Dialysis and other health care providers would use their own demographic data to address disparities affecting their patients.
- *Identification of Meaningful Performance Differences*—This section reviews several strategies for identifying meaningful differences in performance when ESRD QIP measures apply stratification or disparity reporting that are easily understood but remain useable by dialysis providers.
- *Guiding Principles for Reporting Disparity Results*—This final section reviews considerations we would consider in determining how ESRD QIP would report disparity results to dialysis providers, as well as the ways different reporting strategies would hold providers accountable.

We then solicited public input on these topics.

b. Identification of Goals and Approaches for Measuring Health Care Disparities and Using Measure Stratification in ESRD QIP

Our goal in developing methods to measure disparities in care is to provide actionable and useful results to dialysis providers. By quantifying health care disparities (that is, through quality measure stratification), we aim to provide useful tools for dialysis providers and facilities to drive improvements. In the CY 2023 ESRD PPS proposed rule, we stated our belief that these results would support dialysis providers and facilities efforts in examining the underlying drivers of disparities in their patients' care and to develop their own innovative and targeted quality improvement interventions (87 FR 38558). 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 for reporting health disparities. In recent years, we have focused on identifying health care disparities by reporting stratified results for acute care hospitals in two complementary ways. First, stratification by a given social risk factor or demographic variable has generated measure results for subgroups of patients cared for by individual providers that can be directly compared. This type of comparison identifies important disparities, such as gaps in care and outcomes between patient groups. This approach is sometimes referred to as ''within-provider'' disparity. This can be done for most measures that include patient-level data and can be helpful to quantitatively express a provider's disparity in care. However, similar to the measure itself, the approach to perform this type of comparison would differ based on the measure's complexity. For example, when risk adjustment is used in the measure, the stratification approach would have to be adapted to address clinical risk adjustment.[362] Second, a health care provider's performance on a measure for only the subgroup of patients with that social risk factor can be compared to other providers' performance for that same subgroup of patients (sometimes referred to as ''across-provider'' disparities measurement). This type of comparison illuminates the health care provider's performance for only the population with a given social risk factor, allowing comparisons for specific performance to be better understood and compared to peers or State and national benchmarks. These approaches are reviewed and recommended by The Assistant Secretary of Planning and Evaluation (ASPE) as ways to measure health equity in their 2020 Report to Congress.[363]

Alone, each approach may provide an incomplete picture of disparities in care for a particular measure, but when reported together with overall quality performance can give detailed information about where differences in care exist. For example, a dialysis provider may underperform when compared to national averages for patients with a given risk factor, but if they also underperform for patients without that risk factor, the measured difference, or disparity in care, could be negligible even though performance for the group historically underserved group remains poor. In this case, simply stratifying the measure results could show little difference in care between patient groups within the facility, comparing results for only the group that has been historically marginalized would signal the need to improve care for this population.

In the proposed rule, we stated that 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 that is introduced through stratified reporting.[364] Furthermore, results of stratified reporting must be evaluated for any type of selection bias that fails

[362] 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.*

[363] 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.*

[364] 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.

to capture disparity due inadequate representation of subgroups of patients in measure cohorts. During measure re-evaluation, we would aim to carefully examine stratified results and methods to mitigate the potential for drawing incorrect conclusion from results.

c. Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting

In the proposed rule, we stated our intent to begin our efforts to provide stratified reporting for ESRD QIP measures, provided they offer meaningful and valid feedback to dialysis and other health care providers on their care for ESRD patients that may face social disadvantage or other forms of discrimination or bias (87 FR 38559). Further development of stratified reporting of ESRD QIP measures can provide dialysis and other health care providers with more granular results that support targeting resources and initiatives to improve health equity. We noted that we are mindful that it may not be possible to calculate stratified results for all ESRD QIP measures, or there may be situations where stratified reporting may not be desired. To help inform prioritization of the candidate ESRD QIP measures for stratified reporting, we stated that we aim to receive feedback on several systematic principles under consideration that we believe would help us prioritize measures for disparity reporting across programs.

These considerations, when assessed within the context of specific programs, like the ESRD QIP, help gauge the utility and potential uses of stratified measure results to provide usable and impactful information on disparity broadly across our programs. While we aim to standardize approaches where possible, we also recognize that the variety of measures and care settings involved and the contextual nature of stratified reporting would require decisions to be made at the program level.

In the CY 2023 ESRD PPS proposed rule, we noted that we have developed the following guiding principles for prioritizing ESRD QIP measures for disparity reporting:

• *Prioritize validated clinical quality measures*—When considering disparity reporting of stratified quality measures, there are several advantages to focusing on recognized measures which have met industry standards for measure reliability and validity. First, existing measures highlight agreed upon priority areas for quality measurement specific to the program setting, which have been developed under adherence to the CMS Measures Management System Blueprint [365] and have been reviewed for their clinical and population relevance by experts knowledgeable about the nuances of care delivered in these settings. Furthermore, these measures have been reviewed for clinical significance, applicability, and scientific rigor by additional organizations, such as the National Quality Forum (NQF), and have been selected for inclusion in programs with their recommendations in mind. Adapting these existing tools to measure disparity through stratification maintains adherence to predefined measurement priorities and utilizes a great deal of extant expert and methodological validation. The application of stratified reporting to validated clinical quality measures which are used across the health care sector also aim to mitigate any potential additional administrative burden on health care providers, hospitals, and facilities.

• *Prioritizing Measures with Identified Disparity in Treatment or Outcomes Among Participating Facilities for Selected Social or Demographic Factors*—Candidate ESRD QIP measures for stratification should be supported by evidence of underlying health care 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 or procedure the measure evaluates, or outcome used to score the measure, and should carefully consider both social risk factors and patient demographics. Disparity related to the measure could be based on the outcome or procedures and practices assessed by the measure. In addition, analysis of Medicare-specific data should be done to demonstrate evidence of disparity in care for some or most health care providers that treat Medicare patients. In addition to disparities in outcomes and quality, 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 would need to have sufficient sample size of enrollees to ensure that reported results of the disparity calculation are reliable and representative. This may be challenging if cohorts with a given social risk factor are small.

In the proposed rule, we stated that ESRD QIP may further consider measures for disparity reporting based on the utility of the stratified information, namely, prioritizing measures for stratification that show large differences in care between patient groups (87 FR 38560). Large differences in care for patients along social or demographic lines may indicate high potential that targeted initiatives could be effective. We noted that this is only one consideration in identifying the most meaningful differences in care, however, as initiatives designed for measures that show small disparities, but have very large cohorts, 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, as high priority quality measures. For example, two key ESRD QIP outcome measures are the SHR clinical measure and the SRR clinical measure, which we are updating so that the measure results are expressed as rates. Such outcome measures remain a priority in the context of disparities measurement. However, measures that focus on access, when available, are also critical tools for addressing health care disparities. Measures that address health care access can counterbalance the risk of creating perverse incentives, for example, whereby a facility may improve its performance on existing quality measures by limiting access to care for populations who are historically underserved.

To complement measure stratification focused on clinical outcomes, we stated in the proposed rule that the ESRD QIP would consider prioritizing measures with a focus on access to or appropriateness of care (87 FR 38560). These measures, when reported in tandem with clinical outcomes, would provide a broader picture of care provided at a facility, illuminate potential performance drivers, and identify organizations that fail to address access to care barriers for patient sub-groups. We acknowledge that the measurement of access and appropriateness of care is a growing field, and quality measures in these areas are limited. However, as our ability to measure these facets of health

[365] Centers for Medicare and 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*.

care improve, they would be high priority for measure stratification.

d. Principles for Social Risk Factor and Demographic Data Selection and Use

There are numerous non-clinical drivers of health associated with 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.[366] [367] [368] [369] [370] [371] [372] [373]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.'' [374] These include factors such as income, education, job insecurity, food insecurity, 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.[375] [376] 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.[377]

In prioritizing among social risk factors and demographic variables, disability, and other markers of disadvantage for stratified reporting, the ESRD QIP would develop approaches that have the most relevance for the existing measure set. 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 the most accurate way to attribute social risk.[378] Although some of this information is currently reported on Form 2728—ESRD Medical Evidence Report Medicare Entitlement And/or Patient Registration (OMB control number 0938–0046), in the proposed rule we stated our belief that additional development of patient-reported social risk factor and demographic variable data sources may be necessary to collect data that is complete enough to consider for disparity reporting (87 FR 38560). We noted that currently, there are many efforts underway to further develop data collection for self-reported patient social risk and demographic variables. Yet, given that data sources are small, they may only have the ability to provide statistically significant disparity results for a small proportion of care facilities.

We would continue to evaluate patient-reported sources of social risk and demographic information. Until validated data are available, in the proposed rule we stated that we are 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 enrollment and claims 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 facility burden. In the proposed rule, we noted that there are, however, limitations in these data's usability for stratification analysis. Our 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.[379] 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.[380] If the collection of social risk factor data improves in administrative data, we would 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.[381] [382] These reports found that in the context of VBP programs, dual eligibility, as an

[366] 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.

[367] 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.

[368] 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.

[369] 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.

[370] 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-incomehealth-status-recap.pdf*.

[371] 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*.

[372] 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.

[373] 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.

[374] World Health Organization. Social Determinants of Health. Available at: *https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1*.

[375] 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.

[376] 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*.

[377] White House. (2021). Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Available at: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/*.

[378] 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.

[379] 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.

[380] 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*.

[381] 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*.

[382] 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*.

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,[383] Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry Social Vulnerability Index (CDC/ATSDR SVI),[384] and Health Resources and Services Administration Area Deprivation Index,[385] 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.[386] This tool was originally developed by the RAND Corporation, and further customized for the Medicare population to improve existing CMS 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 what the individual would self-identify as given a set of racial and ethnic groups to choose from including: American Indian or Alaska Native, Asian or Pacific Islander, Black, Hispanic, Multiracial, and White. In no case would the estimated probability be used for making inferences about a 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 facility, or the members of a given plan. MBISG 2.1 is currently used by CMS' 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.[387]

While the use of area-based indicators and imputed data sources are not meant to replace efforts to improve patient-level data collection, in the proposed rule we noted that we are considering how they might be used to quickly 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 significant validation study has been completed, including evaluation by key interested parties 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.[388] Even more potent, when patient-level information is not available, are the combination of several sources of imputed or area-level data to provide diverse perspectives on social risk of a population.

e. Identification of Meaningful Performance Differences

In examining potential ways to report disparity data in the ESRD QIP, including the results of quality measure stratification, in the proposed rule we stated that we would consider different approaches to identifying meaningful differences in performance. Stratified results can be presented in a number of 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. We noted our aim to provide information that offers meaningful information to dialysis providers. While we aim to use standardized approaches where possible, identifying differences in performance on stratified results would be made at the program level due to contextual variations across programs and settings. We stated that we looked forward to feedback on the benefits and limitations of the possible reporting approaches we have described in this Request for Information.

• *Statistical Differences*—When aiming to examine differences in disparities results among facilities, 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 health care providers in a

[383] 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.

[384] 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.*

[385] Center for Health Disparities Research. About the Neighborhood Atlas. Available at: *https://www.neighborhoodatlas.medicine.wisc.edu/.*

[386] 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/.*

[387] 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/.*

[388] 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.

ranked system is another option for reporting disparity results in a meaningful way. In this system, facilities could be ranked based on their performance on disparity measures to quickly allow them to compare their performance to other similar health care providers. This approach works well as a way for facilities 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 health care providers, the difference between the top and bottom ranked facilities 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, facilities 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 interested parties by giving a clear indication that outcomes are not considered equal. However, this method does not convey the degree of disparity between facilities or the potential for improvement based on the performance of other facilities. 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 facilities 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 facilities. Interested parties have stated that comparisons between facilities have limited meaning if the facilities 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.

f. Guiding Principles for Reporting Disparity Results

In the proposed rule, we stated that there are several options for reporting of disparity results to drive improvements in quality (87 FR 38562). Confidential reporting, or reporting results privately to providers, is an approach we have used for new newly adopted measures in a CMS quality program to give providers an opportunity to become more familiar with calculation methods and to begin improvement activities before other forms of reporting. Providing early results to facilities is an important way to provide facilities the information they need to design impactful strategies to reduce disparity. Public reporting, or reporting results publicly, is a second reporting option. This method could provide ESRD QIP participants and ESRD patients with important information on facility quality, and by turn relies on market forces to incentivize health care providers to improve and become more competitive in their markets without directly influencing payment from CMS. Payment accountability could potentially offer a direct line for us to reward health care providers for having low disparity rates, or for performing well for medically underserved population groups.

We stated that we are exploring the most optimal methods of reporting disparity results. Initially, confidential reporting may be prudent for facilities and health care providers to understand stratification methodology and the presentation of stratified results, and to begin to implement programs to reduce disparities at their facilities. We noted that we are considering this approach to begin having an impact on disparity, while allowing providers time to interpret results and set up processes to address disparities.

It would be important to carefully consider the context of reporting, including measure specifications, data sources, care setting, and dialysis providers' and patients' perspectives before implementing a reporting strategy. In the proposed rule, we identified risks to applying stratification to all measures using all available social risk factor and demographic variables, such as the chance that unexpected results may exacerbate disparity. In the proposed rule, we stated our intent to consider these risks compared to the benefits of different reporting strategies when developing implementation plans.

Regardless of the methods used to report results, it is important to report stratified measure data alongside overall measure results. Review of both 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 health care 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.

g. Solicitation of Public Comments

In the proposed rule, we stated that the goal of this request for information was to describe key considerations that we would acknowledge when advancing the use of measure stratification as one quality measurement tool to address health care disparities and advance health equity in the ESRD QIP. We also stated that this was important as a means of setting priorities and expectations for the use of stratified measures. We specifically noted that several important factors may limit the use of stratification or may need to be taken into consideration.

We invited general comments on the principles and approaches listed previously, or additional thoughts about disparity measurement or stratification guidelines suitable for overarching consideration across our programs. Specifically, we invited comment on:

- Overarching goals for measuring disparity that should be considered across CMS quality programs, including: the importance of pairing stratified results to evaluate gaps in care among groups of patients attributed to a given facility and comparison of care for a subgroup of patients across facilities, and the goal that these stratified results are reported alongside overall measure results to have a comprehensive view of disparities.
- 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 facilities; 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, including the importance of identifying new social risk factor and demographic variables to use to stratify measures. We also sought 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 versus public reporting.

We received comments in response to this request for information and have summarized them here.

Comment: Many commenters supported efforts to address disparity measurement and health equity in the ESRD QIP. Several commenters specifically supported stratification as a potential approach to identifying the impact of health disparities in diverse population groups. One commenter stated that health disparities measurement will advance policies and practices that will promote health equity and improve health outcomes in patients from populations that are historically underserved. A few commenters noted that measure stratification will reveal the impact of social risk factors on health outcomes. One commenter identified the Percentage of Prevalent Patients Waitlisted (PPPW) measure as priority for stratification if the ESRD QIP measure set. A commenter stated that measure stratification by race, ethnicity, and dual eligibility status may be too broad to decipher the underlying cause of health disparities, but supports collection of this data as an important preliminary step. One commenter expressed general support for the creation of an ESRD Facility Equity Score and believes dialysis facilities should be accountable for closing health equity gaps with support and guidance from CMS. A commenter recommended that CMS work with interested parties to identify evidence-based measurable solutions to addressing health disparities.

Several commenters expressed concerns about the implementation of health disparities measurement in the ESRD QIP. A few commenters identified the potential for increased administrative burden as a concern. A few commenters expressed concern about CMS's plans to ensure that valid data collection and subsequent analytic procedures are in place. One commenter was concerned that measure stratification could potentially increase financial penalties for facilities that serve patients experiencing poverty or another disadvantage. Another commenter noted that dialysis facilities may have difficulties with data collection due to resource limitations and patient preferences.

Commenters offered multiple recommendations for future measurement of health disparities in the ESRD QIP. A few commenters recommended that CMS consider potential administrative burden in development of data collection and reporting procedures. Another commenter recommended that CMS include specific health equity measures in the ESRD QIP measure set to ensure financial accountability for facilities. One commenter noted the disproportionate impact of ESRD on patients from communities that are historically under-resourced and recommended enhanced attention to CKD prevention, quality of life improvement for CKD and ESRD patients and increased access to home dialysis and transplantation as treatment modalities. A commenter noted the importance of fairly applying quality incentives to promote equitable access to high-quality care and recommended incorporation of social risk factors into future analytic methodologies. One commenter recommended that patients be able to opt-out of participation in health disparities data collection.

Many commenters noted that they would like to see health disparity measurement linked to actionable planning that will advance health equity, and several commenters provided multiple recommendations for measuring health disparities. A few commenters supported using ''within-provider'' and ''across-provider'' approaches. A few commenters requested that CMS work with interested parties to define performance methodologies and reporting requirements, specifically related to stratification of measures. These commenters were especially concerned that CMS consider efforts to reduce administrative burden and financial penalization associated with serving patients from communities that are historically underserved while ensuring accurate and fair assessment performance evaluation at the facility level.

A few commenters recommended that CMS prioritize measures that have a sufficient sample size so that comparisons are reliable and representative. A few commenters suggested that CMS prioritize outcome measures and measures of access and appropriateness of care. A few commenters requested that CMS clarify the definition of access and appropriateness of care measures. One commenter recommended that CMS prioritize validated and reliable clinical quality measures over reporting measures. Another commenter recommended that CMS prioritize measures that are supported by evidence of disparities identified for selected social or demographic factors. One commenter recommended prioritization of measures that are directly related to patient outcomes, measures for which disparities are the largest, measures for which disparities are worsening, and measures that are actionable. One commenter recommended that CMS establish standards for stratification and robust segmentation to identify existing gaps in outcomes within patient groups. One commenter recommended initial prioritization of measures that facilities have experience with collecting and reporting to ensure that stratified measures have been validated and align with CMS priorities such as clinical quality, safety, and patient experience measures.

Several commenters recommended that CMS leverage existing data sources, including patient-level self-reported data, to stratify ESRD QIP measures by such factors as race and ethnicity, income, insurance status at the initiation of dialysis treatment and geographic area of residence. One commenter recommended that CMS develop and make available datasets that will track how closely the community generally, and each provider specifically, provides care across key demographic groups and whether that care aligns with the demographics of the service area. A few commenters noted the importance of collecting social drivers of health data for future resource allocation. A few commenters believed that z-code data would be a meaningful approach to increasing understanding of the impact of demographic and social risk factors in ESRD patients. A few commenters recommended that CMS take a stepwise approach to stratification of ESRD QIP measures, suggesting stratification according to dual-eligibility status as an appropriate starting place. One commenter recommended that CMS account for physical disability and limited English proficiency as key variables because patients with these characteristics may generate greater costs to the healthcare system due to mobility restrictions and need for translators. One commenter recommended that CMS make stratified health disparities data publicly available so that interested parties can better assess the diverse needs of different patient populations.

Several commenters provided recommendations for applying risk adjustment methods to identification of meaningful differences in disparity results. One commenter noted that risk adjustment should not include patients' clinical conditions because differences due to these factors are excluded from quality performance comparison. A few commenters stated that risk should control for clinical conditions and basic demographic characteristics (age and sex), which are legitimate reasons for variation in outcomes since they are biologically based and would potentially quantify outcome differences related to non-biological and/or social factors like race, ethnicity, and poverty that contribute to health inequities. One commenter believed risk adjustment methodologies incorporate utilization and cost variables to identify facility-level factors that may contribute to differences in ESRD patient outcomes including program design, provider characteristics and biases in care delivery or other non-clinical social factors. One commenter recommended identifying meaningful performance differences beyond process measures with more attention given to data-driven improved patient outcomes, including potentially avoidable hospital admissions, complications, readmissions, ambulatory complications, and emergency department visits that are adjusted for clinical and social risk. This commenter believed that reporting disparity results should track appropriate utilization to permit benchmarking for clinically similar cohorts because this approach would elucidate actual versus expected differences in utilization outcomes. One commenter recommended that CMS consider using the Social Deprivation Index (SDI) tool to ascertain a more granular perspective on social risk factors in the ESRD population to prevent masking of additional disparities apart from race and ethnicity. Another commenter emphasized that it will be important for CMS to work with experts to test proposed methods and identify best practices for data collection and stratification to avoid inadvertent quality measurement bias and exacerbation of existing health disparities. One commenter did not support the use of rank ordering or percentiles to identify differences in performance because such approaches can potentially mask the actual performance between top and bottom ranked facilities. One commenter believed that using statistical differences, thresholds, and benchmarking are more appropriate methods for identifying meaningful differences.

Several commenters recommended that CMS initially implement confidential facility-level reporting. A few commenters supported confidential reporting prior to public reporting. A few commenters noted that initial confidential reporting would allow time for evaluation of data collection and analytic methodologies which can reduce risk of misinterpretation of facility-level data and selection bias among patients. One commenter believed that de-identified aggregate reporting of disparity results may be helpful for sharing results beyond the facility level. A few commenters stated that publicly reporting disparity data in the future will promote transparency and accountability. One commenter cautioned against public reporting of disparity data because facilities have resource constraints that prohibit them from providing patients with social supports. Another commenter recommended that CMS collaborate with the kidney care community in future efforts to identify and address health disparities in ESRD patients.

Response: We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of CMS health equity efforts. We will continue to take all concerns, comments, and suggestions into account for future policy development and expansion of our strategic vision for advancing health equity. For more information on these ongoing efforts, we refer readers to our recently released CMS National Quality Strategy (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*), the CMS Strategic Plan for Health Equity (*https://www.cms.gov/files/document/health-equity-fact-sheet.pdf*), and the CMS Framework for Health Equity (*https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/framework-for-health-equity*) in which we describe our five priorities for advancing health equity.

V. End-Stage Renal Disease Treatment Choices (ETC) Model

A. Background

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of these programs. The purpose of the ETC Model is to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians to encourage greater utilization of home dialysis and kidney transplantation, support Beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. As described in the Specialty Care Models final rule (85 FR 61114), beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. ESRD Beneficiaries require dialysis or kidney transplantation to survive, and the majority of ESRD Beneficiaries receiving dialysis receive hemodialysis in an ESRD facility. However, as described in the Specialty Care Models final rule, alternative renal replacement modalities to in-center hemodialysis, including home dialysis and kidney transplantation, are associated with improved clinical outcomes, better quality of life, and lower costs than in-center hemodialysis (85 FR 61264).

The ETC Model is a mandatory payment model. ESRD facilities and Managing Clinicians are selected as ETC Participants based on their location in Selected Geographic Areas—a set of 30 percent of Hospital Referral Regions (HRRs) that have been randomly selected to be included in the ETC Model, as well as HRRs with at least 20 percent of ZIP codes™ located in Maryland.[389] CMS excludes all U.S. Territories from the Selected Geographic Areas.

Under the ETC Model, ETC Participants are subject to two payment adjustments. The first is the Home Dialysis Payment Adjustment (HDPA), which is an upward adjustment on certain payments made to participating ESRD facilities under the ESRD Prospective Payment System (PPS) on home dialysis claims, and an upward adjustment to the Monthly Capitation Payment (MCP) paid to participating Managing Clinicians on home dialysis-related claims. The HDPA applies to claims with claim service dates beginning January 1, 2021 and ending December 31, 2023.

The second payment adjustment under the ETC Model is the PPA. For the PPA, we assess ETC Participants' home dialysis rates and transplant rates during a Measurement Year (MY), which includes 12 months of performance data. Each MY has a corresponding PPA Period—a 6-month period that begins 6 months after the conclusion of the MY. We adjust certain

[389] ZIP code™ is a trademark of the United States Postal Service.

payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate, calculated as the sum of the transplant waitlist rate and the living donor transplant rate, during the corresponding MY.

Based on an ETC Participant's achievement in relation to benchmarks based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year, and the ETC Participant's improvement in relation to their own home dialysis rate and transplant rate during the Benchmark Year, we will make an upward or downward adjustment to certain payments to the ETC Participant. The magnitude of the positive and negative PPAs for ETC Participants increases over the course of the Model. These PPAs apply to claims with claim service dates beginning July 1, 2022 and ending June 30, 2027.

In the CY 2022 ESRD PPS final rule, we finalized a number of changes to the ETC Model. We made adjustments to the calculation of the home dialysis rate (86 FR 61951 through 61955) and the transplant rate (86 FR 61955 through 61959) and updated the methodology for attributing Pre-emptive Living Donor Transplant (LDT) Beneficiaries (86 FR 61950 through 61951). We modified the achievement benchmarking and scoring methodology (86 FR 61959 through 61968), as well as the improvement benchmarking and scoring methodology (86 FR 61968 through 61971). We specified the method and requirements for sharing performance data with ETC Participants (86 FR 61971 through 61984). We also made a number of updates and clarifications to the kidney disease patient education services waivers and made certain related flexibilities available to ETC Participants (86 FR 61984 through 61994).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the ETC Model

The CY 2023 ESRD PPS proposed rule appeared in the June 28, 2022 version of the **Federal Register**, with a comment period that ended on August 22, 2022. In that proposed rule, we proposed to make several changes to the ETC Model, effective January 1, 2023. We received 33 timely public comments on our proposals, including comments from ESRD facilities and dialysis organizations; national renal, nephrologist, and patient organizations; manufacturers; healthcare systems; and individual clinicians.

We also received comments related to issues that we did not discuss in the CY 2023 ESRD PPS proposed rule. These include, for example, general expressions of support for the ETC Model, the focus on increasing rates of home dialysis and transplantation, and the policies related to reducing disparities; recommendations for additional ways to refine the model, including changes to ETC Participant selection and ESRD Beneficiary attribution, aggregation group construction, and the achievement benchmarking methodology; concerns related to the impact of COVID–19 and the COVID–19 PHE on the ETC Model and ETC Participants; and recommendations to make the ETC Model, or specific elements of the ETC Model, available nationally. While we are generally not addressing those comments in this final rule, we thank commenters for their input and may consider their recommendations in future rulemaking.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the ETC Model. These policies take effect January 1, 2023.

1. Performance Payment Adjustment Achievement Scoring Methodology

Under the ETC Model, the PPA is a positive or negative adjustment on dialysis and dialysis-related Medicare payments for both home dialysis and in-center dialysis. To calculate an ETC Participant's PPA, we assess the ETC Participant's performance on the home dialysis rate and the transplant rate in relation to achievement and improvement benchmarks, as described in 42 CFR 512.370(b) and (c), respectively.

An ETC Participant's achievement is scored at the aggregation group level in relation to achievement benchmarks, which are constructed based on the home dialysis rate and transplant rate observed among aggregation groups located in Comparison Geographic Areas during corresponding Benchmark Years. Achievement benchmarks are percentile based, and set at the <30th, >30th, >50th, >75th, and >90th percentile of rates for Comparison Geographic Areas during the Benchmark Year. An ETC Participant receives the achievement points that correspond with its performance, at the aggregation group level, on the home dialysis rate and transplant rate in relation to the achievement benchmarks, as described in § 512.370(b)(1).

In the CY 2022 ESRD PPS final rule, we modified the achievement benchmarking methodology such that, beginning MY3, achievement benchmarks are stratified based on the proportion of beneficiary years attributed to the ETC Participant's aggregation group for which attributed beneficiaries are dually eligible for Medicare and Medicaid or receive the Low Income Subsidy (LIS). Beginning MY3, we create two strata, with the cutpoint set at 50 percent of attributed beneficiary years being for attributed beneficiaries who were dual-eligible or received the LIS, as described in § 512.370(b)(2).

As discussed in the CY 2023 ESRD PPS proposed rule, based on subsequent analysis, we found that stratifying achievement benchmarks in this way has increased the likelihood that the lowest benchmark—set at the 30th percentile—could be set at a home dialysis rate or transplant rate of zero. This change occurred because dividing the set of attributable beneficiaries in Comparison Geographic Areas into two strata means that there are fewer observations per strata, changing the underlying distributions.

We explained that awarding achievement points for a home dialysis rate or transplant rate of zero is inconsistent with the design and goals of the ETC Model. The purpose of the ETC Model is to test the use of certain payment adjustments to increase rates of home dialysis and transplantation, thereby improving or maintaining quality and reducing Medicare expenditures. Awarding achievement points, which are used to determine the magnitude and direction of an ETC Participant's PPA, for a home dialysis rate or a transplant rate of zero is antithetical to the ETC Model's design.

To address this issue, in the CY 2023 ESRD PPS proposed rule, we proposed to further modify the achievement scoring methodology for the ETC Model. Specifically, we proposed to add a requirement, to be codified in a new provision at § 512.370(b)(3), to specify that, beginning MY5, an ETC Participant's aggregation group must have a home dialysis rate or a transplant rate greater than zero to receive an achievement score for that rate. We sought comment on this proposal.

The comments on this proposal, and our responses to the comments, are set forth below.

Comment: Several commenters expressed support for our proposal to modify the achievement scoring methodology such that an ETC Participant's aggregation group must have a home dialysis rate or a transplant rate greater than zero to receive an achievement score for that rate. One of these commenters stated that they

agreed with our statement that awarding points for a home dialysis rate or a transplant rate of zero was counter to the intent of the model.

Response: We appreciate the commenters' support.

Comment: Several commenters stated that they appreciated CMS's continued efforts to refine the ETC Model regarding assessing ETC Participant achievement. Of these commenters, a few stated that they did not oppose this proposal, but suggested additional changes to assessing ETC Participant achievement, including changes to the achievement benchmarking methodology, such as weighting aggregation groups by size, increasing the number of strata, and basing achievement benchmarks on something other than rates observed in Comparison Geographic Areas during the Benchmark Year.

Response: We appreciate the commenters' continued engagement with the design of the ETC Model and the methodology by which we assess ETC Participant achievement. In the CY 2023 ESRD PPS proposed rule, we did not propose modifications to the achievement benchmarking methodology, and as such, we are not finalizing any changes to the achievement benchmarking methodology in this final rule. We may take these suggestions under consideration for potential future modifications to the ETC Model.

Final Rule Action: After considering the comments received, we are finalizing our proposal to add a requirement, by revising § 512.370(b) and adding § 512.370(b)(3), to specify that, for MY5 through MY10, an ETC Participant's aggregation group must have a home dialysis rate or a transplant rate greater than zero to receive an achievement score for that rate.

2. Kidney Disease Patient Education Services

Under section 1861(ggg)(1) of the Act and § 410.48 of our regulations, Medicare Part B covers outpatient, face-to-face kidney disease patient education services provided by certain qualified persons to beneficiaries with Stage IV chronic kidney disease. As noted in the Specialty Care Models final rule, kidney disease patient education services play an important role in educating patients about their kidney disease and helping them make informed decisions on the appropriate type of care and/or dialysis needed for them (85 FR 61337). In addition, as we noted in the Specialty Care Models final rule, kidney disease patient education services are designed to educate and inform beneficiaries about the effects of kidney disease, their options for transplantation, dialysis modalities, and vascular access (85 FR 61337).

Because kidney disease patient education services have been infrequently billed, we found it necessary for purposes of testing the ETC Model to waive select requirements of kidney disease patient education services as authorized in section 1861(ggg)(1) of the Act and in the implementing regulation at 42 CFR 410.48. Specifically, to broaden the availability of kidney disease patient education services under the ETC Model, we used our authority under section 1115A(d) of the Act to waive certain requirements for individuals and entities that furnish and bill for kidney disease patient education services. We codified these waivers at § 512.397(b). These include waivers to allow a broader scope of beneficiaries to have access to kidney disease patient education services, as well as greater flexibility in how the kidney disease patient education services are performed. CMS also waived the requirement that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish kidney disease patient education services to allow kidney disease patient education services to be provided by clinical staff under the direction of and incident to the services of the Managing Clinician who is an ETC Participant.

Specifically, under § 512.397(b)(1), kidney disease patient education services may be provided by ''qualified staff,'' which includes any qualified person (as defined at § 410.48(a)) as well as clinical staff. In the CY 2022 ESRD PPS final rule (86 FR 61988), we defined ''clinical staff'' under 42 CFR 512.310 of our regulations to mean a licensed social worker or registered dietician/nutrition professional who furnishes services for which payment may be made under the physician fee schedule under the direction of and incident to the services of the Managing Clinician who is an ETC Participant.

In addition, in the CY 2022 ESRD PPS final rule, we added a new provision at § 512.397(c) permitting an ETC Participant to reduce or waive the 20 percent coinsurance requirement for kidney disease patient education services furnished on or after January 1, 2022, if several conditions are satisfied, including a requirement that the individual or entity that furnished the services is qualified staff and was not leased from or otherwise provided by an ESRD facility or related entity. We finalized this cost-sharing reduction policy because we believed this patient incentive would advance the ETC Model's goal of increasing access to kidney disease patient education services and make beneficiaries more aware of their choices in kidney treatment, including the choice of receiving home dialysis, self-dialysis, or nocturnal in-center dialysis, rather than traditional in-center dialysis. We also determined that under § 512.397(c)(3), the federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect the kidney disease patient education coinsurance waivers that satisfy the requirements of such safe harbor and § 512.397(c)(1).

We recognized in the CY 2022 ESRD PPS final rule that ESRD facilities and other entities sometimes enter into arrangements with clinicians or other parties to provide certain services (86 FR 61991). We also recognized that some ETC Participants may wish to furnish kidney disease patient education services using staff or other resources furnished under a contractual arrangement with an ESRD facility or other entity. We were concerned, however, that even if such arrangements were structured to comply with all applicable fraud and abuse laws, they could nevertheless result in program abuse. Specifically, such arrangements could operate to circumvent the statutory prohibition against ESRD facilities furnishing kidney disease patient education services. For example, the staff or resources furnished to the ETC Participant from an ESRD facility or related entity could be used to market a specific ESRD facility or chain of ESRD facilities to beneficiaries who may need to choose an ESRD facility in the future. We stated that we did not believe that ETC Participants should obtain safe harbor protection for the reduction or waiver of cost-sharing on kidney disease patient education services if such services were furnished by personnel leased from an ESRD facility or related entity. We explained that a ''related entity'' would include any entity that is directly or indirectly owned in whole or in part by an ESRD facility and that this policy aligns with the statutory provision that excludes ESRD facilities from the individuals and entities that can furnish kidney disease patient education services.

Currently, the prohibition against the furnishing of kidney disease patient education services by qualified staff who are leased from or otherwise provided by an ESRD facility or related entity does not apply unless an ETC Participant reduces or waives the

Beneficiary's coinsurance obligation for kidney disease patient education services. In the CY 2023 ESRD PPS proposed rule, we proposed that a similar prohibition would apply with respect to ''clinical staff'' regardless of whether the ETC Participant is reducing or waiving the kidney disease patient education coinsurance obligation. Specifically, we proposed to add a sentence to § 512.397(b)(1) stating that, for purposes of the waiver under § 512.397(b)(1) of our regulations, beginning for MY5, ''clinical staff'' may not be leased from or otherwise provided to the ETC Participant by an ESRD facility or related entity. Applying this prohibition on ''clinical staff'' could also protect beneficiaries and their care choices and limit the likelihood that the ''clinical staff'' furnished to the ETC Participant from an ESRD facility or related entity would result in steering a Beneficiary to a specific ESRD facility or chain of ESRD facilities.

To further ensure that beneficiaries are not unduly influenced to choose a particular ESRD facility, we also considered whether the final rule should include a requirement that, for purposes of the waiver under § 512.397(b)(1), the content of the kidney disease patient education furnished by clinical staff cannot market a specific ESRD facility or chain of ESRD facilities to beneficiaries. However, we recognized that some forms of marketing can be quite subtle. For example, a Beneficiary's treatment choices could be unduly biased if the Beneficiary is made aware of the leased staff person's employment by an ESRD facility (for example, by the trainer's responses to Beneficiary questions or discussion of personal experience, or even by a logo on the trainer's clothing or educational materials). Because it would be difficult for us to enforce this content restriction in many cases of subtle marketing, we did not think this restriction would sufficiently protect against improper influence of Beneficiary choice with respect to the selection of an ESRD facility unless we also finalized our proposal to prohibit qualified staff from furnishing kidney disease patient education services if they are leased from or otherwise provided by an ESRD facility.

We solicited public comments on these proposed changes to § 512.397(b)(1). The comments on this proposal, and our responses to the comments, are set forth below.

Comment: Several commenters supported our proposal to prohibit an ESRD facility or related entity from leasing or otherwise providing ''clinical staff'' for the purposes of furnishing kidney disease patient education services regardless of whether the ETC Participant reduces or waives the Beneficiary's coinsurance obligation. One commenter noted that the proposed prohibition against the furnishing of kidney disease patient education services by qualified staff who are leased from or otherwise provided by an ESRD facility or related entity would protect patient choice. Another commenter agreed that beneficiaries should not be steered to any specific ESRD facility or chain of ESRD facilities.

Response: We appreciate the commenters' support.

Comment: Several commenters opposed our proposal to prohibit an ESRD facility or related entity from leasing or otherwise providing ''clinical staff'' for the purposes of furnishing kidney disease patient education services regardless of whether the ETC Participant reduces or waives the Beneficiary's coinsurance obligation. A few commenters opposed our proposal because they stated it could exacerbate the underutilization of kidney disease patient education services. One commenter stated that beneficiaries should have kidney disease patient education services furnished by the best qualified professionals, regardless of where they are employed. Several commenters who opposed our proposal stated that they would be willing to work with CMS to address issues with steering beneficiaries to a specific ESRD facility or chain of ESRD facilities if they were to arise. Commenters also stated that CMS could create guardrails around steering beneficiaries to a specific ESRD facility or chain of ESRD facilities by producing non-branded materials for use in furnishing kidney disease patient education services.

Response: We appreciate the commenters' feedback. In the Specialty Care Models final rule, we waived certain Medicare payment requirements regarding kidney disease patient education services to give ETC Participants additional access to tools to educate beneficiaries about their renal replacement options (85 FR 61114). Educating patients about the management of comorbidities, prevention of complications, and therapeutic options and ensuring access to the best qualified health care professionals is essential to protecting Beneficiary choice. We agree that Beneficiaries should have access to the best qualified professionals, but we do not agree that the Beneficiary protections we are finalizing in this rule will preclude access to these professionals. We appreciate commenters' concerns that the inability to perform these services using staff leased from an ESRD facility or related entity could result in underutilization of kidney disease patient education services, but it is important that these services are furnished without any undue pressure on beneficiaries. While we appreciate commenters' willingness to work with CMS to address issues with steering that arise, we do not believe that we should finalize a policy that would simply result in remedial action if some patient education services were to result in patient steering. Because patient steering can be difficult for CMS to discover, we prefer to finalize a policy that would prevent the abuse from occurring in the first instance. Similarly, we do not believe that we have the resources to develop non-branded materials for use in furnishing kidney disease patient education services. We continue to believe that adding a sentence to § 512.397(b)(1) stating that, for purposes of the waiver under § 512.397(b)(1) of our regulations, beginning for MY5, ''clinical staff'' may not be leased from or otherwise provided to the ETC Participant by an ESRD facility or related entity, is necessary to preserve patient choice regarding their treatment modality and the ESRD facility or chain of ESRD facilities from which they may receive treatment.

Comment: Several commenters expressed their support for further improving access to kidney disease patient education services. A few commenters recommended that CMS increase the types of qualified staff who would be permitted to provide kidney disease patient education services under the direction of and incident to the services of the Managing Clinician who is an ETC Participant.

Response: We thank commenters for their engagement with the waivers provided for the ETC Model test. We may take the recommendation to increase the types of qualified staff who would be permitted to provide kidney disease patient education services under consideration for potential future modifications to the ETC Model.

Final Rule Action: After considering the comments received, we are finalizing our proposal to add a sentence to § 512.397(b)(1) stating that, for purposes of the waiver under § 512.397(b)(1) of our regulations, beginning for MY5, only ''clinical staff'' that are not leased from or otherwise provided to the ETC Participant by an ESRD facility or related entity may provide kidney disease patient education services. We believe this requirement is necessary to preserve

patient choice of modality and ESRD facility or chain of ESRD facilities.

3. Publication of Participant Performance

In the Specialty Care Models final rule, CMS established certain general provisions in subpart A of 42 CFR part 512 that apply to the ETC Model. One such general provision pertains to rights in data. Specifically, in the Specialty Care Models final rule, we stated that to enable CMS to evaluate the Innovation Center models (defined to include the ETC Model and Radiation Oncology Model) as required by section 1115A(b)(4) of the Act and to monitor the Innovation Center models pursuant to § 512.150, in § 512.140(a) we would use any data obtained in accordance with §§ 512.130 and 512.135 to evaluate and monitor the Innovation Center models (85 FR 61124). We also stated that, consistent with section 1115A(b)(4)(B) of the Act, CMS would disseminate quantitative and qualitative results and successful care management techniques, including factors associated with performance, to other providers and suppliers and to the public. We stated that the data to be disseminated would include, but would not be limited to, patient de-identified results of patient experience of care and quality of life surveys, as well as patient de-identified measure results calculated based upon claims, medical records, and other data sources. We finalized these policies in 42 CFR 512.140(a).

Consistent with these provisions, as discussed in the CY 2023 ESRD PPS proposed rule, we intend to publish patient de-identified results from all MYs of the ETC Model, including results from MYs that have already been completed. Specifically, for each MY, we intend to post the aggregate results for the home dialysis rate and the transplant rate for each aggregation group, as well as the individual components of each rate for the aggregation group as a whole. This would include the number of beneficiary months in home dialysis, self-dialysis, or nocturnal dialysis and the number of beneficiary months on the transplant waitlist, as well as the number of living donor transplants and, if applicable, pre-emptive living donor transplants performed. We would also identify all of the ESRD facilities or Managing Clinicians in the aggregation group for the MY. The results would be published on the ETC Model website. We explained that because the ETC Model includes a process for ETC Participants to request a targeted review of the calculation of the modality performance score (MPS)—which is calculated based on the various rates we intend to publish—CMS intends to publish these rates only after they have been finalized and CMS has resolved any targeted review requests timely received from ETC Participants under 42 CFR 512.390(c). We noted that we believed that the release of this information would inform the public about the cost and quality of care and about ETC Participants' performance in the ETC Model. This would supplement the annual evaluation reports that CMS is required to conduct and release to the public under section 1115A(b)(4) of the Act.

We sought comment on our intent to post this information to our website, as well as the information we intend to post and the manner and timing of the posting. The comments and our responses are set forth below.

Comment: Several commenters supported our plan to publish de-identified ETC Model results on the ETC Model website.

Response: We appreciate the feedback from commenters and are planning to post the results on the ETC Model website at *https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model,* to promote transparency and to help educate the public about the effects of the ETC Model on beneficiaries.

Comment: We received requests for more details about what CMS will post, including requests for specific information about how publicly posted results will account for members of an aggregation group.

Response: CMS appreciates this feedback. As we described in the CY 2023 ESRD PPS proposed rule, we are only planning to post results at the aggregation group level, as well as a list of the relevant Managing Clinicians or ESRD facilities within the aggregation group. We plan to share results using a method similar to how we shared results with ETC Participants for each MY, which will give the overall payment adjustment and break down the individual components that go into the home dialysis rate and transplant rate, de-identified in accordance with 45 CFR 164.514(b).

Comment: We received multiple requests for the ability to pre-review results before they are posted publicly.

Response: CMS appreciates this feedback from commenters, but believes that the targeted review process outlined in 42 CFR 512.390(c) provides a sufficient opportunity for ETC Participants to review the results before they are posted publicly. As we described in the CY 2023 ESRD PPS proposed rule, we will post de-identified results at the aggregation group level, which will have already been reviewed by ETC Participants as part of the targeted review process.

Final Rule Action: CMS will publish performance data for Managing Clinicians and ESRD facilities after the conclusion of each Measurement Year. Consistent with the discussion in the proposed rule, we will also publish results from MYs that have already been completed. We appreciate the feedback from commenters about how we should publish results and will represent results for aggregated performance groups in a clear manner.

VI. Collection of Information Requirements

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

1. ESRD QIP—Wage Estimates (OMB Control Numbers 0938–1289 and 0938–1340)

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates. In the CY 2016 ESRD PPS final rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to CROWNWeb (now EQRS) and NHSN, as well as compiling and submitting patient records for the purpose of data validation studies. In the proposed rule, we stated that the most recently available median hourly wage of a Medical Records and Health Information Technician is $21.20 per hour (87 FR 38566).[390] In this final rule, we are updating the median hourly wage to $22.43 per hour, which reflects the most recently available data.[391]

[390] *https://www.bls.gov/oes/2020/may/oes292098.htm.*

[391] *https://www.bls.gov/oes/current/oes292072.htm.* Accessed on September 16, 2022.

We also calculate fringe benefit and overhead at 100 percent. We adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. We stated that these are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, we stated that there is no practical alternative and we believe that these are reasonable estimation methods. Therefore, using these assumptions, in the proposed rule we estimated an hourly labor cost of $42.40 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP (87 FR 38566). In this final rule, we are updating our previously estimated hourly labor cost to $44.86 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP.

We used this updated wage estimate, along with updated facility and patient counts to re-estimate the total information collection burden in the ESRD QIP for PY 2025 that we discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38566) and to estimate the total information collection burden in the ESRD QIP for PY 2026. We provide the re-estimated information collection burden associated with the PY 2025 ESRD QIP and the newly estimated information collection burden associated with the PY 2026 ESRD QIP in section VII.C.3 of this final rule. Although we also proposed updates for PY 2023 and PY 2024, these proposals did not affect our estimates of the annual burden associated with the program's information collection requirements, and therefore, we are not updating our previously finalized information collection burden estimates associated with the PY 2023 or PY 2024 ESRD QIP due to our finalized policies in this final rule. Although we are finalizing the suppression of seven measures for PY 2023 instead of six measures as originally proposed, as discussed further in section IV.B.2 of this final rule, we believe that this will not impact the information collection burden, as facilities are still expected to continue to collect measure data during this time period for both suppressed and non-suppressed measures.

2. Estimated Burden Associated With the Data Validation Requirements for PY 2025 and PY 2026 (OMB Control Numbers 0938–1289 and 0938–1340)

In the CY 2020 ESRD PPS final rule, we finalized a policy to adopt the CROWNWeb data validation methodology that we previously adopted for the PY 2016 ESRD QIP as the methodology we would use to validate CROWNWeb data for all payment years, beginning with PY 2021 (83 FR 57001 through 57002). Although we are now using EQRS to report data that was previously reported in CROWNWeb, the data validation methodology remains the same. Under this methodology, 300 facilities are selected each year to submit 10 records to CMS, and we reimburse these facilities for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. In the proposed rule, we did not propose any changes to the EQRS data validation process. However, in this final rule, we are updating these burden estimates using a newly available wage estimate of a Medical Records Specialist. In the CY 2020 ESRD PPS final rule, we estimated that it would take each facility approximately 2.5 hours to comply with this requirement (84 FR 60787). If 300 facilities are requested to submit records, we estimated that the total combined annual burden for these facilities would be 750 hours (300 facilities × 2.5 hours). Since we anticipate that Medical Records Specialists or similar administrative staff would submit these data, we estimate that the aggregate cost of the EQRS data validation each year would be approximately $33,645 (750 hours × $44.86), or an annual total of approximately $112.15 ($33,645/300 facilities) per facility in the sample. The burden cost increase associated with these requirements will be revised in the information collection request (OMB control number 0938–1289).

In the CY 2021 ESRD PPS final rule, we finalized our policy to reduce the number of records that a facility selected to participate in the NHSN data validation must submit to a CMS contractor, beginning with PY 2023 (85 FR 71471 through 71472). Under this finalized policy, a facility is required to submit records for 20 patients across any two quarters of the year, instead of 20 records for each of the first two quarters of the year. The burden associated with this policy is the time and effort necessary to submit the requested records to a CMS contractor. In the proposed rule, we did not propose any changes to the NHSN data validation process. However, in this final rule we are updating these burden estimates using a newly available wage estimate of a Medical Records Specialist. Applying our policy to reduce the number of records required from each facility participating in the NHSN validation, we estimated that it would take each facility approximately 5 hours to comply with this requirement. If 300 facilities are requested to submit records each year, we estimated that the total combined annual burden hours for these facilities per year would be 1,500 hours (300 facilities × 5 hours). Since we anticipate that Medical Records Specialists or similar staff would submit these data, using the newly available wage estimate of a Medical Records Specialist, we estimate that the aggregate cost of the NHSN data validation each year would be approximately $67,290 (1,500 hours × $44.86), or a total of approximately $224.30 ($67,290/300 facilities) per facility in the sample. While the burden hours estimate would not change, the burden cost updates associated with these requirements will be revised in the information collection request (OMB control number 0938–1340).

3. EQRS Reporting Requirements for PY 2023 and PY 2024 (OMB Control Number 0938–1289)

To determine the burden associated with the EQRS reporting requirements (previously known as the CROWNWeb reporting requirements), we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to EQRS for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into EQRS, and the number of facilities submitting data to EQRS. In the CY 2021 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2023 ESRD QIP was approximately $208 million (85 FR 71475).

As discussed in section IV.B.2 of this final rule, we are finalizing our six measure suppressions that would apply for PY 2023. We are also finalizing the suppression of the Standardized Fistula Rate clinical measure for PY 2023. However, we believe that finalizing these measure suppressions would not affect our estimates of the annual burden associated with the Program's information collection requirements, as

facilities are still expected to continue to collect measure data during this time period for all ESRD QIP measures, including both suppressed and non-suppressed measures. Although we are updating the SHR and SRR clinical measure results to be expressed as rates beginning in PY 2024 in section IV.D of this final rule, these technical updates would not affect our estimates of the annual burden associated with the Program's information collection requirements.

4. EQRS Reporting Requirements for PY 2025 and PY 2026 (OMB Control Number 0938–1289)

To determine the burden associated with the EQRS reporting requirements (previously known as the CROWNWeb reporting requirements), we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to EQRS for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into EQRS, and the number of facilities submitting data to EQRS. In the CY 2022 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2025 ESRD QIP was approximately $215 million for approximately 5,085,050 total burden hours (86 FR 61999).

We did not propose any changes in the proposed rule that would affect the burden associated with EQRS reporting requirements for PY 2025 or PY 2026. However, we have re-calculated the burden estimate for PY 2025 using updated estimates of the total number of ESRD facilities, the total number of patients nationally, and wages for Medical Records Specialists or similar staff as well as a refined estimate of the number of hours needed to complete data entry for EQRS reporting. Consistent with our approach in the CY 2022 ESRD PPS final rule (86 FR 61999), in the proposed rule we estimated that the amount of time required to submit measure data to EQRS was 2.5 minutes per element and did not use a rounded estimate of the time needed to complete data entry for EQRS reporting. We are further updating these estimates in this final rule. There are 229 data elements for 514,406 patients across 7,847 facilities. At 2.5 minutes per element, this yields approximately 625.49 hours per facility. Therefore, the PY 2025 burden is 4,908,291 hours (625.49 hours × 7,847 facilities). Using the wage estimate of a Medical Records Specialist, we estimate that the PY 2025 total burden cost is approximately $220 million (4,908,291 hours × $44.86). There is no net incremental burden change from PY 2025 to PY 2026 because we are not changing the reporting requirements for PY 2026.

5. Additional Reporting Requirements Beginning With PY 2025

In section IV.E.1.a of the preamble of this final rule, we are finalizing our proposal to adopt a COVID–19 Vaccination Coverage among HCP reporting measure beginning with the PY 2025 ESRD QIP. Facilities would submit data through the CDC NHSN. The NHSN is a secure, internet-based system maintained by the CDC and provided free.[392] Currently, the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC information collection requirement (ICR) approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[393] Although the burden associated with the COVID–19 Vaccination Coverage among HCP reporting measure is not accounted for under the CDC ICR 0920–1317 or 0920–0666 due to the NCVIA waiver, the estimated cost and burden information are included in section VII.D.2.b and would be accounted for by the CDC under OMB control number 0920–1317.

We estimate that it would take each facility, on average, approximately 1 hour per month to collect data for the COVID–19 Vaccination Coverage among HCP reporting measure and enter it into NHSN. We have estimated the time to complete this entire activity, since it could vary based on provider systems and staff availability. This burden is comprised of administrative hours and wages. We believe it would take an Administrative Assistant[394] between 45 minutes and 1 hour and 15 minutes to enter this data into NHSN. For PY 2025 and subsequent years, facilities would incur an additional annual burden between 9 hours (0.75 hours/month × 12 months) and 15 hours (1.25 hours/month × 12 months) per facility and between 70,623 hours (9 hours/facility × 7,847 facilities) and 117,705 hours (15 hours/facility × 7,847 facilities) for all facilities. Each facility would incur an estimated cost of between $324.18 (9 hours × $36.02/hour) and $540.30 annually (15 hours × $36.02/hour). The estimated cost across all facilities would be between $2,543,840.46 ($324.18/facility × 7,847 facilities) and $4,239,734.10 ($540.30/facility × 7,847 facilities) annually. We recognize that many health care facilities are also reporting other COVID–19 data to HHS. We believe the benefits of reporting data on the COVID–19 Vaccination Coverage among HCP reporting measure to monitor, track, and provide transparency for the public on this important tool to combat COVID–19 outweigh the costs of reporting.

We did not receive any comments on the ESRD QIP collection of information discussions.

VII. Regulatory Impact Analysis

A. Statement of Need

1. ESRD PPS

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This final rule provides updates and policy changes to the CY 2023 ESRD wage index values, the wage index budget-neutrality adjustment factor, the outlier payment threshold amounts, and the TPNIES offset amount. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2023 for renal dialysis services furnished to ESRD beneficiaries.

This rule also has a number of policy changes to improve payment stability and adequacy under the ESRD PPS. As discussed in section II.B.1.a.(1) of this final rule, we are finalizing our proposal to rebase and revise the ESRDB market

[392] More information on the NHSN can be found at: *https://www.cdc.gov/nhsn/index.html.*

[393] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

[394] *https://www.bls.gov/oes/current/oes436013.htm* (accessed on March 29, 2022). The adjusted hourly wage rate of $36.02/hour includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

basket to reflect a CY 2020 base year. We are also finalizing our proposals to increase the ESRD PPS wage index floor as discussed in section II.B.1.b.(3) of this final rule, and to apply a permanent 5-percent cap on wage index decreases for CY 2023 and subsequent years, as discussed in section II.B.1.b.(2) of this final rule. Lastly, as discussed in section II.B.1.c.(4) of this final rule, we are finalizing our proposal to change our methodology for calculating the FDL amount for adults to target more effectively ESRD PPS outlier payments that equal 1 percent of total ESRD PPS payments. We believe that each of these changes will improve payment stability and adequacy under the ESRD PPS.

Furthermore, as discussed in section II.B.1.f. of this final rule, we are finalizing our proposal to modify the definition of ''oral-only drug'' at § 413.234(a) to specify that equivalence refers to functional equivalence, in line with our current drug designation process and reliance on the ESRD PPS functional categories. We believe this change will improve beneficiaries' access to renal dialysis drugs, promote health equity, and advance other goals as discussed in that section of this final rule. Lastly, we are finalizing our proposal to clarify the descriptions of several existing ESRD PPS functional categories to ensure our descriptions are as clear as possible for potential TDAPA applicants and the public. We believe this clarification will improve public understanding of the ESRD PPS functional categories and drug designation process.

2. AKI

This final rule updates the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. As discussed in section III.B.2 of this final rule, we are also finalizing our proposal to apply to all AKI dialysis payments in an ESRD facility the same wage index floor and permanent 5-percent cap on wage index decreases that we will apply under the ESRD PPS. We believe that these changes will improve payment stability and adequacy for AKI dialysis in ESRD facilities. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2023 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

3. ESRD QIP

Section 1881(h)(1) of the Act requires a payment reduction of up to 2 percent for eligible facilities that do not meet or exceed the mTPS established with respect to performance standards for the ESRD QIP each year. This final rule finalizes updates for the ESRD QIP, including the suppression of several ESRD QIP measures for PY 2023 under our previously finalized measure suppression policy, an update to the PY 2023 performance standards, updates regarding the SHR clinical measure and the SRR clinical measure for PY 2024, and updates regarding the STrR and Hypercalcemia measures, the adoption of the COVID–19 Vaccination Coverage among HCP reporting measure, as well as a policy to create a new reporting measure domain and to re-weight measure domains, beginning in PY 2025.

4. ETC Model

We believe it is necessary to make certain changes to the ETC Model. ETC Participants will continue to receive adjusted payments but beginning MY5, certain aspects of the ETC Model used to determine those payment adjustments will change. The change to the PPA achievement scoring methodology is necessary to increase fairness and accuracy of the PPA. The change to the kidney disease patient education services waiver and the discussion of our intent to disseminate participant-level model performance information to the public are necessary to support ETC Participants operating in the ETC Model.

B. Overall Impact

We have examined the impacts of this 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. Therefore, OMB has reviewed these regulations, and the Departments have provided an assessment of their impact in the following sections of this CY 2023 ESRD PPS final rule.

We solicited comments on the regulatory impact analysis provided in the CY 2023 ESRD PPS proposed rule.

Comment: Several individual commenters raised concerns that payment impacts for certain ESRD facilities, particularly several rural facilities, would be lower than the overall impact analysis presented in the proposed rule.

Response: As we noted in the CY 2023 ESRD PPS proposed rule (87 FR 38568), proposed updates to the wage index would have distributive impacts and would affect different ESRD facilities in different ways. We always strive to present as much information as possible in the proposed rule so that the costs and benefits of rulemaking can be effectively analyzed. In addition, we provide a facility-level impact file as an addendum to present impacts at a more granular level than can be presented in the **Federal Register**.

Final Decision: After consideration of the comments, we are finalizing our proposed methodology for analyzing the impacts of rulemaking. We have revised

our impact analysis to reflect more recent data sources and information for this final rulemaking.

C. Impact Analysis

1. ESRD PPS

We estimate that the revisions to the ESRD PPS will result in an increase of approximately $300 million in payments to ESRD facilities in CY 2023, which includes the amount associated with updates to the outlier thresholds, payment rate update, updates to the wage index, and continuation of the approved TPNIES and TDAPA from CY 2022.

2. AKI

We estimate that the updates to the AKI payment rate will result in an increase of approximately $2 million in payments to ESRD facilities in CY 2023.

3. ESRD QIP

We estimate that the finalized updates to the ESRD QIP will result in an additional $32 million in estimated payment reductions across all facilities for PY 2025.

4. ETC Model

We estimate that the finalized changes to the ETC Model will not impact the Model's projected direct savings from payment adjustments alone. We estimate that the Model will generate $28 million in direct savings related to payment adjustments over 6.5 years.

D. Detailed Economic Analysis

In this section, we discuss the anticipated benefits, costs, and transfers associated with the changes in this final rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this final rule.

1. Benefits

Under the CY 2023 ESRD PPS and AKI payment, ESRD facilities will continue to receive payment for renal dialysis services furnished to Medicare beneficiaries under a case-mix adjusted PPS. We continue to expect that making prospective payments to ESRD facilities will enhance the efficiency of the Medicare program. Additionally, we expect that updating ESRD PPS and AKI payments by 3.0 percent based on the CY 2023 ESRD PPS market basket update less the CY 2023 productivity adjustment will improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services.

2. Costs

a. ESRD PPS and AKI

We do not anticipate the provisions of this final rule regarding ESRD PPS and AKI rates-setting will create additional cost or burden to ESRD facilities.

b. ESRD QIP

As discussed in section IV.B.2 of this final rule, we are adopting measure suppressions that would apply for PY 2023. However, we believe that none of the policies that we are finalizing in this final rule would affect our estimates of the annual burden associated with the Program's information collection requirements, as facilities are still expected to continue to collect measure data during this time period. For PY 2025 and PY 2026, we have re-estimated the costs associated with the information collection requirements under the ESRD QIP with updated estimates of the total number of ESRD facilities, the total number of patients nationally, wages for Medical Records Specialists or similar staff, and a refined estimate of the number of hours needed to complete data entry for EQRS reporting. We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for the EQRS validation study (previously known as the CROWNWeb validation study), the NHSN validation study, and EQRS reporting.

We also finalized the payment reduction scale using more recent data for the measures in the ESRD QIP measure set. We estimate approximately $220 million in information collection burden, which includes the cost of complying with this rule, and an additional $32 million in estimated payment reductions across all facilities for PY 2025, for an impact of $252 million as a result of the policies we have previously finalized and the policies we have finalized in this final rule.

For PY 2026, we estimate that the finalized revisions to the ESRD QIP would result in $220 million in information collection burden, and $32 million in estimated payment reductions across all facilities, for an impact of $252 million as a result of the policies we have previously finalized and the policies we have finalized in this final rule.

3. Transfers

We estimate that the updates to the ESRD PPS and AKI payment rate will result in a total in increase of approximately $300 million in payments to ESRD facilities in CY 2023, which includes the amount associated with updates to the outlier thresholds, and updates to the wage index. This estimate includes an increase of approximately $2 million in payments to ESRD facilities in CY 2023 due to the updates to the AKI payment rate, of which approximately 20 percent is increased beneficiary co-insurance payments. We estimate approximately $240 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately $60 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary co-insurance payments as a result of this final rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final 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 final 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 thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We did not receive any public comments specific to our solicitation.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

We sought public comments on this assumption. We did not receive any public comments specific to our solicitation.

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 will take approximately 316 minutes (5.3 hours) for the staff to review half of this final rule, which is approximately 79,000 words. For each entity that reviews the rule, the estimated cost is $610.67 (5.2 hours × $115.22).

Therefore, we estimate that the total cost of reviewing this regulation is $177,704.97 ($610.67 × 291).

5. Impact Statement and Table

a. CY 2023 End-Stage Renal Disease Prospective Payment System

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2022 to estimated payments in CY 2023. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2022 and CY 2023 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this final rule, we used CY 2021 data from the Part A and Part B Common Working Files as of July 30, 2022, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2021 claims to 2022 and 2023 using various updates. The updates to the ESRD PPS base rate are described in section II.B.1.d of this final rule. Table 31 shows the impact of the estimated CY 2023 ESRD PPS payments compared to estimated payments to ESRD facilities in CY 2022.

TABLE 31: Impacts of the Changes in Payments to ESRD Facilities for CY 2023[1]

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Changes to Outlier Policy (C)	Change to LRS (D)	Wage Index Changes (E)	Total Percent Change[2] (F)
All Facilities	7,882	35.5	0.0%	0.0%	0.0%	3.1%
Type						
Freestanding	7,506	34.1	0.0%	0.0%	0.0%	3.0%
Hospital based	376	1.4	0.1%	0.0%	0.0%	3.1%
Ownership Type						
Large dialysis organization	6,109	27.9	0.0%	0.0%	0.0%	3.0%
Regional chain	902	4.2	0.0%	0.2%	0.1%	3.4%
Independent	474	2.0	0.0%	0.3%	-0.1%	3.2%
Hospital based	376	1.4	0.1%	0.0%	0.0%	3.1%
Unknown	21	0.0	0.0%	0.1%	0.3%	3.4%
Geographic Location						
Rural	1,286	5.1	0.0%	-0.6%	-0.2%	2.3%
Urban	6,596	30.4	0.0%	0.1%	0.0%	3.2%
Census Region						
East North Central	1,224	4.8	0.0%	-0.2%	-0.4%	2.5%
East South Central	622	2.4	0.0%	-0.7%	-0.3%	2.0%
Middle Atlantic	895	4.4	0.1%	0.3%	0.0%	3.3%
Mountain	439	1.9	0.0%	-0.1%	-0.1%	2.9%
New England	202	1.2	0.0%	0.2%	-0.6%	2.7%
Pacific[3]	972	5.7	0.0%	0.8%	0.6%	4.5%
Puerto Rico and Virgin Islands	52	0.2	0.0%	-1.9%	7.1%	8.2%
South Atlantic	1,832	8.1	0.1%	-0.3%	-0.2%	2.5%
West North Central	517	2.0	0.1%	-0.3%	-0.3%	2.5%

West South Central	1,127	4.9	0.0%	-0.4%	0.3%	2.9%
Facility Size						
Less than 4,000 treatments	1,310	1.7	0.0%	-0.2%	-0.2%	2.6%
4,000 to 9,999 treatments	3,375	11.3	0.0%	-0.2%	-0.1%	2.7%
10,000 or more treatments	3,163	22.5	0.0%	0.1%	0.1%	3.2%
Unknown	34	0.0	0.1%	0.2%	0.5%	3.7%
Percentage of Pediatric Patients						
Less than 2%	7,766	35.3	0.0%	0.0%	0.0%	3.1%
Between 2% and 19%	48	0.2	0.1%	-0.2%	-0.2%	2.7%
Between 20% and 49%	12	0.0	0.0%	-0.3%	-0.4%	2.3%
More than 50%	56	0.0	0.1%	0.0%	-0.2%	2.8%

[1] CY 2022 TPNIES for the Tablo® System and TDAPA for KORSUVA™ will continue in CY 2023 under the ESRD PPS. We estimate approximately $4.8 million in TPNIES and TDAPA spending, of which, approximately $958,000 would be attributed to beneficiary coinsurance amounts.

[2] This column includes the impact of the updates in columns (C) through (E) in Table 31, and of the ESRD market basket increase factor for CY 2023 (3.1 percent), reduced by 0.1 percentage point for the productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the changes to the outlier payment policy described in section II.B.1.c of this final rule is shown in column C. For CY 2023, the impact on all ESRD facilities as a result of the changes to the outlier payment policy will be a 0.0 percent increase in estimated payments. All ESRD facilities are anticipated to experience a positive effect in their estimated CY 2023 payments as a result of the outlier policy changes.

Column D shows the effect of the update to the LRS for CY 2023 of 55.2 percent. This update is implemented in a budget neutral manner, so the total impact of this change is 0.0 percent; however, there are distributional effects of the change among different categories of ESRD facilities. Facilities located in rural areas are estimated to experience a 0.6 percent decrease in payments, and those located in urban areas are estimated to experience a 0.1 percent increase in payments.

Column E shows the effect of the updates to the wage index, as described in section II.B.1.b of this final rule. That is, this column reflects the update from the CY 2022 ESRD PPS wage index continuing to use the 2018 OMB delineations as finalized in the CY 2021 ESRD PPS final rule, with a basis of the FY 2023 pre-floor, pre-reclassified IPPS hospital wage index data in a budget neutral manner. This column also includes the increase of the wage index floor to 0.6000 and the permanent 5-percent cap on wage index decreases. The total impact of this change is 0.0 percent; however, there are distributional effects of the change among different categories of ESRD facilities. The largest estimated increase will be 7.1 percent for facilities located in Puerto Rico and the Virgin Islands, and the largest estimated decrease will be 0.6 percent for facilities in New England.

Column F reflects the overall impact, that is, the effects of the outlier policy changes, the updated wage index, and the payment rate update as described in section II.B.1.d of this final rule. The ESRD PPS payment rate update is 3.0 percent, which reflects the ESRDB market basket percentage increase factor for CY 2023 of 3.1 percent and the productivity adjustment of 0.1 percent. We expect that overall ESRD facilities will experience a 3.1 percent increase in estimated payments in CY 2023. The categories of types of facilities in the impact table show impacts ranging from a 2.0 percent increase to an 8.2 percent increase in their CY 2023 estimated payments.

(2) Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2023, we estimate that the ESRD PPS will have zero impact on these other providers.

(3) Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2023 will be approximately $ 7.9 billion. This estimate considers a projected decrease in fee-for-service Medicare ESRD beneficiary enrollment of 3.5 percent in CY 2023.

(4) Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 3.1 percent overall increase in the CY 2023 ESRD PPS payment amounts, we estimate that there will be an increase in beneficiary co-insurance payments of 3.1 percent in CY 2023, which translates to approximately $60 million.

(5) Alternatives Considered

(i) CY 2023 Impacts: 2019–2020 Versus 2021 Claims Data

Each year CMS uses the latest available ESRD claims to update the outlier threshold, budget neutrality factor, and payment rates. Due to the COVID–19 PHE, we compared the impact of using CY 2019 or CY 2020 claims against CY 2021 claims to determine if there was any substantial difference in the results that would justify potentially deviating from our longstanding policy to use the latest available data. Analysis suggested that ESRD utilization did not change substantially during the pandemic, likely due to the patients' vulnerability and need for these services. Consequently, we finalized our proposal to use the CY 2021 data because it does not negatively impact ESRD facilities and keeps with our longstanding policy to make updates using the latest available ESRD claims data.

(ii) Outlier Methodology Alternatives

As discussed in section II.B.1.c.(4) of this final rule, we are finalizing a change to the methodology used to determine the outlier FDL amounts for adult beneficiaries. We also considered but did not propose maintaining the current outlier methodology or decreasing the 1.0 percent outlier target. In addition, we considered but did not propose a reconciliation process for the outlier methodology.

b. Continuation of Approved Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) and Transitional Drug Add-On Payment Adjustments (TDAPA) for New Renal Dialysis Drugs or Biological Products for CY 2023

(1) Tablo® System

One product, the Tablo® System, that was approved for the TPNIES in CY 2022 will continue to be eligible for the TPNIES in CY 2023. In this final rule we are continuing our CY 2022 estimates into CY 2023. We estimate $2.5 million in spending of which, approximately $490,000 would be attributed to beneficiary coinsurance amounts.

(2) KORSUVA™ (difelikefalin)

One renal dialysis drug for which the TDAPA was paid in CY 2022 will continue to be eligible for the TDAPA in CY 2023. CMS Transmittal 11295,[395] implemented the 2-year TDAPA period specified in § 413.234(c)(1) for KORSUVA™ (difelikefalin). The TDAPA payment period began on April 1, 2022 and will continue in CY 2023. As set forth in § 413.234(c), TDAPA payment is based on 100 percent of average sales price (ASP). If ASP is not available, then the TDAPA is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

We based the CY 2023 impacts on the most current 72x claims data; from April 1, 2022 through July 31, 2022. The average number of beneficiaries per month, receiving KORSUVA™ during this timeframe is 50. However, we anticipate that this number will double in CY 2023 as more ESRD facilities incorporate KORSUVA™ into their business operations. If the estimated 100 beneficiaries were to receive thirteen doses per month (100 * 13 = 1,300) for 12 months, the estimated number of doses would be 15,600 (1,300 * 12 = 15,600) in CY 2023. Although dosing varies by patient weight, we have based our estimates on a single dose vial. Current KORSUVA™ pricing is estimated at $150.00 per single dose vial.[396] Multiplying the 15,600 estimated doses by the current pricing of $150 per single dose vial would result in approximately $2,340,000 in spending (15,600 * $150.00 = 2,340,000), of which, approximately $468,000 ($2,340,000 * 0.20 = $468,000) would be attributed to beneficiary coinsurance amounts.

c. Payment for Renal Dialysis Services Furnished to Individuals With AKI

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated payments in CY 2022 to estimated payments in CY 2023. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the estimates of payments in CY 2022 and CY 2023 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this final rule, we used CY 2021 data from the Part A and Part B Common Working Files as of July 30, 2022, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2021 claims to 2022 and 2023 using various updates. The updates to the AKI payment amount are described in section III.B of this final rule. Table 32 shows the impact of the estimated CY 2023 payments for renal dialysis services furnished to individuals with AKI compared to estimated payments for renal dialysis services furnished to individuals with AKI in CY 2022.

[395] CMS Transmittal 11295 rescinded and replaced CMS Transmittal 11278, dated February 24, 2022 and is available at: *https://www.cms.gov/files/document/r11295CP.pdf*

[396] CMS ESRD PPS Transitional Drug Add-on Payment Adjustment web page. Payment Amounts for New Renal Dialysis Drugs and Biological Products Currently Eligible for the TDAPA. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/Drugs-and-Biologicals-Eligible-for-TDAPA.pdf*. Accessed on September 12, 2022.

TABLE 32: Impacts of the Changes in Payments for Renal Dialysis Services Furnished to Individuals with AKI for CY 2023

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Change to LRS (C)	Wage Index Changes (D)	Total Percent Change[1] (E)
All Facilities	5,347	307.4	0.0%	0.0%	2.9%
Type					
Freestanding	5,222	301.9	0.0%	0.0%	2.9%
Hospital based	125	5.6	-0.3%	0.1%	2.8%
Ownership Type					
Large dialysis organization	4,440	257.7	0.0%	0.0%	2.9%
Regional chain	583	32.1	0.1%	0.0%	3.0%
Independent	193	12.0	0.2%	-0.2%	3.0%
Hospital based[2]	125	5.6	-0.3%	0.1%	2.8%
Unknown	6	0.1	0.4%	0.1%	3.5%
Geographic Location					
Rural	910	50.1	-0.6%	-0.1%	2.3%
Urban	4,437	257.4	0.1%	0.0%	3.1%
Census Region					
East North Central	887	54.1	-0.2%	-0.4%	2.4%
East South Central	415	22.9	-0.7%	-0.3%	2.0%
Middle Atlantic	562	33.0	0.2%	0.0%	3.3%
Mountain	306	18.8	0.0%	0.0%	3.1%
New England	139	7.4	0.2%	-0.5%	2.7%
Pacific[3]	678	47.4	0.8%	0.6%	4.5%
Puerto Rico and Virgin Islands	1	0.0	-1.9%	7.6%	8.6%
South Atlantic	1,296	73.5	-0.3%	-0.3%	2.4%
West North Central	343	15.4	-0.3%	-0.2%	2.5%
West South Central	720	34.9	-0.4%	0.2%	2.8%
Facility Size					
Less than 4,000 treatments	598	23.4	-0.2%	-0.1%	2.8%
4,000 to 9,999 treatments	2,336	121.1	-0.2%	-0.2%	2.6%
10,000 or more treatments	2,407	162.6	0.1%	0.1%	3.2%
Unknown	6	0.3	0.0%	-0.4%	2.5%
Percentage of Pediatric Patients					

Less than 2%	5,332	307.1	0.0%	0.0%	2.9%
Between 2% and 19%	14	0.3	-0.3%	-0.1%	2.6%
Between 20% and 49%	0	0.0	0.0%	0.0%	0.0%
More than 50%	1	0.0	0.1%	0.4%	3.5%

[1] This column includes the impact of the updates in columns (C) and (D) in Table 32, and of the ESRD market basket increase factor for CY 2023 (3.1 percent), reduced by 0.1 percentage point for the productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

[2] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of AKI dialysis treatments (in thousands). Column C shows the effect of the update to the LRS for CY 2023 of 55.2 percent. Column D shows the effect of the CY 2023 wage indices, including the increase to the wage index floor and the 5-percent cap on wage index decreases.

Column E shows the overall impact, that is, the effects of the LRS, wage index updates, and the payment rate update of 3.0 percent, which reflects the ESRDB market basket percentage increase factor for CY 2023 of 3.1 percent and the productivity adjustment of 0.1 percent. We expect that overall ESRD facilities will experience a 2.9 percent increase in estimated payments in CY 2023. The categories of types of facilities in the impact table show impacts ranging from an increase of 2.0 percent to 8.6 percent in their CY 2023 estimated payments.

(2) Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we proposed to update the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The patient and his or her physician make the decision about where the renal dialysis services are furnished. Therefore, this change will have zero impact on other Medicare providers.

(3) Effects on the Medicare Program

We estimate approximately $80 million will be paid to ESRD facilities in CY 2023 as a result of patients with AKI receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

(4) Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent co-insurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients will continue to be responsible for a 20 percent coinsurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

(5) Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients and as such, including those policies and adjustment is inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring will assist us in developing knowledgeable, data-driven proposals.

d. ESRD QIP

(1) Effects of the PY 2023 and PY 2024 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to prevent reductions in the quality of ESRD facility services provided to beneficiaries. The general methodology that we use to determine a facility's TPS is described in our regulations at 42 CFR 413.178(e).

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2023 and PY 2024 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2023 and CY 2024, respectively, as codified in our regulations at 42 CFR 413.177.

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2025 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2025, as codified in our regulations at 42 CFR 413.177.

For the PY 2023 ESRD QIP, we estimate that, of the 7,847 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 10.1 percent or 795 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2023. Among an estimated 795 facilities that would receive a payment reduction, approximately 62 percent or 492 facilities would receive the smallest payment reduction of 0.5 percent. We are presenting an estimate for the PY 2023 ESRD QIP to update the estimated impact that was provided in the CY 2021 ESRD PPS final rule (85 FR 71479 through 71481). Based on our final policies, the total estimated payment reductions for all the 795 facilities expected to receive a payment reduction in PY 2023 would be approximately $5,548,652.69. Facilities that do not receive a TPS do not receive a payment reduction.

Table 33 shows the overall estimated distribution of payment reductions resulting from the PY 2023 ESRD QIP.

TABLE 33: Estimated Distribution of PY 2023 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	6727	89.43%
0.5%	492	6.54%
1.0%	127	1.69%
1.5%	82	1.09%
2.0%	94	1.25%

*325 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2023, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims, excluding the measures that we are suppressing for PY 2023 as discussed in section IV.B.2 of this final rule. Payment reduction estimates are calculated using the most recent data available (specified in Table 34) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 34.

For all measures except the seven measures we are suppressing in IV.B.2 of this final rule, as well as the STrR measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For the STrR reporting measure, facilities were required to have at least 10 patient-years at risk to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that were consistent with the final policies outlined in sections IV.B and IV.C of this final rule. Facility reporting measure scores were estimated using available data from CY 2021 for MedRec, UFR, Clinical Depression, Hypercalcemia, and NHSN Dialysis Event. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2023 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2021 and December 2021 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

TABLE 34: Data Used to Estimate PY 2023 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey*	N/A	N/A
SRR*	N/A	N/A
SHR*	N/A	N/A
PPPW*	N/A	N/A
Kt/V Dialysis Adequacy Comprehensive*	N/A	N/A
VAT		
Standardized Fistula Rate*	N/A	N/A
% Catheter*	N/A	N/A
Hypercalcemia	Jan 2019-Dec 2019	Jan 2021-Dec 2021
NHSN BSI	Jan 2019-Dec 2019	Jan 2021-Dec 2021

*Note: We are finalizing our proposals to suppress the ICH CAHPS measure, the SRR clinical measure, the SHR clinical measure, the PPPW clinical measure, the Kt/V Dialysis Adequacy Comprehensive measure, and the Long-Term Catheter Rate measure for PY 2023, as well as to suppress the Standardized Fistula Rate measure for PY 2023, as discussed in section IV.B.2 of this final rule.

(2) Effects of the PY 2025 ESRD QIP on ESRD Facilities

For the PY 2025 ESRD QIP, we estimate that, of the 7,847 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 47.87 percent or 3,592 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2025. Among an estimated 3,592 facilities that would receive a payment reduction, approximately 55 percent or 1,983 facilities would receive the smallest payment reduction of 0.5 percent. We are presenting an estimate for the PY 2025 ESRD QIP to update the estimated impact that was provided in the CY 2022 ESRD PPS final rule (86 FR 62008 through 62011). Based on our final policies, the total estimated payment reductions for all the 3,592 facilities expected to receive a payment reduction in PY 2025 would be approximately $32,457,692.52. Facilities that do not receive a TPS do not receive a payment reduction.

Table 35 shows the overall estimated distribution of payment reductions resulting from the PY 2025 ESRD QIP.

TABLE 35: Estimated Distribution of PY 2025 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	3,912	52.13%
0.5%	1,983	26.43%
1.0%	1,190	15.86%
1.5%	369	4.92%
2.0%	50	0.67%

*343 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2025, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims. Payment reduction estimates are calculated using the most recent data available (specified in Table 36) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 36.

TABLE 36: Data Used to Estimate PY 2025 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SRR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SHR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
PPPW*	N/A	Jan 2019-Dec 2019
Kt/V Dialysis Adequacy Comprehensive	Jan 2018-Dec 2018	Jan 2019-Dec 2019
VAT		
Standardized Fistula Ratio	Jan 2018-Dec 2018	Jan 2019-Dec 2019
% Catheter	Jan 2018-Dec 2018	Jan 2019-Dec 2019
STrR	Jan 2019-Dec 2019	Jan 2021-Dec 2021
NHSN BSI	Jan 2019-Dec 2019	Jan 2021-Dec 2021

*Note: PPPW score is based on achievement score only.

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included in the facility's TPS. For the STrR reporting measure, which we are converting to a clinical measure beginning in PY 2025 in section IV.E.1.b of this final rule, facilities were required to have at least 10 patient-years at risk to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that were consistent with the final policies

outlined in section IV.E of this final rule. Facility reporting measure scores were estimated using available data from CY 2021 for MedRec, UFR, Clinical Depression, Hypercalcemia, and NHSN Dialysis Event. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2025 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2021 and December 2021 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 37 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2025. The table also details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2025 ESRD QIP, the actual impact of the PY 2025 ESRD QIP may vary significantly from the values provided here.

(3) Effects of the PY 2026 ESRD QIP on ESRD Facilities

For the PY 2026 ESRD QIP, we estimate that, of the 7,847 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 47.87 percent or 3,592 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2026. Among an estimated 3,592 facilities that would receive a payment reduction, approximately 55 percent or 1,983 facilities would receive the smallest payment reduction of 0.5 percent. The total payment reductions for all the 3,592 facilities expected to receive a payment reduction is approximately $32,457,692.52. Facilities that do not receive a TPS do not receive a payment reduction.

TABLE 37: Estimated Impact of QIP Payment Reductions to ESRD Facilities for PY 2025

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,847	35.0	7,504	3,592	-0.37%
Facility Type:					
Freestanding	7,471	33.7	7,168	3,405	-0.37%
Hospital-based	376	1.4	336	187	-0.49%
Ownership Type:					
Large Dialysis	5,964	27.1	5,843	2,631	-0.33%
Regional Chain	904	4.3	881	471	-0.45%
Independent	466	2.1	437	301	-0.68%
Hospital-based (non-chain)	376	1.4	336	187	-0.49%
Unknown	137	0.1	7	2	-0.21%
Facility Size:					
Large Entities	6,868	31.4	6,724	3,102	-0.35%
Small Entities[1]	842	3.5	773	488	-0.60%
Unknown	137	0.1	7	2	-0.21%
Rural Status:					
1) Yes	1,281	5.0	1,232	502	-0.30%
2) No	6,566	30.0	6,272	3,090	-0.39%
Census Region:					
Northeast	1,087	5.5	1,041	518	-0.39%
Midwest	1,736	6.6	1,657	819	-0.39%
South	3,570	15.2	3,404	1,743	-0.41%
West	1,393	7.4	1,342	466	-0.24%
US Territories[2]	61	0.3	60	46	-0.64%
Census Division:					
Unknown	9	0.1	9	4	-0.33%
East North Central	1,222	4.7	1,180	621	-0.43%
East South Central	618	2.4	594	294	-0.38%
Middle Atlantic	886	4.3	842	443	-0.41%
Mountain	436	1.9	420	137	-0.23%
New England	201	1.2	199	75	-0.29%
Pacific	957	5.5	922	329	-0.24%
South Atlantic	1,827	8.0	1,741	914	-0.43%
West North Central	514	1.9	477	198	-0.29%
West South Central	1,125	4.8	1,069	535	-0.39%
US Territories[2]	52	0.1	51	42	-0.69%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,229	1.9	1,084	318	-0.24%
4,000-9,999 treatments	3,095	10.1	3,058	1,320	-0.33%
Over 10,000 treatments	3,358	22.9	3,354	1,949	-0.45%
Unknown	165	0.2	8	5	-0.50%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.

[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

Table 38 shows the overall estimated distribution of payment reductions resulting from the PY 2026 ESRD QIP.

To estimate whether a facility would receive a payment reduction in PY 2026, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 39) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 39.

TABLE 38: Estimated Distribution of PY 2026 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	3,912	52.13%
0.5%	1,983	26.43%
1.0%	1,190	15.86%
1.5%	369	4.92%
2.0%	50	0.67%

*Note: 343 facilities not scored due to insufficient data

TABLE 39: Data Used to Estimate PY 2026 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance Period
ICH CAHPS Survey	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SRR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SHR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
PPPW*	N/A	Jan 2019-Dec 2019
Kt/V Dialysis Adequacy Comprehensive	Jan 2018-Dec 2018	Jan 2019-Dec 2019
VAT		
Standardized Fistula Ratio	Jan 2018-Dec 2018	Jan 2019-Dec 2019
% Catheter	Jan 2018-Dec 2018	Jan 2019-Dec 2019
STrR	Jan 2019-Dec 2019	Jan 2021-Dec 2021
NHSN BSI	Jan 2019-Dec 2019	Jan 2021-Dec 2021

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For SHR and SRR, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included in the facility's TPS. For the STrR reporting measure, which we are converting to a clinical measure beginning in PY 2025 in section IV.E.1.b of this final rule, facilities were required to have at least 10 patient-years at risk to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that incorporates the policies outlined in section IV.F of this final rule. Facility reporting measure scores were estimated using available data from CY 2021 for MedRec, UFR, Clinical Depression, Hypercalcemia, and NHSN Dialysis Event. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2026 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2021 and December 2021 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 40 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2026. The table details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2026 ESRD QIP, the actual impact of the PY 2026 ESRD QIP may vary significantly from the values provided here.

TABLE 40: Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2026

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,847	35.0	7,504	3,592	-0.37%
Facility Type:					
Freestanding	7,471	33.7	7,168	3,405	-0.37%
Hospital-based	376	1.4	336	187	-0.49%
Ownership Type:					
Large Dialysis	5,964	27.1	5,843	2,631	-0.33%
Regional Chain	904	4.3	881	471	-0.45%
Independent	466	2.1	437	301	-0.68%
Hospital-based (non-chain)	376	1.4	336	187	-0.49%
Unknown	137	0.1	7	2	-0.21%
Facility Size:					
Large Entities	6,868	31.4	6,724	3,102	-0.35%
Small Entities[1]	842	3.5	773	488	-0.60%
Unknown	137	0.1	7	2	-0.21%
Rural Status:					
1) Yes	1,281	5.0	1,232	502	-0.30%
2) No	6,566	30.0	6,272	3,090	-0.39%
Census Region:					
Northeast	1,087	5.5	1,041	518	-0.39%
Midwest	1,736	6.6	1,657	819	-0.39%
South	3,570	15.2	3,404	1,743	-0.41%
West	1,393	7.4	1,342	466	-0.24%
US Territories[2]	61	0.3	60	46	-0.64%
Census Division:					
Unknown	9	0.1	9	4	-0.33%
East North Central	1,222	4.7	1,180	621	-0.43%
East South Central	618	2.4	594	294	-0.38%
Middle Atlantic	886	4.3	842	443	-0.41%
Mountain	436	1.9	420	137	-0.23%
New England	201	1.2	199	75	-0.29%
Pacific	957	5.5	922	329	-0.24%
South Atlantic	1,827	8.0	1,741	914	-0.43%
West North Central	514	1.9	477	198	-0.29%
West South Central	1,125	4.8	1,069	535	-0.39%
US Territories[2]	52	0.1	51	42	-0.69%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,229	1.9	1,084	318	-0.24%
4,000-9,999 treatments	3,095	10.1	3,058	1,320	-0.33%
Over 10,000 treatments	3,358	22.9	3,354	1,949	-0.45%
Unknown	165	0.2	8	5	-0.50%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.

[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

(4) Effects on Other Providers

The ESRD QIP is applicable to ESRD facilities. We are aware that several of our measures impact other providers. For example, with the introduction of the SRR clinical measure in PY 2017 and the SHR clinical measure in PY 2020, we anticipate that hospitals may experience financial savings as facilities work to reduce the number of unplanned readmissions and hospitalizations. We are exploring various methods to assess the impact these measures have on hospitals and other facilities, such as through the impacts of the Hospital Readmissions Reduction Program and the Hospital-Acquired Condition Reduction Program, and we intend to continue examining the interactions between our quality programs to the greatest extent feasible.

(5) Effects on the Medicare Program

For PY 2026, we estimate that the ESRD QIP would contribute approximately $32,457,692.52 in Medicare savings. For comparison, Table 41 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2026.

TABLE 41: Estimated ESRD QIP Aggregate Payment Reductions for Payment Years 2018 through 2026

Payment Year	Estimated Payment Reductions
PY 2026	$32,457,692.52
PY 2025	$32,457,692.52
PY 2024	$17,104,030.59 (86 FR 62011)
PY 2023	$5,548,652.69
PY 2022	$0[397] (86 FR 62011)
PY 2021	$32,196,724 (83 FR 57062)
PY 2020	$31,581,441 (81 FR 77960)
PY 2019	$15,470,309 (80 FR 69074)
PY 2018	$11,576,214 (79 FR 66257)

(6) Effects on Medicare Beneficiaries

The ESRD QIP is applicable to ESRD facilities. Since the Program's inception, there is evidence on improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. We are in the process of monitoring and evaluating trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We would provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more. However, in future years we are interested in examining these impacts through the analysis of available data from our existing measures.

(7) Alternatives Considered

In section IV.B.2 of this final rule, we are finalizing the suppression of seven measures for PY 2023 due to the impacts of the COVID–19 PHE on CY 2021 data. We considered not suppressing these seven measures for PY 2023. However, we concluded that measure suppression was appropriate under our previously finalized measure suppression policy due to the impact of the COVID–19 PHE on these PY 2023 ESRD QIP measures. This approach would help to ensure that a facility would not be penalized for performance on measures which have been impacted by extraordinary circumstances beyond the facility's control.

e. ETC Model

(1) Overview

The ETC Model is a mandatory payment model designed to test payment adjustments to certain dialysis and dialysis-related payments, as discussed in the Specialty Care Models final rule (85 FR 61114) and the CY 2022 ESRD PPS final rule (86 FR 61874), for ESRD facilities and for Managing Clinicians for claims with dates of service from January 1, 2021 to June 30, 2027. The requirements for the ETC Model are set forth in 42 CFR part 512, subpart C.

The changes in this final rule (discussed in detail in section V.B of this final rule) will impact model payment adjustments for PPA Period 5, starting July 1, 2024. The change that is most likely to affect the impact estimate for the ETC Model is the additional parameter to the PPA achievement scoring methodology such that an ETC Participant's aggregation group must have a positive home dialysis rate or transplant rate to receive an achievement score for that rate, as described in section V.B.1 of this final rule. We do not anticipate that the policy to clarify the requirements for qualified staff to furnish and bill kidney disease patient education services under the ETC Model's Medicare program waivers or the policy to post certain model data, described in section V.B.2 of this final rule, will affect the impact estimate for the ETC Model.

The ETC Model is not a total cost of care model. ETC Participants will still bill FFS Medicare, and items and services not subject to the ETC Model's payment adjustments will continue to be paid as they would in the absence of the ETC Model.

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of the changes to the ETC Model relative to baseline expenditures, where baseline expenditures were defined as data from CYs 2018 and 2019 without the changes applied. The simulation relied upon statistical assumptions derived from retrospectively constructed ESRD facilities' and Managing Clinicians' Medicare dialysis claims, transplant claims, and transplant waitlist data reported during 2018 and 2019, the most recent years of complete data available before the start of the ETC Model. Both datasets and the risk-adjustment methodologies for the ETC Model were developed by the CMS Office of the Actuary (OACT).

For the modeling exercise used to estimate changes in payment to providers and suppliers and the resulting savings to Medicare, OACT maintained the previous method to simulate identification of ETC Participants (including aggregation group construction), beneficiary attribution (and exclusions), calculation of home dialysis rates and transplant rates, calculation of achievement benchmarks, and calculation of improvement scores. For a detailed description of this methodology, see the detailed economic analysis included in the CY 2022 ESRD PPS final rule (86 FR 62012 through 62014).

Beginning for MY5 and beyond, the PPA achievement scoring methodology included one modification. Specifically, achievement scores were only awarded for the home dialysis rate or the transplant rate to ETC Participants in aggregation groups with a home dialysis rate or transplant rate greater than zero, respectively, in accordance with the change described in section V.B.1 of this final rule. To clarify, no changes to the achievement scoring methodology were

made to MY1 through MY4. For a detailed description of the methodology for simulating achievement scoring methodology, see the CY 2022 ESRD PPS final rule (86 FR 60213 through 60214).

No changes were made to the payment structure for the HDPA calculation, as no changes were proposed. Similarly, no changes were made to the kidney disease patient education services utilization and cost calculations, as the change does not impact expected utilization. For a detailed description of this methodology, see the detailed economic analysis included in the CY 2022 ESRD PPS final rule (86 FR 62014).

(3) Medicare Estimate—Primary Specification, Assume Achievement Scoring Update

TABLE 42: Estimates of Medicare Program Savings (Rounded $M) for ESRD Treatment Choices (ETC) Model

	Year of Model							
	2021	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**6.5 Year Total***
Net Impact to Medicare Spending	15	9	-1	-9	-12	-19	-9	-28
Overall PPA Net & HDPA	14	7	-3	-11	-15	-22	-12	-43
Clinician PPA Downward Adjustment		-1	-2	-2	-3	-3	-2	-13
Clinician PPA Upward Adjustment		0	1	1	1	1	1	6
Clinician PPA Net		0	-1	-1	-2	-2	-1	-7
Clinician HDPA	0	0	0					0
Facility Downward Adjustment		-9	-20	-25	-31	-39	-21	-145
Facility Upward Adjustment		5	12	15	18	19	10	79
Facility PPA Net		-3	-8	-10	-14	-20	-11	-66
Facility HDPA	14	10	6					29
Total PPA Downward Adjustment		-9	-22	-27	-34	-43	-23	-158
Total PPA Upward Adjustment		6	13	16	19	21	11	84
Total PPA Net		-4	-9	-11	-15	-22	-12	-73
Total HDPA	14	10	6					30
Kidney Disease Patient Education Services Costs	0	1	1	1	1	1	1	5
HD Training Costs	1	1	1	1	2	2	2	10

*Totals may not sum due to rounding and from beneficiaries that have dialysis treatment spanning multiple years. Negative spending reflects a reduction in Medicare spending. The kidney disease patient education services benefit costs are less than $1M each year, but are rounded up to $1M to show what years they apply to. Similarly, the HD Training Costs are less than $1M for years 2021-2024, but are rounded up to $1M to indicate that costs were applied those years.

Table 42 summarizes the estimated impact of the ETC Model when the achievement benchmarks for each year are set using the average of the home dialysis rates for year *t*-1 and year *t*-2 for the HRRs randomly selected for participation in the ETC Model. We estimate that the Medicare program will save a net total of $43 million from the PPA and HDPA between January 1, 2021 and June 30, 2027 less $15 million in increased training and education expenditures. Therefore, the net impact to Medicare spending is estimated to be $28 million in savings. This is consistent with the net impact to Medicare spending estimated for the CY 2022 ESRD PPS final rule, in which the net impact to Medicare spending was also estimated to be $28 million in savings (86 FR 62014 through 62016).

In Table 42, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase. The results for this table were generated from an average of 400 simulations under the assumption that benchmarks are rolled forward with a 1.5-year lag. For a detailed description of the key assumptions underlying the impact estimate, see the CY 2022 ESRD PPS final rule (86 FR 60214 through 60216).

As was the case in the Specialty Care Models final rule (85 FR 61353) and the CY 2022 ESRD PPS final rule (86 FR 61874), the projections do not include the Part B premium revenue offset because the payment adjustments under the ETC Model will not affect Beneficiary cost-sharing. Any potential effects on Medicare Advantage capitation payments were also excluded

from the projections. This approach is consistent with how CMS has previously conveyed the primary FFS effects anticipated for an uncertain model without also assessing the potential impact on Medicare Advantage rates.

(4) Effects on the Home Dialysis Rate, the Transplant Rate, and Kidney Transplantation

The changes in this final rule will not impact the findings reported for the effects of the ETC Model on the home dialysis rate or the transplant rate described in the CY 2022 ESRD PPS final rule (86 FR 62017).

(5) Effects on Kidney Disease Patient Education Services and HD Training Add-Ons

The changes in this final rule will not impact the findings reported for the effects of the ETC Model on kidney disease patient education services and HD training add-ons described in the Specialty Care Models final rule (85 FR 61355) or the CY 2022 ESRD PPS final rule (85 FR 62017).

(6) Effects on Medicare Beneficiaries

The changes in this final rule will not impact the findings reported for the effects of ETC Model on Medicare beneficiaries regarding the ETC Model's likelihood of incentivizing ESRD facilities and Managing Clinicians to improve access to home dialysis and transplantation for Medicare beneficiaries.

As previously noted in the Specialty Care Models final rule (85 FR 61357) and the CY 2022 ESRD PPS final rule (86 FR 62017), we continue to anticipate that the ETC Model will have a negligible impact on the cost to beneficiaries receiving dialysis. Under current policy, Medicare FFS beneficiaries are generally responsible for 20 percent of the allowed charge for services furnished by providers and suppliers. This policy will remain the same for most beneficiaries under the ETC Model. However, we will waive certain requirements of title XVIII of the Act as necessary to test the PPA and HDPA under the ETC Model and hold beneficiaries harmless from any effect of these payment adjustments on cost sharing.

In addition, the Medicare Beneficiary's quality of life has the potential to improve if the Beneficiary elects to have home dialysis, or nocturnal in-center dialysis, as opposed to in-center dialysis. As discussed in the Specialty Care Models final rule, studies have found that home dialysis patients experienced improved quality of life as a result of their ability to continue regular work schedules or life plans; as well as better overall, physical, and psychological health in comparison to other dialysis options (85 FR 61264 through 61270).

(7) Alternatives Considered

Throughout this final rule, we have identified our policies and alternatives that we have considered, and provided information as to the likely effects of these alternatives and rationale for each of our policies

This final rule addresses a model specific to ESRD. It provides descriptions of the requirements that we will waive, identifies the performance metrics and payment adjustments to be tested, and presents rationales for our changes, and where relevant, alternatives considered. For context related to alternatives previously considered when establishing and modifying the ETC Model we refer readers to the Specialty Care Models final rule (85 FR 61114) and the CY 2022 ESRD PPS final rule (86 FR 61874), respectively, for more information on policy-related stakeholder comments, our responses to those comments, and statements of final policy preceding the limited modifications proposed here.

E. Accounting Statement

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*), we have prepared an accounting statement in Table 43 showing the classification of the impact associated with the provisions of this final rule.

TABLE 43: Accounting Statement: Classification of Estimated Transfers and Costs/Savings	
ESRD PPS and AKI (CY 2023)	
Category	**Transfers**
Annualized Monetized Transfers	$230 million
From Whom to Whom	Federal Government to ESRD providers
Category	**Transfers**
Increased Beneficiary Co-insurance Payments	$60 million
From Whom to Whom	Beneficiaries to ESRD providers
ESRD QIP for PY 2023	
Category	Transfers
Annualized Monetized Transfers	-$5.5 million
From Whom to Whom	Federal Government to ESRD providers.
ESRD QIP for PY 2025	
Category	Transfers
Annualized Monetized Transfers	-$32 million
From Whom to Whom	Federal Government to ESRD providers.
ESRD QIP for PY 2026	
Category	Transfers
Annualized Monetized Transfers	-$32 million
From Whom to Whom	Federal Government to ESRD providers
ETC Model for July 1, 2022 through June 30, 2027	
Category	**Transfers**
Annualized Monetized Transfers	$0.03 million
From Whom to Whom	Federal Government to ESRD facilities and Managing Clinicians

F. Regulatory Flexibility Act Analysis (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and states are not included in the definition of a small entity. Therefore, the number of small entities estimated in this RFA analysis includes the number of ESRD facilities that are either considered small businesses or nonprofit organizations.

According to the Small Business Administration's (SBA) size standards,[398] an ESRD facility is classified as a small business if it has total revenues of less than $41.5 million in any 1 year. For the purposes of this analysis, we exclude the ESRD facilities that are owned and operated by LDOs and regional chains, which will have total revenues of more than $9.5 billion in any year when the total revenues for all locations are combined for each business (LDO or regional chain), and are not, therefore, considered small businesses. Because we lack data on individual ESRD facilities' receipts, we cannot determine the number of small proprietary ESRD facilities or the proportion of ESRD facilities' revenue derived from Medicare payments. Therefore, we assume that all ESRD facilities that are not owned by LDOs or regional chains are considered small businesses. Accordingly, we consider the 474 facilities that are independent and 376 facilities that are hospital-based, as shown in the ownership category in Table 31 to be small businesses. These facilities represent approximately 11 percent of all ESRD facilities in our data set.

Additionally, we identified in our analytic file that there are 825 facilities that are considered nonprofit organizations, which is approximately 10 percent of all ESRD facilities in our data set. In total, accounting for the 382 nonprofit ESRD facilities that are also considered small businesses, there are 1,293 ESRD facilities that are either small businesses or nonprofit organizations, which is approximately 16 percent of all ESRD facilities in our data set.

For the ESRD PPS updates in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of ESRD facility) is estimated to receive a 3.1 percent increase in payments for CY 2023. An independent facility (as defined by ownership type) is likewise estimated to receive a 3.2 percent increase in payments for CY 2023. As shown in Table 31, we estimate that the overall revenue impact of this final rule on all ESRD facilities is a positive increase to Medicare payments by approximately 3.1 percent.

For AKI dialysis, we are unable to estimate whether patients will go to ESRD facilities, however, we have estimated there is a potential for $80 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the ESRD QIP, we estimate that of the 3,592 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2025 ESRD QIP, 488 are ESRD small entity

[398] More information available at *http://www.sba.gov/content/small-business-size-standards* (Kidney Dialysis Centers are listed as North American Industry Classification System (NAICS) code 621492 with a size standard of $41.5 million).

facilities. We present these findings in Table 35 (''Estimated Distribution of PY 2025 ESRD QIP Payment Reductions'') and Table 37 (''Estimated Impact of QIP Payment Reductions to ESRD Facilities for PY 2025'').

For the ETC Model, this final rule includes as ETC Participants Managing Clinicians and ESRD facilities required to participate in the Model, pursuant to § 512.325(a). We assume for the purposes of the regulatory impact analysis that the great majority of Managing Clinicians are small entities by meeting the SBA definition of a small business. The greater majority of ESRD facilities are not small entities, as they are owned, partially or entirely, by entities that do not meet the SBA definition of small entities. Under the ETC Model, the HDPA is a positive adjustment on payments for specified home dialysis and home dialysis-related services. The PPA, which includes both positive and negative adjustments on payments for dialysis and dialysis-related services, excludes aggregation groups with fewer than 132 attributed beneficiary-months during the relevant year. The aggregation methodology groups ESRD facilities owned in whole or in part by the same dialysis organization within a Selected Geographic Area and Managing Clinicians billing under the same Tax Identification Number (TIN) within a Selected Geographic Area. Taken together, the low volume threshold exclusions and aggregation policies, coupled with the fact that the ETC Model affects Medicare payment only for select services furnished to Medicare FFS beneficiaries; we have determined that the provisions of the final rule for the ETC Model will not have a significant impact on spending for a substantial number of small entities.

The HDPA is a positive adjustment on payments for specified home dialysis and home dialysis-related services. The PPA, which includes both positive and negative adjustments on payments for dialysis and dialysis-related services, excludes aggregation groups with fewer than 132 attributed beneficiary-months during the relevant year. The aggregation methodology groups ESRD facilities owned in whole or in part by the same dialysis organization within a Selected Geographic Area and Managing Clinicians billing under the same Tax Identification Number (TIN) within a Selected Geographic Area, which increases the statistical liability of the home dialysis rate and the transplant rate for ETC Participants in the aggregation group. Taken together, the low volume threshold exclusions and aggregation policies, coupled with the fact that the ETC Model affects Medicare payment only for select services furnished to Medicare FFS beneficiaries; we have determined that the provisions of the final rule will not have a significant impact on spending for a substantial number of small entities.

The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. As a result, since the overall estimated impact of these updates is a net increase of greater than 3 percent in revenue across almost all categories of ESRD facility, the Secretary has determined that this final rule will have a significant positive revenue impact on a substantial number of ESRD facilities identified as small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this final rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 121 rural hospital-based ESRD facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 121 rural hospital-based ESRD facilities will experience an estimated 2.2 percent increase in payments. Therefore, the Secretary has certified that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act Analysis (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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 is approximately $165 million. This final rule does not mandate any requirements for State, local, or tribal governments, in the aggregate, or by the private sector of more than $165 million in any 1 year. Moreover, HHS interprets UMRA as applying only to unfunded mandates. We do not interpret Medicare payment rules as being unfunded mandates, but simply as conditions for the receipt of payments from the Federal Government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, State, local, or tribal.

H. Federalism

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. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of States, local or Tribal governments.

I. Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

VIII. Files Available to the Public via the Internet

The Addenda for the annual ESRD PPS proposed and final rule will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet and will be posted on the CMS website under the regulation number, CMS–1768–F at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices*. In addition to the Addenda, limited data set files are available for purchase at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile*. Readers who experience any problems accessing the Addenda or LDS files, should contact CMS by sending an email to CMS at the following mailbox: *ESRDPayment@cms.hhs.gov*.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 25, 2022.

List of Subjects

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

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

■ 1. 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.

■ 2. Effective January 1, 2023, § 413.178 is amended by revising paragraphs (a)(8) and (d)(2), and adding paragraph (i) to read as follows:

§ 413.178 ESRD quality incentive program.

(a) * * *

(8) Minimum total performance score (mTPS) means, with respect to a payment year except payment year 2023, the total performance score that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national ESRD facility performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.

* * * * *

(d) * * *

(2) For purposes of paragraph (d)(1) of this section, the baseline period that applies to each of payment year 2023 and payment year 2024 is calendar year 2019 for purposes of calculating the achievement threshold, benchmark and minimum total performance score, and calendar year 2019 for purposes of calculating the improvement threshold. The baseline period that applies to payment year 2025 is calendar year 2021 for purposes of calculating the achievement threshold, benchmark and minimum total performance score, and calendar year 2022 for purposes of calculating the improvement threshold, and the performance period that applies to payment year 2025 is calendar year 2023. Beginning with payment year 2026, the performance period and corresponding baseline periods are each advanced 1 year for each successive payment year.

* * * * *

(i) *Special rules for payment year 2023.* (1) CMS will calculate a measure rate for, but will not score facility performance on or include in the TPS for any facility under paragraph (e) of this section, the following measures: Standardized Hospitalization Ratio (SHR) clinical measure, Standardized Readmission Ratio (SRR) clinical measure, Long-Term Catheter Rate clinical measure, Standardized Fistula Rate clinical measure, ICH CAHPS clinical measure, Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure, and Kt/V Dialysis Adequacy clinical measure.

(2) The mTPS for payment year 2023 is the total performance score that an ESRD facility would receive if, during the calendar year 2019 baseline period, it performed at the 50th percentile of national ESRD facility performance on Hypercalcemia clinical measure, NHSN Blood Stream Infection (BSI) clinical measure, and the median of national ESRD facility performance on Clinical Depression Screening and Follow-Up reporting measure, Standardized Transfusion Ratio (STrR) reporting measure, Ultrafiltration Rate reporting measure, NHSN Dialysis Event reporting measure, and Medication Reconciliation (MedRec) reporting measure.

■ 3. Effective January 1, 2023, § 413.231 is amended by adding paragraphs (c) and (d) to read as follows:

§ 413.231 Adjustment for wages.

* * * * *

(c) Beginning January 1, 2023, CMS applies a cap on decreases to the wage index, such that the wage index applied to an ESRD facility is not less than 95 percent of the wage index applied to that ESRD facility in the prior calendar year.

(d) Beginning January 1, 2023, CMS applies a floor of 0.6000 to the wage index, such that the wage index applied to an ESRD facility is not less than 0.6000.

§ 413.234 [Amended]

■ 4. Effective January 1, 2025, § 413.234, amend paragraph (a) (effective January 1, 2025) by adding the word ''functional'' before the word ''equivalent'' in the definition of ''Oral-only drug''.

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 5. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 6. Effective January 1, 2023, § 512.370 is amended by revising paragraph (b) introductory text and adding paragraph (b)(3) to read as follows:

§ 512.370 Benchmarking and scoring.

* * * * *

(b) *Achievement Scoring.* CMS assesses ETC Participant performance at the aggregation group level on the home dialysis rate and transplant rate against achievement benchmarks constructed based on the home dialysis rate and transplant rate among aggregation groups of ESRD facilities and Managing Clinicians located in Comparison Geographic Areas during the Benchmark Year. Achievement benchmarks are calculated as described in paragraph (b)(1) of this section and, for MY3 through MY10, are stratified as described in paragraph (b)(2) of this section. For MY5 through MY10, the ETC Participant's achievement score is subject to the restriction described in paragraph (b)(3) of this section.

* * * * *

(3) For MY5 through MY10, CMS will assign an achievement score to an ETC Participant for the home dialysis rate or the transplant rate only if the ETC Participant's aggregation group has a home dialysis rate or a transplant rate greater than zero for the MY.

* * * * *

■ 7. Effective January 1, 2023, §512.397 is amended by revising paragraph (b)(1) to read as follows:

§ 512.397 ETC Model Medicare program waivers and additional flexibilities.

* * * * *

(b) * * *

(1) CMS waives the requirement under section 1861(ggg)(2)(A)(i) of the Act and § 410.48(a) of this chapter that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish kidney disease patient education services to allow kidney disease patient education services to be provided by clinical staff (as defined at § 512.310) under the direction of and incident to the services of the Managing Clinician who is an ETC Participant. The kidney disease patient education services may be furnished only by qualified staff (as defined at § 512.310). Beginning MY5,

only clinical staff that are not leased from or otherwise provided by an ESRD facility or related entity may furnish kidney disease patient education services pursuant to the waiver described in this section.

* * * * *

Dated: *October 27, 2022.*

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–23778 Filed 10–31–22; 4:15 pm]

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Part III

Department of the Interior

Bureau of Land Management

43 CFR Parts 2800, 2860, 2880, and 2920
Update of the Communications Uses Program, Cost Recovery Fee Schedules, and Section 512 of FLPMA for Rights-of-Way; Proposed Rule

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Parts 2800, 2860, 2880, and 2920

[LLHQ350000.L51020000.ER0000, 22X]

RIN 1004–AE60

Update of the Communications Uses Program, Cost Recovery Fee Schedules, and Section 512 of FLPMA for Rights-of-Way

AGENCY: Bureau of Land Management, Interior.

ACTION: Proposed rule.

SUMMARY: The Bureau of Land Management (BLM) proposes to amend its existing regulations to enhance the communications uses program, update its cost recovery fee schedules, and add provisions governing the development and approval of operations, maintenance, and fire prevention plans and agreements for rights-of-way (ROWs) for electric transmission and distribution facilities (powerlines). Communication uses and powerlines are two of many ROW activities authorized under the Federal Land Policy and Management Act of 1976, as amended (FLPMA). Cost recovery fees apply to most ROW activities authorized under either Title V of FLPMA or the Mineral Leasing Act of 1920, as amended (MLA), as well as to land use authorizations under Title III of FLPMA.

DATES: Please submit comments on or before January 6, 2023. The BLM is not obligated to consider any comments received after this date in making its decision on the final rule.

Information Collection Requirements: This document includes proposed new information collection requirements that must be approved by the Office of Management and Budget (OMB). If you wish to comment on the new information collection requirements in this document, please note that such comments should be sent directly to the OMB, and that the OMB is required to make a decision concerning the collection of information contained in this proposed rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to the OMB on the proposed information collection revisions is best assured of being given full consideration if the OMB receives it by January 6, 2023.

ADDRESSES:

Mail, personal, or messenger delivery: U.S. Department of the Interior, Director (HQ–630), Bureau of Land Management, Room 5646, 1849 C St. NW, Washington, DC 20240, Attention: Regulatory Affairs: 1004–AE60.

Federal eRulemaking Portal: https://www.regulations.gov. In the Searchbox, enter ''RIN 1004–AE60'' and click the ''Search'' button. Follow the instructions at this website.

Information Collection Activities

Information Collection Requirements: Written comments and suggestions on the information collection requirements should be submitted by the date specified above in the **DATES** section to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. If you submit comments on the information collection burdens, you should provide the BLM with a copy at one of the addresses shown earlier in this section, so that we can summarize all written comments and address them in the final rulemaking. Please indicate ''Attention: OMB Control Number 1004–NEW (RIN 1004–AE60).'' Comments not pertaining to the proposed rule's information collection burdens should not be submitted to OMB. The BLM is not obligated to consider or include in the Administrative Record for the final rule any comments that are improperly directed to OMB.

FOR FURTHER INFORMATION CONTACT: Erica Pionke via email at *epionke@blm.gov* or via phone at (202) 570–2624; or Jennifer Noe via email at *jnoe@blm.gov* for information relating to the general rulemaking process. Individuals in the United States who are deaf, blind, 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.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

If you wish to comment on this proposed rule, you may submit your comments to the BLM, marked with the number RIN 1004–AE60, by mail, personal or messenger delivery, or through *https://www.regulations.gov* (see the **ADDRESSES** section). Please note that comments on this proposed rule's information collection burdens should be submitted to the OMB as described in the **ADDRESSES** section.

Please make your comments on the proposed rule as specific as possible, confine them to issues pertinent to the proposed rule, and explain the reason for any changes you recommend. Where possible, your comments should reference the specific section or paragraph of the proposal that you are addressing. The comments and recommendations that will be most useful and likely to influence agency decisions are:

1. Those supported by quantitative information or studies; and

2. Those that include citations to, and analyses of, the applicable laws and regulations.

The BLM is not obligated to consider or include in the Administrative Record for the final rule comments that we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

Comments, including names and street addresses of respondents, will be available for public review at the address listed under ''**ADDRESSES**: Mail, personal, or messenger delivery'' during regular business hours (7:45 a.m. to 4:15 p.m. EST), Monday through Friday, except holidays. Before including your address, telephone number, email address, or other personal identifying information in your comment, be advised 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 from public review your personal identifying information, we cannot guarantee that we will be able to do so.

II. Background

A. Introduction

The subject matter of this proposed rule pertains principally to the BLM's ROW program under 43 CFR parts 2800 and 2880, land use authorizations under part 2920, and newly proposed part 2860. Although the discussion in this preamble focuses on ROWs, and most revisions in the proposed rule relate to ROWs issued under parts 2800 and 2880, and proposed part 2860, similar revisions are being proposed that would apply to authorizations under part 2920.

In order for the reader to better understand the following discussion, as defined in 43 CFR 2801.5, a ''grant'' means any authorization or instrument (*e.g.,* easement, lease, license, or permit) BLM issues under Title V of FLPMA. A

''right-of-way'' means the public lands that the BLM authorizes a holder to use or occupy under a particular grant or lease.

In this rule, there are three distinct topics being considered. The first topic is communications uses. The second topic, cost recovery for the ROW program, addresses the reimbursement of costs, as authorized by FLPMA (43 U.S.C. 1701 *et seq.*) or the MLA (30 U.S.C. 185 *et seq.*), for the Federal Government's expenses in undertaking ROW work. The third topic pertains to a recent amendment to add a new Section 512 to Title V of FLPMA (43 U.S.C. 1772) and addresses the risk of fires from powerline ROWs on public lands. Each of these topics is discussed in this preamble; however, proposed changes in regulations pertaining to these topics are discussed in the section-by-section discussion in the order in which they are or would be found in the regulatory text. The proposed revisions should be considered separately. If a court holds any provision of one part of this proposed rule invalid, it should not affect the other parts of the proposed rule. Additionally, this proposed rule adds a severability clause to part 2860 for consistency with similar existing provisions in parts 2800 and 2880. The BLM is especially interested in receiving public comments and information discussing the BLM's proposed updates to its cost recovery fee categories for Federal ROW work activities, and whether the proposed regulations implementing the amendment to Title V of FLPMA effectively capture the statutory requirements.

Communications Uses

In the 21st century, broadband is just as vital as roads and bridges, electric lines, and sewer systems. At the community level, an advanced telecommunications network is critical for supporting growth, allowing small businesses to flourish, creating jobs, strengthening the first-responder network in remote areas, and making it possible for these areas to remain competitive in the information-age economy. At the individual level, access to broadband—and the expertise to use it—opens the door to employment opportunities, educational resources, health care information, government services, and social networks.

Although there have been great strides in expanding broadband services in the United States over the past several years, rural and Tribal areas lag behind in broadband deployment. Successive Presidential administrations and Congress have made it a priority to increase broadband deployment in underserved areas. As the land management agency with the responsibility to manage the largest inventory of public land within the Federal Government, the BLM proposes to amend regulatory provisions for the processing and monitoring of various ROWs, including those for communications uses. Currently, there are approximately 1,500 communications sites on BLM lands. By making it easier for industry to collocate in and on existing communications facilities or build out new communications infrastructure on public lands, the BLM can play a strong role in increasing connectivity throughout the United States. Communications uses, including fiber optic and telephone, may be collocated within the 6,000 miles of energy corridors administered by the BLM and the U.S. Forest Service (USFS).

While communications companies, cooperatives, and other private entities ultimately make decisions on locations to construct and/or upgrade broadband infrastructure, from communications towers to linear ROWs for fixed terrestrial broadband access, the Department of the Interior (Department) administers a significant amount of land as well as existing permitted infrastructure that can be leveraged for increased connectivity in rural America.

This proposed rule would revise the existing regulations pertaining to communications uses by streamlining processes and establishing new customer service standards. The rule also proposes several technical changes to clarify the communications regulations.

Cost Recovery

Both the FLPMA and MLA authorize the Federal Government to collect fees, called cost recovery, for the costs that it expends in processing a ROW application, taking administrative actions, or monitoring the construction, operation, and termination of a facility authorized by a grant. In 2005, the BLM finalized regulations that established a cost recovery processing and monitoring fee schedule for ROW applications and grants and an annual process whereby the BLM updates the schedule to account for changes in the Implicit Price Deflator Gross Domestic Product (IPD–GDP). The IPD–GDP measures annual changes in the prices of goods and services produced in the United States. Despite those annual adjustments, the fee amounts in the current cost recovery schedule do not presently reflect the costs associated with the work. These costs include both direct and indirect costs, exclusive of management overhead costs. The indirect administrative cost rate is determined at the beginning of each Fiscal Year (FY) and incorporates administrative support. Annual cost recovery adjustments are made to take effect at the beginning of each calendar year. BLM managers and employees, when engaged in either project or program activities where the indirect administrative cost rate assessment is applicable, must include the indirect costs when calculating the cost of providing services to another Federal agency, or ROW or grant applicant.

This proposed rule would increase the cost recovery fees to better reflect the current costs of processing and monitoring minor category ROWs. Additionally, minor category ROWs are those that take less than 50 hours under the current rule and would take less than 64 hours under the proposed rule for a BLM realty specialist to process. This would allow more applications to qualify as a minor category, eliminating the labor to establish, monitor, and maintain appropriate accounting of major category cost recovery accounts on those applications. The BLM believes this proposed change would increase operational efficiency. Lastly, this rule proposes several technical changes to 43 CFR parts 2800 and 2880, that would clarify and expedite other ROW tasks.

Section 512 of FLPMA

In March of 2018, Congress amended FLPMA to add Section 512 (43 U.S.C. 1772), which establishes requirements for the BLM and the USFS to develop and implement final regulations to govern review and approval of operations, maintenance, and fire prevention plans and agreements for vegetation and facility management on public lands within powerline ROWs and on abutting Federal lands. The proposed rule would revise regulations governing the issuance, renewal, and amendment of grants for powerlines. The BLM administers nearly 17,000 existing ROWs for powerlines on public lands. The USFS published a proposed rule on September 25, 2019 (84 FR 50698), a final rule on July 10, 2020 (85 FR 41387), an amendment to the final rule on August 11, 2020 (85 FR 48475), and draft policy on December 10, 2020 (85 FR 79463) to implement Section 512 of FLPMA on land managed by USFS.

The BLM's proposed rule would add a definition for *hazard tree* consistent with the definition in Section 512, and make other changes intended to implement Section 512, including its provisions related to emergency

conditions. This proposed rule is consistent with the direction in Section 512(b)(1) for the BLM to issue guidance ''[t]o enhance the reliability of the electric grid and reduce the threat of wildfire damage to, and wildfire caused by vegetation-related conditions within, electric transmission and distribution ROWs and abutting Federal land, including hazard trees.'' Finally, this proposed rule is also consistent with the policies issued by each of the BLM State Offices regarding vegetation management on ROWs.

B. Need for the Proposed Rule

Communications Uses

It is an Administration priority to bring affordable, reliable, high-speed broadband to every American, including the more than 35 percent of rural Americans who lack access to broadband at minimally acceptable speeds.

On January 8, 2018, Executive Order (E.O.) 13821 was issued to promote better access to broadband internet service in rural America. E.O. 13821 states that ''Americans need access to reliable, affordable broadband internet service to succeed in today's information-driven, global economy'' and establishes a policy ''to use all viable tools to accelerate the deployment and adoption of affordable, reliable, modern high-speed broadband connectivity in rural America, including rural homes, farms, small businesses, manufacturing and production sites, Tribal communities, transportation systems, and healthcare and education facilities.''

On January 8, 2018, in association with the release of E.O. 13821, a Presidential Memorandum (Memorandum) was issued to the Secretary of the Interior (Secretary) entitled, ''Supporting Broadband Tower Facilities in Rural America on Federal Properties Managed by the Department of the Interior.'' This Memorandum states that it is the policy of the executive branch to make Federal assets more available for rural broadband deployment, with due consideration for national security concerns. The Memorandum directs the Secretary to ''develop a plan to support rural broadband development and adoption by increasing access to tower facilities and other infrastructure assets managed by the Department of the Interior'' and ''identify assets that can be used to support rural broadband deployment and adoption.''

On March 23, 2018, the Consolidated Appropriations Act, 2018 was signed into law. (Pub. L. 115–141, 132 Stat. 348.) Title VI of Division P of that law, called the ''Making Opportunities for Broadband Investment and Limiting Excessive and Needless Obstacles to Wireless Act'' or ''MOBILE NOW Act,'' amended section 6409 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96, 126 Stat. 156 (codified at 47 U.S.C 1455)).

This proposed rule would incorporate the new timing requirements established by the MOBILE NOW Act into the BLM's regulations. As amended by the MOBILE NOW Act, 47 U.S.C. 1455(b)(3)(A) states:

In General—Not later than 270 days after the date on which an executive agency receives a duly filed application for an easement, right-of-way, or lease under this subsection, the executive agency shall—

(i) grant or deny, on behalf of the Federal Government, the application; and

(ii) notify the applicant of the grant or denial.

This proposed rule would provide for the electronic filing of ROW applications, along with other document submissions. E.O. 13821 states, ''Federal property managing agencies shall use the GSA [General Services Administration] common form application for wireless service antenna structure siting developed by the [GSA] Administrator for requests to locate broadband facilities on Federal property.''

The MOBILE NOW Act also requires the use of a common form for all applications to install, construct, modify, or maintain communications facilities (including broadband infrastructure) on federally owned lands. The BLM provides Standard Form (SF)–299 for applicants seeking authorization for such purposes on public lands. The GSA, through collaboration with other agencies, decided the SF–299 would be the common form for Federal authorization of communications uses. The proposed rule would require use of the SF–299 for all communications uses grants, thereby making the proposed rule consistent with the MOBILE NOW Act.

By updating regulations, the BLM could improve response times and address the current lack of certainty in the communications uses grant process, which impacts industry construction schedules and may increase construction costs.

Cost Recovery

The current ROW regulations, found in 43 CFR parts 2800 and 2880, became effective June 21, 2005, and require the BLM to reevaluate its cost recovery fees for each cost recovery category, and the categories themselves, within 5 years after their effective date and at 10-year intervals thereafter (43 CFR 2804.15 and 2884.15). The BLM completed its initial cost recovery reevaluation in December 2010 and has continued to evaluate data received through the end of FY 2020. These data show that the existing cost recovery fee collections do not adequately cover the costs incurred by the BLM for processing and monitoring ROW applications and grants under both the FLPMA and the MLA. These proposed regulations would revise the existing cost recovery fee categories to better reflect updates in technology, the procedures for processing applications and monitoring grants, and statutes and regulations relating to the ROW program.

The BLM reviewed current labor and other costs and the time required to perform work on minor category (currently Categories 1–4) ROW applications and grants. For applications or grants that would take the BLM more than 64 hours to process, the BLM would continue to collect cost recovery under Categories 5 or 6 under this rule. In addition, this rule proposes several technical changes to the previously cited regulations that would clarify and expedite completion of other ROW-related tasks.

This proposed rule, which would update cost recovery processes, addresses FLPMA grants for ROWs, MLA grants and temporary use permits (TUPs), and leases, permits, and easements that cross public lands. General provisions for ROW grants are found in 43 CFR subparts 2801 and 2881.

Most of the steps involved in performing necessary work pertaining to ROW authorizations, terminations, assignments, etc., are the same for both FLPMA and MLA ROWs. Typically, unless exempt, an applicant must reimburse the BLM for its reasonable costs incurred in processing and monitoring a FLPMA ROW activity, including conducting an environmental review as required by the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*). Unlike FLPMA, under the MLA, an applicant must reimburse the United States for its actual costs in completing ROW activities. The Federal Government collects cost recovery before the BLM begins tasks related to a ROW application or other ROW-related activity.

The existing ROW cost recovery fee structure is also applicable to leases, permits, and easements issued under Section 302(b) of FLPMA (43 U.S.C.

1732) and 43 CFR part 2920. The proposed rule would revise the regulations for these authorizations, found in § 2920.8(b), to provide consistency with the revisions made to the cost recovery provisions proposed to change under this rule in part 2800.

Section 512 of FLPMA

On March 23, 2018, Congress amended the FLPMA by adding Section 512, entitled ''Vegetation Manag[e]ment, Facility Inspection, and Operation and Maintenance Relating to Electrical Transmission and Distribution Facility Rights of Way'' (43 U.S.C. 1772). The proposed rule would add definitions for *hazard tree* and *operations, maintenance, and fire prevention plan,* as well as make other revisions pertaining to ROW administration to address fire risks on public lands. This proposed rule would define *operations, maintenance, and fire prevention plan* as a plan that provides for long-term, cost-effective, efficient, and timely inspection, operation, maintenance, and vegetation management of a ROW and on abutting Federal lands, including management of hazard trees, to enhance electric reliability, promote public safety, and avoid fire hazards.

The BLM's mission is to sustain the health, diversity, and productivity of the public lands for the use and enjoyment of present and future generations. The BLM administers approximately 245 million surface acres. According to the National Interagency Fire Center (NIFC), approximately 109 million acres across the United States (including both Federal and non-Federal lands) burned in wildfires between 2006 and 2020. Wildfire is a known risk to and from powerlines and may be caused by a variety of factors, including vegetation coming into contact with live powerlines or structural failures of powerline infrastructure.

Right-of-Way Renewals

Each year, about 500 oil and gas pipeline ROWs and 400 power transmission and distribution ROWs expire. Due to resources challenges, over the years the BLM has not kept pace renewing these authorizations. The updated provisions in the proposed rule would help expedite processing of expired and expiring ROWs.

C. Statutory Authority

Section 310 of FLPMA (43 U.S.C. 1740) authorizes the Secretary to promulgate regulations to implement the statute with respect to public lands. The FLPMA also provides comprehensive authority for the administration and protection of the public lands and their resources and directs that the public lands be managed ''under principles of multiple use and sustained yield,'' unless otherwise provided by law (43 U.S.C. 1732(a)). A similar authority for promulgating regulations to implement the MLA's pipeline ROW provisions is found at 30 U.S.C. 185(f).

Both the FLPMA (43 U.S.C. 1734(b) and 1764(g)) and the MLA (30 U.S.C. 185(l)) authorize the BLM and other Federal agencies to require ROW applicants or holders to reimburse an agency for costs incurred processing a ROW application and inspecting and monitoring an authorized ROW.

The Consolidated Appropriations Act, 2018 amended FLPMA by adding a new Section 512 (43 U.S.C. 1772) and directed the Secretary to promulgate regulations to implement this new section.

III. Discussion of the Proposed Rule

43 CFR Part 2800 Rights-of-Way Authorized Under FLPMA

Part 2800 of title 43 of the Code of Federal Regulations describes requirements for general ROWs issued under the FLPMA and MLA. This proposed rule would revise the cost recovery fee schedule and its categories. The communications uses provisions found in this part would either be moved to new part 2860 or removed. Other minor modifications would correct or clarify existing regulations.

Subpart 2801—General Information

Section 2801.2 What is the objective of the BLM's right-of-way program?

The proposed rule would add the words ''wherever practical'' to the objective described in § 2801.2(c). This proposed revision would more closely align the objective of promoting ROWs in common with the requirement described in Section 503 (43 U.S.C. 1763) of the FLPMA:

In order to minimize adverse environmental impacts and the proliferation of separate rights-of-way, the utilization of rights-of-way in common shall be required to the extent practical.

Section 2801.5 What acronyms and terms are used in the regulations in this part?

In section 2801.5, the proposed rule would move several terms associated with communications uses to the definitions section for a new part 2860, which specifically addresses communications uses.

The proposed rule would add the term and a definition of ''complete application'' to clarify that an application is only complete when it contains all necessary information found under § 2804.12 and when the BLM notifies the applicant that it is complete. This is an important clarification, because the BLM's customer service standards for processing applications apply only when an application is complete. This is consistent with existing BLM practice, but the proposed rule would clarify this requirement.

The proposed rule would add the term and a definition of ''cost recovery'' to clarify that it is a fee for the processing and monitoring associated with any proposed or authorized ROW.

The proposed rule would add the term and a definition of ''exempt from rent'' to clarify when an authorization would be automatically exempt from rental. This definition is consistent with existing § 2806.14 and proposed § 2866.14.

The proposed rule would revise the definition of the term ''facility'' by removing the last sentence. This part of the definition applies only to communications uses and would be moved into new § 2861.5, which is the definitions section for the new part 2860 that would be added by this proposed rule to consolidate provisions that address communications uses ROWs.

The proposed rule would add the statutory term ''hazard tree,'' and would define that term consistent with the definition in Section 512(a)(1) of FLPMA. The definition would apply in the limited context of powerline ROWs subject to newly proposed § 2805.22 and would help holders of such ROWs to understand what is required of them and what authorization their ROW provides. (See proposed § 2805.22(b)(3).)

The proposed rule would revise the term ''monitoring'' to be ''monitoring activities'' and would revise the definition of that term. Monitoring activities would mean those activities the Federal Government performs to ensure compliance with a ROW grant.

The proposed rule would also revise the explanation of the monitoring categories for consistency with the proposed revisions to § 2804.14(a).

The proposed rule would add the term and a definition of ''operations and maintenance,'' which would include activities conducted by a ROW holder to manage facilities and vegetation within and adjacent to the ROW boundary.

The proposed rule would add the term and a definition of ''operations, maintenance, and fire prevention plan,'' which would be a plan submitted to the BLM by the holder of a ROW that

describes how the holder plans to operate, maintain, and inspect the applicable ROW and facilities in a cost-effective, efficient, and timely manner to enhance electric reliability, promote public safety, and avoid fire hazards, including vegetation in or adjacent to the ROW.

The proposed rule would add the term and a definition of ''processing activities.'' Processing activities would be defined as work that the Federal Government undertakes to evaluate an application for a ROW grant. The principal outcome of ROW processing is a determination of whether to approve the application by issuance of a grant and identification of appropriate terms and conditions for each grant. The proposed definition also includes preparation of an environmental document, compliance with other legal requirements, and ROW administrative actions, such as assignments, amendments, and renewals, as different processing activities. This would not be a change from existing BLM practice but would clarify to the public that the BLM collects cost recovery for these ROW-related activities. This proposed definition would explain what activities would generally be associated with applications found under each cost recovery category.

The proposed rule would revise the definition of ''substantial deviation'' to clarify that general operation and maintenance activities, including safety-related activities, are not considered a substantial deviation. Additionally, the definition would clarify that activities to prevent or suppress wildfires on lands within or adjacent to the ROW are not considered a substantial deviation.

The proposed rule would revise the definition of ''transportation and utility corridor'' to clarify the process for establishing transportation and utility corridors. Furthermore, the amended definition would clarify the need for compatible uses.

The proposed rule would add the term and a definition of ''waived from rent'' to clarify the differences between being ''waived from rent'' and ''exempt from rent.'' While a holder may be exempted from rent by statute or regulation, the BLM may also waive a part or all of a holder's rent (see §§ 2806.15 and 2866.15).

The proposed rule would revise the definition of ''zone'' by removing the number ''eight'' from the description of the number of zones. The current linear rent schedule for ROWs has 15 zones, so the current definition is not accurate. Removing the number of zones would not affect the definition.

Section 2801.9 When do I need a grant?

The proposed rule would remove paragraph (a)(5) of this section and redesignate paragraphs (a)(6) and (7) as (a)(5) and (6). The paragraph to be removed requires the public to obtain a grant for systems for transmitting or receiving electronic signals and other means of communication. This is a communications uses-specific requirement that would be removed from part 2800. The uses described in the removed paragraph (a)(5) would be covered under proposed § 2861.9, which would describe the circumstances under which a holder must obtain a communications uses grant.

Subpart 2802—Lands Available for FLPMA Grants

Section 2802.10 What lands are available for grants?

The proposed rule would revise paragraph (c) of this section by removing the specific requirement to notify the BLM office nearest the lands you seek to use. The proposed rule instructs you to contact the BLM to determine the appropriate office with which you should coordinate. The appropriate office is the BLM office with jurisdiction over the lands you seek to use, which may not be the same as the BLM office nearest the lands you seek to use.

Subpart 2803—Qualifications for Holding FLPMA Grants

Section 2803.11 Can another person act on my behalf?

Proposed § 2803.11 would add new provisions that describe the process for the holder to notify the BLM when another person or entity is authorized to act on the holder's behalf. This proposed revision would standardize what documents the BLM would require prior to allowing another person or entity to act on behalf of the holder. The BLM expects this change to streamline and expedite processing times for grant holders.

Proposed paragraph (a) would require the holder to follow several steps before designating another individual or entity to act on their behalf. These requirements are necessary for the BLM to understand the legal relationship between the holder and the third party acting on their behalf.

Proposed paragraph (a)(1) would explain which BLM office must be notified. The office with jurisdiction over a grant retains the official case file and therefore needs the official documentation. This proposed paragraph would also require the holder to provide a copy of the power of attorney, if one exists. This is often the instrument used to authorize another party to act on the holder's behalf. This requirement is not expected to create any additional burden because the requested information is simply a copy of documents already possessed by the holder.

Proposed paragraph (a)(2) would require the holder to provide and maintain current contact information for their intended agent. This requirement is important for when the BLM needs to contact the agent. Without updated and current contact information, processing times can be delayed. This requirement is anticipated to streamline interactions between the BLM and holders or their agents.

Proposed paragraph (b) would inform the ROW holder how the BLM would administer the grant. The BLM would like to simplify the formal communication process by establishing expectations of responsibility for any actions taken by an authorized agent. As a result of this proposed change, the BLM anticipates a reduction in processing times for requests related to a ROW application.

Section 2803.12 What happens to my grant if I die?

Because an application is not an inheritable interest, the BLM proposes to change the title of this section from ''What happens to my application or grant if I die?'' to ''What happens to my grant if I die?'' Paragraph (a) would also be revised to remove the reference to applications.

Subpart 2804—Applying for FLPMA Grants

Section 2804.12 What must I do when submitting my application?

In § 2804.12, the BLM proposes to change § 2804.12(a) by adding a sentence following the first sentence to read: ''The application must include the applicant's original signature or meet the BLM standards for electronic commerce.'' This addition would clarify that when an application for a ROW is filed electronically, a manual signature may not be required.

Proposed revisions to § 2804.12(a)(4) would require an applicant to submit the project map and Geographic Information Systems (GIS) shapefiles for the project, as requested by the BLM. When a BLM office is conducting an analysis under NEPA, it is not uncommon for the various resource specialists to request that the applicant provide project data electronically in a GIS format to ensure that the correct

area for the proposed project is analyzed. It is likely the individual or entity responsible for the application already has the proposed project data in a GIS format, and therefore, the BLM is not adding a significant burden upon the applicant. This new requirement would be expected to reduce application processing times by allowing the BLM to integrate project locations into existing resource datasets and analyze the potential resource impacts more quickly.

Section 2804.14 What are the fee categories for cost recovery?

The proposed rule would revise the title of this section to read: ''What are the fee categories for cost recovery?'' The proposed cost recovery categories in this section would apply to both processing and monitoring activities, whereas the existing title of § 2804.14 refers only to processing fees for grant applications. The BLM proposes to amend § 2804.14(a) to clarify that cost recovery fees include both processing and monitoring activities. The BLM proposes to amend § 2804.14(a) to maintain consistency with the proposed changes in § 2804.16 that would provide for waiver of, rather than exemption from, processing and monitoring fees.

The United States, under the FLPMA, generally collects cost recovery fees from ROW holders and applicants for the reasonable costs of Federal work related to a ROW. Existing regulations contain a table of categories for ''processing fees'' under § 2804.14(b) and a table of ''monitoring fees'' under § 2805.16(a). The monitoring cost recovery fee schedule, currently found under § 2805.16(a), would be combined with the category description table located at existing § 2804.14(b) in a new table in proposed § 2804.14(b). This revised table would apply to all cost recovery fees.

The BLM determines which category a project falls into based on its estimate of the total Federal work hours associated with the project. If the project falls into a minor category, then the applicant is assessed the fee that corresponds to the appropriate category within the cost recovery schedule.

Following the methodology of the 2005 rule, the BLM proposes to update the fee schedule for minor cost recovery categories by multiplying a calculated average wage which includes both direct and indirect costs by the midpoint of the hours in each minor category. We describe that process in detail below.

Proposed § 2804.14(b) would remove the first sentence in § 2804.14(b), which states, ''There is no processing fee if the BLM's work is estimated to take one hour or less.'' This change would address the fact that the time spent on ROW work activities generally is not less than 1 hour. Even simple actions, such as ROW assignments and name changes, take more than 1 hour to complete, except in very rare circumstances. The BLM would be interested in hearing from the public if this would create a burden on the industry for any particular actions that are frequently performed in under 1 hour.

The BLM conducted a review of ROW cases between FY 2012 and FY 2018, and found that the existing cost recovery schedule, which provides that projects with up to 50 estimated work hours may be considered for the ''minor'' cost recovery categories (Categories 1, 2, 3, or 4), should be expanded. The BLM is concerned that, due to the 50-work-hour limit, more projects are being assigned to Category 6, when it would be more efficient operationally to increase the ''minor'' cost recovery limit to 64 hours, or an even 8 workdays. This would allow more applications to qualify as a minor category, eliminating the labor to establish, monitor, and maintain appropriate accounting of major category cost recovery accounts on those applications. The BLM proposes a new schedule that would adjust the hours thresholds for Categories 1, 2, 3, and 4 to account for the expected type of workload and to set the minor category work hour cap at 64 hours.

Proposed Category 1 would apply to activities with an estimated workload of 8 Federal work hours or less. Proposed Category 2 would apply to activities with an estimated workload of 8 to 24 Federal work hours. Proposed Category 3 would apply to activities with an estimated workload of 24 to 40 Federal work hours. Proposed Category 4 would apply to activities with an estimated workload of 40 to 64 Federal work hours. By expanding the range of hours in the minor categories, it is anticipated that the BLM would have fewer major Category determinations, thereby giving the applicants with moderate projects some relief from the cost recovery fees and additional workload associated with such a determination. This proposed rule change would allow more applications to qualify as a minor category, eliminating the labor to establish major category cost recovery accounts on those applications.

The proposed rule would adjust the cost recovery fees for each of the minor categories to reflect the current reasonable cost of the associated hours. The process that the BLM uses currently to adjust the fees is detailed in Section 5 of the Economic and Threshold Analysis (or ''economic analysis'') that accompanies the proposed rule.

First, the BLM calculated an average wage (including pay additives and indirect costs) for processing and monitoring activities taking place from FY 2018 to FY 2020. The calculated average hourly wage over this three-year period was $67.74.

The BLM then multiplied that average wage by the midpoint of the work hours in each of the proposed categories to determine the fee amounts for each category. During previous rulemakings on this subject, we received comments that most users felt more comfortable if a midpoint were used, as opposed to another statistical method or evaluation of the data. With this proposed rule, the BLM would maintain the use of midpoints for calculating the fees for the minor categories.

The result of this formulation is proposed fees of $271, $1,084, $2,168, and $3,522 for minor Categories 1, 2, 3, and 4 in the first FY of adoption, respectively. These fees would be applied in the base year and adjusted annually for changes in the IPD–GDP, per current practice. With the proposed increase in cost recovery fees, the BLM believes that it would be closer to recovering the reasonable costs for activities in Categories 1 through 4, as FLPMA requires.

The proposed rule would clarify that, for Master Agreements under Category 5, preliminary application review fees may be included in the Master Agreement. See the discussion of § 2804.18 in this preamble for further discussion of proposed changes to Master Agreements.

Under the proposed rule, Category 6 would cover any ROW for which the BLM estimates that Federal work will exceed 64 hours or which would result in the preparation of an Environmental Impact Statement (EIS). The BLM would continue to collect costs for work performed under this category, which would now specifically include preliminary application review. The cost recovery fees under both the existing and proposed category frameworks are shown in Table 1 below.

TABLE 1—EXISTING AND PROPOSED COST RECOVERY SCHEDULES

Existing cost recovery fee schedule (FY 2022)			Proposed cost recovery fee schedule		
Category	Estimated work hours	Fee amount	Category	Estimated work hours	Fee amount
1	> 1 ≤ 8	$136	1	8 or less	$271.
2	> 8 ≤ 24	$480	2	> 8 ≤ 24	$1,084.
3	> 24 ≤ 36	$904	3	> 24 ≤ 40	$2,168.
4	> 36 ≤ 50	$1,296	4	> 40 ≤ 64	$3,522.
5	Varies depending on agreement.	Determined by agreement	5	Varies depending on agreement	Determined by agreement.
6	> 50	All processing and monitoring costs.	6	>64	All processing and monitoring costs.

The adjustments in the fee schedule are driven by two factors. First, the BLM has proposed to expand the number of hours covered by Categories 3 and 4. Second, the average labor wage has risen significantly since the 2005 rule was promulgated.

For example, if the BLM determines your application would take 40 hours to process, currently you would be in Category 4 with an FY 2022 fee of $1,296. Under the proposed rule, the same application would be in Category 3 with a fee of $2,168. The $2,168 would represent the midpoint between the range of hours in Category 3 (which is 32 hours), times the average wage calculation. The BLM coordinates with the USFS to provide consistency with respect to ROW cost recovery fees.

The proposed rule would revise § 2804.14(c) to update and re-order the locations where you can obtain a copy of the current cost recovery category fee schedule.

The proposed rule would revise § 2804.14(d) for consistency with other proposed changes and to reflect that these cost recovery categories would apply to all ROW activities including monitoring, not just the processing of applications.

Section 2804.15 When does the BLM reevaluate the cost recovery fees?

The proposed rule would revise the title of this section to change ''processing and monitoring'' to ''cost recovery.'' This proposed change is necessary for consistency with the proposed changes to § 2804.14.

Section 2804.16 When will the BLM waive cost recovery fees?

The proposed rule would amend § 2804.16 by revising the title to read ''When will the BLM waive cost recovery fees?'' rather than ''Who is exempt from paying processing and monitoring fees?'' Proposed § (a) of this section contains the undesignated introductory text of existing § 2804.16. This language would be revised to refer to cost recovery fees, instead of processing and monitoring fees, and would change the existing definitive exemption from fees to a waiver of fees that the BLM has discretion to apply or not apply.

Proposed paragraph (a)(1) of this section contains the provision of existing § 2804.16(a) and would state that ROW cost recovery fees may be waived if an applicant is a State or local government, and the application is for governmental purposes that benefit the general public. Under this proposed paragraph, the waiver would not apply if charges levied on customers are similar to those of a profit-making entity. This is different from the existing exception which applies only when such charges are the ''principal source of revenue.''

The waiver for governmental entities is intended to provide financial relief to governmental entities seeking to provide a benefit to the public. However, some of these entities are charging rent beyond the operating costs to use their facility. The proposed change would make the waiver unavailable to applicants who would otherwise receive an authorization at no charge and then collect fees from other users.

Proposed paragraph (a)(2) of this section contains the text from existing paragraph (b) of this section, which remains unchanged.

Proposed paragraph (a)(3) would allow the BLM to waive cost recovery fees for Federal agencies for applications belonging to cost recovery Categories 1 through 4. The current regulations require Federal agencies to pay cost recovery fees on all ROW applications. Under an earlier version of the regulations, Federal agencies were exempt from all cost recovery. The proposed rule strikes a middle path by allowing the BLM to waive fees for Federal agencies in some, but not all circumstances. Transferring funds between agencies is costly and administratively slow. Costs associated with processing the transfer often exceed the fees being transferred. Therefore, it is not cost effective for the BLM to collect cost recovery fees from other Federal agencies for Categories 1 through 4. However, if a Federal agency's action would take the BLM more than 64 hours to complete, the BLM would collect cost recovery fees under Category 5 or 6.

The proposed rule adds a new paragraph (b) to this section stating that the BLM will not waive your fees if you are in trespass. This paragraph makes existing BLM policy explicit in the regulations.

Section 2804.17 What is a Master Agreement (Cost Recovery Category 5) and what information must I provide to the BLM when I request one?

The proposed rule would modify § 2804.17(a) to change the cross-reference from § 2805.16 (currently the table for monitoring fees) to proposed § 2804.14, which would contain the combined cost recovery table for all ROW activities.

Section 2804.18 What provisions do Master Agreements contain and what are their limitations?

Section 2804.18 describes how Master Agreements function. Proposed § 2804.18(a)(2) would provide that a Master Agreement describes work to be done by the applicant and the BLM to complete a number of ROW permitting and monitoring activities. The revisions to this paragraph would allow Master Agreements to be used for any type of ROW activity, not just ROW processing. Proposed paragraph (a)(5) would make this language more consistent with other updates in the proposed rule. The BLM believes the expanded use of Master Agreements would streamline processing and monitoring activities. Master Agreements are designed to consolidate some of the processing and monitoring steps associated with ROWs,

including combining budgeting processes into one project work breakdown structure. Also, many Master Agreements fund or partially fund staffing of Realty Specialists and other key interdisciplinary teams which can help expedite processing when funds are not otherwise available (§ 2804.22).

Section 2804.18(c) would be amended to say, ''cost recovery fees,'' instead of ''processing and monitoring fees.'' These proposed changes would be consistent with the expanded definition of a Master Agreement.

Section 2804.19 How will the BLM manage my Category 6 project?

Section 2804.19 would be amended by revising the title from ''How will BLM process my Processing Category 6 application?'' to read ''How will the BLM manage my Category 6 project?'' This section would be revised to explain that cost recovery for Category 6 projects would include monitoring the grant in addition to processing the application. The proposed rule would make editorial changes for clarity and consistency with the other proposed changes.

Proposed § 2804.19(a) would eliminate the requirement for a work and financial plan for some Category 6 applications at the discretion of the authorized officer and would instead provide only that the BLM ''may require'' such plans. Preparing a work and financial plan takes an average of 6 months to complete. The preparation of a work and financial plan may not be necessary if both the applicant and the BLM authorized officer can agree, in writing, on the cost to process the action. This change would reduce the time associated with establishing a cost recovery account and improve the Category 6 cost recovery process, particularly for those actions close to 64 hours.

The proposed rule would add a new paragraph (b)(4) and redesignate existing paragraphs (b)(4) and (b)(5) as (b)(5) and (b)(6), respectively. Proposed paragraph (b)(4) of this section would state that the BLM may collect a deposit before beginning work on a Category 6 project. Currently, when an application falls under Category 6, it takes an average of 6 months to finalize the details of the agreement, which includes a work and financial plan. The communications industry has indicated that when they are charged a Category 6 cost recovery fee, the deposit is usually between $11,000 and $15,000. The advanced collection of a deposit would shorten the time for processing an application by allowing the BLM to begin processing the application during the 6 months it usually takes to finalize a cost recovery agreement. If the BLM determines the deposit is not adequate, the applicant would prepare a work and financial plan to provide additional funds under a cost recovery agreement.

Section 2804.20 How does the BLM determine reasonable costs for Category 6 right-of-way activities?

Section 2804.20 would be amended by revising the title from ''How does BLM determine reasonable costs for Processing Category 6 or Monitoring Category 6 applications?'' to read ''How does the BLM determine reasonable costs for Category 6 right-of-way activities?''

The proposed rule would revise the last sentence in the introductory text of this section, which states, ''While we consider your written analysis, BLM will not process your Category 6 application.'' Under the proposed rule, if the BLM requests additional information, we would continue to work on your application while you are responding to our request, as long as a deposit has been received by the BLM as provided in proposed § 2804.19(b)(4).

Paragraph (a) of this section describes how the BLM would apply the factors articulated in Section 304(b) of FLPMA to assess whether costs are ''reasonable'' for your project, to determine the actual costs owed to the BLM. The proposed rule would remove the reference to the BLM State Director and instead refer only to the BLM. This would not change how the BLM applies these factors, and the decision would still be appealable under § 2801.10. This proposed change would improve the cost recovery process by enabling the BLM to make this determination at the appropriate level on a case-by-case basis.

Section 2804.21 What other factors will the BLM consider in determining cost recovery fees?

The proposed rule would amend this section by revising the title, paragraph (a), paragraph (a)(2), and paragraph (a)(7) by removing references to ''processing and monitoring'' and replacing those references with more general references to all ROW activities to which cost recovery applies. This change would be consistent with the changes described in § 2804.14.

Paragraph (b) of this section describes how the BLM reviews your analysis of the factors for your project to determine the fees owed to the BLM. The proposed rule would remove the reference to the BLM State Director and instead refer only to the BLM.

Section 2804.25 How will the BLM process my application?

The proposed rule would amend paragraph (a)(1) of this section to add ''unless your fees are exempt.'' This clarifying edit is necessary because the BLM would not be required to identify your cost recovery fee if you are exempt from fees.

The proposed rule would redesignate paragraph (c)(2) of this section as (c)(3) and add a new paragraph (c)(2). Proposed paragraph (c)(2) of this section would require an operations, maintenance, and fire prevention plan for all powerline ROWs. Section 512 of FLPMA calls on the BLM to provide ''owners and operators of electric transmission or distribution facilities located on public lands . . . with the option to develop and submit a plan'' (43 U.S.C. 1772(c)(1)). Under existing § 2804.25(c), the BLM may require applicants to submit a plan of development (POD) for a ROW, as necessary. The operations, maintenance, and fire prevention plan may be included in the POD. The BLM generally requires PODs for large projects but believes the risk of wildfire associated with powerline ROWs merits an explicit requirement.

The BLM may also require other information to process the application. Under this proposed rule, the BLM relies on its general authority to condition ROW grants (43 U.S.C. 1761(b)(1)) to require applicants to submit operations, maintenance, and fire prevention plans for all new powerline ROWs. Applications to amend and renew ROWs must follow the same procedures as applications for new ROWs and, therefore, would also be subject to the proposed requirement for an operations, maintenance, and fire prevention plan.

However, if you already have an approved plan that meets the requirements of proposed § 2805.21(c) (''What is an operations, maintenance, and fire prevention plan for electric transmission and distribution rights-of-way?''), then you would not be required to submit a separate operations, maintenance, and fire prevention plan.

The proposed rule would revise paragraph (d) of this section by changing ''completed application'' to ''complete application.'' This proposed revision is consistent with the addition of this term in proposed § 2801.5. The proposed rule would also revise the table in paragraph (d) of this section by adding the word ''Master'' in front of the word ''Agreement.''

Section 2804.26 Under what circumstances may the BLM deny my application?

The proposed rule would add paragraph (a)(9) to this section, which would state that the BLM could deny your ROW application if you fail to comply with a deficiency notice. The BLM inadvertently removed this paragraph when this section was amended by a rule to support solar and wind energy development (see 81 FR 92121, December 19, 2016).

Section 2804.27 What fees must I pay if the BLM denies my application or if I withdraw my application or I relinquish my grant?

This rule would amend § 2804.27 by revising the title to read ''What fees must I pay if the BLM denies my application or if I withdraw my application or I relinquish my grant?'' This title revision would add the relinquishment of a grant to the situations where you may have to pay fees.

The proposed rule would make minor revisions to paragraphs (a) and (b) to make the language more consistent with the existing and proposed regulations. Proposed paragraph (c) would be added to explain how cost recovery fees would be applied under Category 5 or 6 if a holder relinquishes their grant. The holder would be liable for all costs the United States has incurred in connection with the grant, including relinquishment of the grant. Any outstanding fees would be due to the BLM within 30 days after the holder receives the bill. The holder would be refunded the amount of fees paid that the BLM does not use to process the holder's grant.

This new paragraph is consistent with existing BLM practice but is necessary to clarify and make explicit the process for relinquishing a grant and explain to holders what is required of them.

Subpart 2805—Terms and Conditions of Grants

Section 2805.11 What does a grant contain?

The proposed rule would add a new § 2805.11(b) to provide that grants would include access (ingress and egress) rights to a ROW. The proposed rule would redesignate existing paragraphs (b) and (c) as paragraphs (c) and (d), respectively. Many ROWs need access to and from the ROW from outside the boundaries of the ROW for operations and maintenance. The proposed rule would add an explicit requirement for the authorized officer to include rights of ingress and egress in the grant. Prior to 2005, the regulations had included provisions for ingress and egress. The BLM is re-introducing these provisions to address the need for grants to include explicit provision for continued access throughout the term of the grant. While most projects include authorization for temporary access for initial construction, if those temporary access rights expire, then access for future operations and maintenance requires an additional authorization. The proposed requirement to include these rights of ingress and egress in the grant would ensure that the holder can engage in timely and efficient operation and maintenance of the grant.

The BLM may charge rent appropriate to the nature of these access routes outside the ROW boundary. For instance, where ROW access is facilitated by existing routes that are open to public use, rent would likely not be appropriate. By contrast, the BLM may charge appropriate rent for newly constructed roads or overland travel to authorized ROWs on public lands. See the preamble discussion of the proposed revisions to § 2806.15(b)(3) for more information.

Section 2805.12 With what terms and conditions must I comply?

Existing paragraph (a)(4) of this section requires holders to do everything reasonable to prevent and suppress wildfires on or within the immediate vicinity of the ROW. The language has been changed from ''immediate vicinity'' to ''adjacent to'' to be consistent with the proposed update to the definition of ''substantial deviation.''

Section 2805.12(a)(8)(vi) requires holders to ensure that they construct, operate, maintain, and terminate facilities in accordance with the authorization, including the approved POD. The proposed rule would add ''any approved operations, maintenance, and fire prevention plan'' to incorporate the new requirements described in this proposed rule.

Section 2805.12(c)(5) and paragraph (d)(3) would be revised to provide that conditions associated with damaged and abandoned facilities that threaten human health or safety are not subject to the existing requirement that the BLM wait 3 months before requiring the holder to act. The BLM has experienced situations where grant holders create human health and safety hazards by abandoning facilities and equipment within their authorized ROW area. If a holder's use is posing a health or safety hazard to the public, the BLM should be empowered to address it as soon as possible.

Section 2805.14 What rights does a grant provide?

The proposed rule would revise the title from ''What rights does a grant convey?'' to ''What rights does a grant provide?'' to eliminate any implication that a grant gives ownership rights.

The proposed rule would revise § 2805.14(d) by removing the word ''minor'' from the description of trimming, pruning, and removal of vegetation and by adding an allowance to undertake those activities to ''protect public health and safety.'' The term ''minor'' has caused confusion for the holders and is imprecise. The added allowance gives the BLM leeway to allow activity aimed at protecting public health and safety.

These proposed revisions provide the necessary detail for the holder as to what vegetation management they can and must do to operate and maintain their ROW or facility, including what does and does not constitute a substantial deviation.

Section 2805.14(e) would be revised to allow the holder to use vegetation removed during maintenance of the ROW. The use of existing vegetation would reduce non-native species intrusion and would expedite maintenance by the holder. The paragraph would also be revised to align with FLPMA's statutory provision that stone, soil, or vegetation may be used only if any necessary authorization to remove or use such materials has been obtained pursuant to applicable laws (43 U.S.C. 1764(f)). The BLM is specifically seeking comment on the practical impact of this proposed change.

Section 2805.15 What rights does the United States retain?

The proposed rule rephrases paragraph (a) of this section to address the nature of BLM's need for access to the lands and facilities covered by an authorization. Some authorizations may be for the use of a facility, while others would be for use of an area on the public lands. The proposed rule would retain the requirement for the BLM to be provided access to and within the lands or facilities.

Proposed § 2805.15(e) would add language to clarify that after a grant is executed, any modification of its terms and conditions generally requires the BLM to issue a new or amended ROW grant. The BLM conducts analyses, including under NEPA, before issuing a grant, and any changes to the terms or conditions of a grant would require the BLM to complete a new decision-making process, and may require the

BLM to conduct additional analyses. Any such new decision must comply with applicable laws, including NEPA, and could require the BLM to complete a new environmental analysis, utilize an existing environmental analysis, or rely on a categorical exclusion.

Under proposed paragraph (f) of this section, the BLM could terminate an authorization for non-compliance. Existing § 2805.12 describes the terms and conditions that a grant holder must comply with and provides that the BLM could terminate a grant for non-compliance. This proposed paragraph would reinforce that this is a potential outcome.

Under proposed paragraph (g) of this section, the BLM could require a holder to submit financial documents related to a holder's authorization. This would be consistent with the requirements of existing § 2805.12(a)(15).

Section 2805.16 If I hold a grant, what cost recovery fees must I pay?

The proposed rule would amend § 2805.16 by changing the word ''monitoring'' in the title to ''cost recovery'' such that the title would read, ''If I hold a grant, what cost recovery fees must I pay?'' The section would also be amended by revising § 2805.16(a), adding a new § 2805.16(b), revising current § 2805.16(b), and redesignating it as paragraph (c).

As previously discussed, the proposed rule would remove the monitoring cost recovery fee table currently located under § 2805.16(a). The proposed rule would add a sentence referring the reader to § 2804.14(b), where they could find the proposed cost recovery table.

Under new § 2805.16(b), the cost recovery fee schedule for Categories 1 through 4 would be updated on an annual basis based on the previous year's change in the IPD–GDP, and the fees for Category 5 would be updated according to the given project's Master Agreement.

Proposed § 2805.16(c), which contains the provisions of existing § 2805.16(b), would explain where to obtain a copy of the current year's cost recovery fee schedule. The proposed rule would provide updated contact information for the holder to request the schedule from the BLM's Division of Lands, Realty and Cadastral Survey.

Section 2805.21 What is an operations, maintenance, and fire prevention plan for electric transmission and distribution and other rights-of-way?

Proposed § 2805.21 would codify many of the provisions of Section 512 of FLPMA in the BLM regulations. Section 512(c) of FLPMA describes the requirements for vegetation management, facility inspection, and operations and maintenance plans. This proposed § 2805.21 describes the requirements for ''operations, maintenance, and fire prevention plans,'' which are consistent with the requirements of the plans described in Section 512 of FLPMA.

Under proposed § 2804.25(c)(2) of the proposed rule, and as reflected in proposed paragraph (a)(1), operations, maintenance, and fire prevention plans would be required for all new, renewed, or amended electric transmission and distribution ROWs. In addition, under proposed paragraph (a)(2), such plans may be submitted to the BLM on a voluntary basis by holders of existing electric transmission and distribution ROWs. Operations, maintenance, and fire prevention plans would be advantageous to both the BLM and the ROW holder by better defining authorized activities, schedules for maintenance, and wildfire risk reduction measures, and by introducing limits on a ROW holder's liability under the specific circumstances described in this section.

Proposed paragraph (b) of this section refers to Electric Reliability Organization (ERO) standards and would provide that those standards may be incorporated into operations, maintenance, and fire prevention plans developed under this section. The Energy Policy Act of 2005 created the ERO: an independent, self-regulating entity that enforces mandatory electric reliability rules on all users, owners, and operators of the nation's transmission system. The North American Electric Reliability Corporation (NERC) develops and enforces reliability standards for North America and is the ERO. NERC reliability standards define the reliability requirements for planning and operating the North American bulk power system. These standards only apply to holders who are a part of a bulk power system, and holders subject to these standards may incorporate them into their operations, maintenance, and fire prevention plan. The ERO reliability standards developed by NERC are requirements the holder must meet for operating and maintaining the ROW and facility, such as frequency of inspections and minimum distance of vegetation clearances from powerlines. Incorporating these industry-wide standards into the operations, maintenance, and fire prevention plan a holder submits to the BLM would help to provide consistency between the BLM and USFS.

Proposed paragraph (c) of this section describes the requirements for operations, maintenance, and fire prevention plans, consistent with Section 512(c) of FLPMA and with the USFS final rule implementing Section 512. Under proposed paragraph (c)(1) of this section, operations, maintenance, and fire prevention plans must identify the applicable facilities to be maintained.

Proposed paragraph (c)(2) of this section would require the operations, maintenance, and fire prevention plan to account for the holder's own operations and maintenance plans for the applicable facilities. Many ROW holders have existing, internal plans for their operations and maintenance that they have not previously been required to submit to the BLM for approval, including those who must comply with ERO standards. The holder may be able to submit these existing internal plans to satisfy the BLM's operations, maintenance, and fire prevention plan requirements. A holder would not need to submit a new operations, maintenance, and fire prevention plan if their existing plan meets the requirements of this section.

Proposed paragraph (c)(3) of this section would require that the plan describe how a holder would operate and maintain the ROW and facility, including for vegetation management. These operations, maintenance, and fire prevention methods may also be those required to comply with applicable law, including fire prevention measures, safety requirements, and reliability standards established by the ERO. While the ERO describes the standards that must be met, the holder must describe in the operations, maintenance, and fire prevention plan how they plan to meet those standards.

Under proposed paragraph (c)(4) of this section, an operations, maintenance, and fire prevention plan would be required to include schedules for the holder to notify the BLM about non-emergency maintenance, including when they must seek approval from the BLM and when the BLM must respond to that request. Non-emergency maintenance will be further discussed in the preamble for proposed § 2805.22.

Proposed paragraph (c)(5) of this section would require the operations, maintenance, and fire prevention plan to describe processes for identifying changes in conditions and modifying the approved operations, maintenance, and fire prevention plan, if necessary. Either the BLM or holder could determine that the conditions in the ROW, which may include environmental conditions or

accessibility, have changed. The operations, maintenance, and fire prevention plan would be required to describe how the BLM and holder would communicate and initiate any necessary plan modifications. (See the preamble discussion for proposed paragraph (e) of this section.)

Proposed paragraph (c)(6) of this section would require the operations, maintenance, and fire prevention plan to include provision for removal and disposal of cut trees and branches, including plans for sale of forest products.

Under proposed paragraph (d) and consistent with Section 512(c)(4)(A) of FLPMA, the BLM would, to the extent practicable, review and approve the operations, maintenance, and fire prevention plan within 120 days of receiving the plan.

Proposed paragraph (e) of this section describes how the BLM would notify the holder that an operations, maintenance, and fire prevention plan requires modifications. The BLM would provide advance reasonable notice to the holder that a modification is necessary, and the holder would submit the proposed modification to the BLM. The BLM would, to the maximum extent practicable, review and approve the proposed operations, maintenance, and fire prevention plan modification in the same 120-day timeframe that applies to approval of new plans. This timeframe would be consistent with the requirements of Section 512 of FLPMA.

Under paragraph (e)(4) of this section, a holder may, while a proposed plan modification is pending approval, continue to operate and maintain the ROW or facility in accordance with the approved operations, maintenance, and fire prevention plan, as long as the activity does not adversely affect the identified condition that necessitates the plan modification. Although a plan modification may be required, the BLM does not intend for operations and maintenance to be unnecessarily delayed in other areas of the ROW that are not impacted.

Proposed paragraph (f) of this section describes how certain holders may enter into an agreement with the BLM in lieu of an operations, maintenance, and fire prevention plan. An agreement must contain the same general requirements of operations, maintenance, and fire prevention plans described in this section. Agreements would need to include schedules, as described in proposed paragraph (c)(4) of this section and would be subject to the same modification requirements of proposed paragraph (e) of this section.

Proposed paragraph (g) of this section describes the criteria that a holder would be required to meet to be eligible to enter into an agreement. A holder could enter into an agreement with the BLM if they are not subject to the ERO reliability standards or if they sold less than 1,000,000 megawatt hours of electric energy for purposes other than resale during each of the 3 calendar years prior to enactment of Section 512 of FLPMA. These eligibility requirements are established by Section 512(d)(1) of FLPMA and would generally apply to rural electric cooperatives and other small entities.

Section 512(d)(2)(A) of FLPMA requires the Secretary to ensure that the minimum requirements of these agreements ''reflect the relative financial resources of the applicable owner or operator compared to other owners or operators of an electric transmission or distribution facility.'' The BLM is seeking comments from the public on how these agreements should be different from operations, maintenance, and fire prevention plans and how the BLM can ensure that it meets the requirements of Section 512(b)(2)(A).

Section 2805.22 Special Provisions for Vegetation Management for Electric Transmission and Distribution Rights-of-Way

Proposed § 2805.22 describes how holders could conduct vegetation management related activities and distinguishes between emergency and non-emergency conditions. This proposed section would implement the requirements of Section 512(c) and (e) of FLPMA.

Proposed paragraph (a) of this section describes the conditions that would be considered Emergency Conditions and what the holder would be allowed to do during Emergency Conditions without immediate notification to the BLM. An Emergency Condition would be if vegetation or hazard trees have contacted, or present an imminent danger of contacting, an electric transmission or distribution line. The proposed rule specifies that this threat could arise from vegetation or a hazard tree within or adjacent to a transmission line ROW. Under proposed paragraph (a)(1) of this section, holders could prune or remove the vegetation or hazard tree to avoid the disruption of electric service and to eliminate immediate fire and safety hazards. Proposed paragraph (a)(2) would require the holder to notify the BLM within one calendar day after conducting these activities.

Proposed paragraph (b) of this section describes Non-Emergency Conditions for which the holder of a powerline ROW could conduct vegetation management activities. The holder could conduct activities without prior approval from the BLM if they are in compliance with the terms and conditions of the ROW grant, §§ 2805.12(a)(4) and 2805.14(d), and any BLM approved operations, maintenance, and fire prevention plan.

Proposed paragraph (b)(1) of this section describes the circumstances under which a holder would need to request approval to conduct vegetation management activities. Under proposed paragraph (b)(1)(i), a holder would need to seek approval from the BLM if the operations, maintenance, and fire prevention plan specifically requires prior approval. Prior approval for an activity may be required in an operations, maintenance, and fire prevention plan if the activity could have cultural or environmental impacts.

Prior approval would be required under proposed paragraph (b)(1)(ii) if the activity is not described in an approved operations, maintenance, and fire prevention plan. Proposed paragraph (b)(2) of this section describes how the BLM would be required to respond to requests under paragraph (b)(1) of this section. If the BLM does not respond to a request within the timeframe described in an approved operations, maintenance, and fire prevention plan, and the vegetation management activity is consistent with the holder's approved operations, maintenance, and fire prevention plan, a holder may proceed with the vegetation treatment activities. This provision would enhance the approval process for vegetation management activities to further support the goals of reducing fire risk.

Holders who do not have a BLM approved operations, maintenance, and fire prevention plan would not be affected by paragraphs (b)(1) or (b)(2) of this section, which describe how activities would be required to comply with operations, maintenance, and fire prevention plans. Existing holders would not have an operations, maintenance, and fire prevention plan until they amend or renew their ROW grant, or until they voluntarily submit an operations, maintenance, and fire prevention plan. The terms and conditions of some existing grants do not sufficiently describe the vegetation management activities that a holder may take. In the absence of an operations, maintenance, and fire prevention plan, holders would be required to comply with the terms and conditions of the grant and §§ 2805.12(a)(4) and 2805.14(d). Even when not required,

holders would be encouraged to submit operations, maintenance, and fire prevention plans for existing ROWs to the BLM to improve coordination regarding vegetation management and wildfire risk reduction.

Proposed paragraph (c) mirrors § 2805.12(a)(4) but adds specific examples of reasonable actions that could be taken by the holder, including pruning or removal of vegetation and cooperation with the BLM to investigate, suppress, or respond to wildfires.

Subpart 2806—Annual Rents and Payments

Section 2806.13 What happens if I do not pay rents and fees or if I pay the rents or fees late?

In proposed § 2806.13(e), the provisions for uncollected or under-collected rent would be modified by removing paragraphs (e)(1), (e)(2), and (e)(3). The current regulations unnecessarily restrict the BLM to only collecting uncollected or under-collected rent in certain circumstances. The proposed rule would remove those conditions, and the BLM would be able to collect any rents and fees due to the United States.

In new proposed § 2806.13(h), the BLM is explicitly providing that rent would be due regardless of whether a courtesy bill has been sent or received. This addition would clarify current BLM practice to the public.

Section 2806.14 Under what circumstances am I exempt from paying rent?

In proposed § 2806.14(a)(4), the provisions governing communications sites would be deleted. The exemptions described in proposed § 2866.14(b) encapsulate the language that would be removed from § 2806.14.

Section 2806.15 Under what circumstances may BLM waive or reduce my rent?

The BLM received feedback from customers about inconsistencies in how waivers or reductions in rent are approved. Therefore, proposed § 2806.15(b) would clarify that a BLM State Director is the authorizing official with respect to rental reductions and waivers.

Under existing paragraph (b)(3) of this section, the BLM could reduce or waive rent if a holder has a ROW in connection with the grant at issue and for which the United States receives compensation. Proposed paragraph (b)(3) of this section would replace the existing provision to allow for a reduction or waiver of rent if a holder's grant describes the use of existing routes outside of the ROW that are used to access the ROW. These proposed revisions are consistent with proposed § 2805.11(b), which would require the grant to include and identify new and/or existing routes that would be used for ingress and egress. The BLM could charge rent appropriate to the nature of these access routes. For instance, where ROW access is facilitated by existing routes that are open to public use, rent would likely not be appropriate. By contrast, the BLM could charge appropriate rent for roads to ROWs on public lands newly constructed by a holder. See the preamble discussion of 2805.11 for more information.

Existing § 2806.15(c) would be redesignated as § 2806.15(b)(5) and revised to maintain consistency with the edits made in § 2806.15(b). With the added reference to the BLM State Director in proposed paragraph (b) of this section, it is appropriate to redesignate existing paragraph (c) as proposed paragraph (b)(5). Waiving or reducing rent under paragraphs (b)(1) through (b)(5), as revised by this proposed rule, would be at the discretion of the BLM State Director. This proposed revision is consistent with existing BLM practice.

Section 2806.20 What is the rent for a linear right-of-way grant?

The proposed section would revise paragraph (c) to update the contact address of the BLM and highlight availability of the Per Acre Rent Schedule on the BLM website.

Sections 2806.30 Through 2806.44

The proposed rule would remove §§ 2806.30 through 2806.44, including the header ''COMMUNICATION SITE RIGHTS–OF–WAY'' between §§ 2806.26 and 2806.30. Many of the requirements of these sections would be moved into new part 2860, which would consolidate all requirements for communications uses. Any substantive changes to those requirements are discussed in the sections of this preamble focused on new part 2860. The following table shows where the requirements of existing §§ 2806.30 through 2806.44 can be found in this proposed rule.

TABLE 2—CURRENT SUBPART 2806 VS. PROPOSED SUBPART 2866

Current section	Current title	Proposed section	Proposed title
Subpart 2806	Annual Rents and Payments	Subpart 2866	Annual Rents and Payments.
§ 2806.30	What are the rents for communication site rights-of-way?	§ 2866.30	What are the rents for Communications Uses?
§ 2806.31	How will BLM calculate rent for a right-of-way for communication uses in the schedule?	§ 2866.31	How will the BLM calculate rent for Communications Uses in the schedule?
§ 2806.32	How does BLM determine the population strata served?	§ 2866.32	How does the BLM determine the population strata served for your facility?
§ 2806.33	How will BLM calculate the rent for a grant or lease authorizing a single use communication facility?	§ 2866.33	How will the BLM calculate the rent for a single use communication facility?
§ 2806.34	How will BLM calculate the rent for a grant or lease authorizing a multiple-use communication facility?	§ 2866.34	How will the BLM calculate the rent for a grant for a multiple-use communication facility?
§ 2806.35	How will BLM calculate rent for private mobile radio service (PMRS), internal microwave, and ''other'' category uses?	§ 2866.35	How will the BLM calculate rent for private mobile radio service (PMRS), internal microwave, and ''other'' category uses?
§ 2806.36	If I am a tenant or customer in a facility, must I have my own grant or lease and if so, how will this affect my rent?	§ 2866.36	If I am a tenant or customer in a facility, must I have my own grant and if so, how will this affect my rent?

TABLE 2—CURRENT SUBPART 2806 VS. PROPOSED SUBPART 2866—Continued

Current section	Current title	Proposed section	Proposed title
§ 2806.37	How will BLM calculate rent for a grant or lease involving an entity with a single use (holder or tenant) having equipment or occupying space in multiple BLM-authorized facilities to support that single use?	§ 2866.37	How will the BLM calculate rent for a grant involving an entity with a single use (holder or tenant) having equipment or occupying space in multiple BLM-authorized facilities to support that single use?
§ 2806.38	Can I combine multiple grants or leases for facilities located on one site into a single grant or lease?	§ 2866.38	Can I combine multiple grants for facilities located at one site into a single grant?
§ 2806.39	How will BLM calculate rent for an lease for a facility manager's use?	§ 2866.39	How will the BLM calculate rent for an grant for a facility manager's use?
§ 2806.40	How will BLM calculate rent for a grant or lease for ancillary communication uses associated with communication uses on the rent schedule?	§ 2866.40	How will the BLM calculate rent for an authorization for ancillary Communications Uses associated with Communications Uses on the rent schedule?
§ 2806.41	How will BLM calculate rent for communication facilities ancillary to a linear grant or other use authorization?	§ 2866.41	How will the BLM calculate rent for communications facilities ancillary to a linear grant or other use authorization?
§ 2806.42	How will BLM calculate rent for a grant or lease authorizing a communication use within a federally-owned communication facility?	§ 2866.42	How will the BLM calculate rent for Communications Uses within a federally owned communications facility?
§ 2806.43	How does BLM calculate rent for passive reflectors and local exchange networks?	§ 2866.43	How does the BLM calculate rent for passive reflectors and local exchange networks?
§ 2806.44	How will BLM calculate rent for a facility owner's or facility manager's grant or lease which authorizes communication uses?	§ 2866.44	How will the BLM calculate rent for a facility owner's or facility manager's grant which authorizes Communications Uses?

Section 2806.52 Rents and Fees for Solar Energy Development Grants

The proposed section would revise paragraphs (a)(6) and (b)(2) to update the contact address of the BLM and highlight availability of the current solar energy acreage rent schedule and the current MW rate schedule for solar energy development on the BLM website.

Section 2806.62 Rents and Fees for Wind Energy Development Grants

The proposed section would revise paragraphs (a)(7) and (b)(2) to update the contact address of the BLM and highlight availability of the current wind energy acreage rent schedule and the current MW rate schedule for wind energy development on the BLM website.

Subpart 2807—Grant Administration and Operation

Section 2807.12 If I hold a grant, for what am I liable?

The proposed rule would redesignate existing paragraph (g) of this section as paragraph (h) and add a new paragraph (g). Proposed paragraph (g) of this section would codify the liability provisions at Section 512(g) of FLPMA and describe when the BLM may not impose strict liability.

Under proposed § 2805.21 of the proposed rule, the BLM would require operations, maintenance, and fire prevention plans for all new, renewed, or amended electric transmission and distribution ROWs; plans could be submitted to the BLM on a voluntary basis by holders of existing electric transmission and distribution ROWs and other types of ROWs. Operations, maintenance, and fire prevention plans would be advantageous to both the BLM and the ROW holder by better defining authorized activities, schedules for maintenance, and wildfire risk reduction measures, and by introducing limits on the ROW holder's liability under the specific circumstances described in this section.

Under proposed paragraph (g)(1) of this section, the BLM could not impose strict liability for damages or injuries resulting when the BLM unreasonably withholds or delays approval of an operations, maintenance, and fire prevention plan. Under paragraph (g)(2) of this section, the BLM could not impose strict liability if the BLM fails to adhere to an applicable schedule in an approved operations, maintenance, and fire prevention plan or agreement.

Section 2807.17 Under what conditions may the BLM suspend or terminate my grant?

The proposed rule would amend § 2807.17(b)(2) to change the word ''terminate'' to ''relinquish.'' This change would make this section consistent with changes to § 2886.17 and would align with the nomenclature that the BLM uses when processing ROWs. The proposed rule would also add § 2807.17(b)(3) to allow the BLM to terminate a ROW grant when a court terminates or requires the BLM to terminate the ROW. The proposed rule would redesignate paragraph (b)(3) as paragraph (b)(4).

Section 2807.20 When must I amend my application, seek an amendment of my grant, or obtain a new grant?

The proposed rule would amend paragraph (b) of this section by replacing ''processing and monitoring fees'' with ''cost recovery fees,'' for consistency with other revisions in this proposed rule.

Section 2807.20(d) explains that pre-FLPMA (before Oct. 21, 1976) grants cannot be amended, renewed, or reinstated.

Section 706 of the FLPMA repealed numerous laws to the extent they applied to the issuance of ROWs by the BLM. Once a law has been repealed, the BLM can no longer approve any actions under the repealed law. The proposed rule would combine existing language from different parts of paragraph (d), including paragraph (d)(2), as proposed paragraph (d)(1) and would revise the text to clarify that, when a holder seeks to amend a pre-FLPMA grant, the BLM would retain the holder's pre-FLPMA ROW for the portion of the holder's ROW not affected by the holder's amendment application unless the

holder agrees to accept a wholly new and comprehensive grant of the ROW under FLPMA.

Proposed paragraph (d)(2) would require a new application and grant for expiring authorizations. Proposed paragraph (d)(3) would require a new application and grant if a pre-FLPMA authorization is terminated due to non-compliance. Finally, existing paragraph (d)(1) is redesignated as proposed paragraph (d)(4) and notes that the BLM would issue any new authorization under the authority of the FLPMA and explains that the new authorization may have the same terms and conditions and annual rents as the original grant.

Section 2807.22 How do I renew my grant?

The proposed rule would establish new customer service standards for the BLM for renewal applications. The proposed rule would modify paragraph (f) of this section to establish a customer service standard of 60 days for the BLM to review an application for a renewal to determine if that application has been timely submitted and is complete and to notify the applicant in writing of the BLM's determination. If the BLM determines that a renewal application was timely submitted and is complete, then its written notice would confirm that, until the BLM issues a decision on the renewal application, the holder's existing grant would remain valid, provided that the holder of the authorization remains in compliance, including with rent and bonding obligations.

The proposed rule would add a new paragraph (h) to this section to provide grant holders a clear understanding of when their renewal applications would be subject to the BLM's customer service standards. If grant holders do not comply with the existing requirement to submit their application at least 120 days before their grant expires, the BLM would not be held to the customer service standards for processing the application.

This proposed paragraph would not be a substantive change from existing practice.

Subpart 2809—Competitive Process for Leasing Lands for Solar and Wind Energy Development Inside Designated Leasing Areas

Section 2809.19 Applications in Designated Leasing Areas or on Lands That Later Become Designated Leasing Areas

The proposed rule would revise paragraph (d) of this section by updating a reference to a section that would be redesignated by this proposed rule. The reference to § 2805.11(b)(2) would be revised to read § 2805.11(c)(2). This change is necessary for consistency with proposed revisions to § 2805.11.

43 CFR Part 2860 Communications Uses

The proposed rule would establish part 2860, Communications Uses. This proposed part would explain the requirements for communications uses grants and consolidate all communications use-specific provisions into one location. The requirements of part 2800 would apply to communications uses grants, unless otherwise described in this new part. Some sections in proposed part 2860 would contain the requirements of sections that would be removed from part 2800. Some sections in 2860 have a direct parallel to existing part 2800 but contain additional requirements that would apply specifically to communications uses. This preamble describes how the proposed rule differs from existing requirements. Proposed subparts 2861 through 2865 and 2868 are based on the requirements in existing subparts 2801 through 2805 and 2808, respectively, but contain additional communications use requirements. Table 3 shows the relationship between proposed subparts 2861 through 2865 and 2868 and existing subparts 2801 through 2805 and 2808. Most of the requirements pertaining to communications uses in existing subpart 2806 would be moved to proposed subpart 2866. Table 4 shows the relationship between proposed subpart 2866 and existing subpart 2806. This preamble describes proposed new or revised provisions. Provisions not discussed are substantially similar to their existing counterpart.

TABLE 3—SECTIONS OF THE PROPOSED RULE SUPPLEMENTING THE 2800 REGULATIONS FOR COMMUNICATIONS USES

Current section	Current title	Proposed section	Proposed title
Subpart 2801	General Information	Subpart 2861	General Information.
New Section		§ 2861.1	What requirements of part 2800 apply to my grant?
§ 2801.2	What is the objective of BLM's right-of-way program?	§ 2861.2	What is the objective of the BLM's Communications Uses program?
§ 2801.5(b)	What acronyms and terms are used in the regulations in this part?	§ 2861.5(b)	What acronyms and terms are used in the regulations in this part?
§ 2801.8	Severability.	§ 2861.8	Severability.
§ 2801.9(a)(5)	When do I need a grant?	§ 2861.9	When do I need a grant?
Subpart 2802	Lands Available for FLPMA Grants	Subpart 2862	Lands Available for Grants.
§ 2802.11	How does the BLM designate right-of-way corridors and designated leasing areas?	§ 2862.11	How does the BLM designate communications sites and establish communications site management plans?
Subpart 2804	Applying for FLPMA Grants	Subpart 2864	Applying for Grants.
§ 2804.10	Who may hold a grant?	§ 2864.10	What should I do before I file my application?
§ 2804.12	What must I do when submitting my application?	§ 2864.12	What must I do when submitting my application?
§ 2804.24	Do I always have to submit an application for a grant using Standard Form 299?	§ 2864.24	Do I always have to use Standard Form 299 when submitting my application for a grant?
§ 2804.25	How will BLM process my application?	§ 2864.25	How will the BLM process my Communications Uses application?
§ 2804.26	Under what circumstances may BLM deny my application?	§ 2864.26	Under what circumstances may the BLM deny my application?
§ 2804.35	How will the BLM prioritize my solar or wind energy application?	§ 2864.35	How will the BLM prioritize my Communications Uses application?
Subpart 2805	Terms and Conditions of Grants	Subpart 2865	Terms and Conditions of Grants.

TABLE 3—SECTIONS OF THE PROPOSED RULE SUPPLEMENTING THE 2800 REGULATIONS FOR COMMUNICATIONS USES—Continued

Current section	Current title	Proposed section	Proposed title
§ 2805.14	What rights does a grant provide?	§ 2865.14	What rights does a grant provide?
Subpart 2808	Trespass	Subpart 2868	Communications Uses Trespass.
§ 2808.10	What is a trespass?	§ 2868.10	What is a Communications Uses trespass?

Subpart 2861—General Information

Section 2861.1 What requirements of part 2800 apply to my grant?

This section explains that the requirements of part 2800 would apply to communications uses grants unless a provision in part 2860 provides otherwise. Part 2800 of the existing and proposed regulations describes requirements for general ROWs. Part 2860 describes requirements that would specifically apply to communications uses grants, which are generally in addition to the requirements described in part 2800.

Section 2861.2 What is the objective of the BLM's Communications Uses program?

Proposed § 2861.2 describes the objectives of the communications uses program. It is based on existing § 2801.2.

Proposed paragraph (b) in this section describes the BLM's objectives of administering the communications uses program through responsible development on the BLM-administered lands and providing a safe environment. This proposed paragraph would not constitute a substantive change from existing policy.

Proposed paragraph (d) of this section explains that the BLM would collect market value rent for communications uses authorized on public lands as required under 43 U.S.C. 1764.

Proposed paragraph (e) describes the BLM's objective of promoting the expansion of communications uses in rural America. The proposed changes in this section reflect E.O. 13821, which directs the BLM to promote communications uses on public land in rural America. The words ''wherever practical'' would be included for consistency with the changes to the objectives in § 2801.2.

Section 2861.5 What acronyms and terms are used in the regulations in this part?

Proposed § 2861.5 defines terms that are specific to communications uses. The proposed section includes terms currently defined in existing § 2801.5. New definitions are proposed to be added to provide clarity for the public when the BLM is administering an authorization for communications uses.

The definitions for ''RMA,'' ''Base Rent,'' ''Customer,'' ''Facility Manager,'' ''Facility Owner,'' ''Site,'' and ''Tenant'' would be moved from § 2801.5, the definitions of ''Facility'' and ''Grant'' would be copied from § 2801.5, and those definitions would be revised slightly to reflect their specific application in the context of communications uses.

The proposed rule would add the term and a definition of ''Annual inventory certification'' to clarify the nature of the document that a holder must provide on an annual basis (see existing § 2806.31(c) and proposed § 2866.31(c)).

The proposed rule would add the term and a definition of ''collocation'' to clarify when an occupant is collocated within or on a holder's facility. This concept is relevant for communications uses rent (see proposed § 2866.31) and when a grant would be required (see proposed § 2866.36).

The proposed rule would add the term and a definition of ''communications site'' to establish what is meant when describing a communications site within an authorization document. The lack of a definition caused confusion because, often, the BLM and industry refer to a ''communications site'' when they really mean a ''communications facility.'' This definition clarifies the difference between the terms.

The proposed rule would add the term and a definition of ''communications site management plans'' to clarify that these plans guide development and operations at communications sites. These plans may be called ''implementation level plans,'' meaning that they take action to implement a land use plan (generally a Resource Management Plan (RMP)), which contains standards and guidelines and describes the communications uses that are allowed or restricted at a communications site. The BLM identifies and names communications sites through the preparation of a communications site management plan. Additionally, the communications site management plan provides holders and future proponents with the development conditions for a particular site.

The proposed rule would add the term and a definition of ''communications uses'' to describe the types of uses considered to be a communications use. This definition includes all ROW uses to which part 2860 would apply.

The definition for the term ''Communications uses rent schedule'' would be moved here from § 2801.5. The change is necessary to maintain consistency in terminology throughout the new proposed part 2860. The term ''communications uses rent schedule'' would continue to apply to all types of communications uses identified in existing § 2801.5 for purposes of identifying and collecting rent, and it would also apply to the following additional uses proposed to be added to this definition: ''facility manager,'' ''internet service provider (ISP),'' ''passive reflector,'' and ''local exchange network.''

The proposed rule would add the term and definition of ''duly filed application'' to explain that it is an application which includes all the elements required by § 2804.25.

The proposed rule would add the term and a definition of ''occupant.'' Occupants are entities, other than the holder of a grant, which use a facility covered by that authorization.

Section 2861.8 Severability

Proposed § 2861.8 is based on the existing § 2801.8 (and also parallels § 2881.9, which is proposed to be changed to § 2881.8) and would provide that any decision finding any provisions in part 2860 to be invalid would not affect the remaining provisions, which would remain in force.

Section 2861.9 When do I need a grant?

Proposed § 2861.9 is based on the existing § 2801.9 and would describe and provide some examples of when an authorization is needed to use public lands for communications uses.

Proposed paragraph (a) of this section provides that an authorization would be required when installing a facility that

is not under a current valid authorization. This is not a new requirement and is consistent with current BLM practice.

Proposed paragraph (b) of this section explains that an authorization would be required when installing a linear communications facility, such as a fiber optic cable. Due to the communications nature of fiber optic cables and telephone lines, proposed part 2860 is an appropriate location for regulations administering these communications uses.

Subpart 2862—Lands Available for Grants

Section 2862.11 How does the BLM designate communications sites and establish communications site management plans?

Proposed § 2862.11 would describe how the BLM designates communications sites and when communications site management plans are prepared.

This proposed section is based on existing § 2802.11, which describes how the BLM designates ROW corridors and designated leasing areas.

Under proposed § 2862.11(a), the BLM would coordinate in the preparation of the communications site management plans with other Federal agencies, State, local, and Tribal governments, and the public, consistent with the coordination requirements of existing § 2802.11(a).

Proposed paragraph (b) would identify factors the BLM considers when determining land suitability for communications uses, in addition to the factors described in existing § 2802.11(b).

Proposed paragraph (c) describes how the BLM would establish communications site management plans. As described under the definition for the plans, they are implementation-level plans that tier to the applicable RMP.

While communications site management plans are generally adopted outside the land use planning process, the BLM often refers to these plans in RMPs. The identification of communications sites and the adoption of their complementary management plans must be supported by appropriate NEPA analysis, which could take the form of an applicable categorical exclusion or determination of NEPA adequacy.

Subpart 2864—Applying for Grants

Section 2864.10 What should I do before I file my application?

Proposed § 2864.10 is based on existing § 2804.10.

Proposed § 2864.10(a) describes the purpose of a preliminary application review meeting. Preliminary application review meetings provide valuable information and reveal project constraints to proponents. This information should result in more thorough and complete applications that would streamline BLM application processing, consistent with E.O. 13821 and a Presidential Memorandum directed to the Secretary, both issued on January 8, 2018. A preliminary application review meeting is not a requirement but is strongly encouraged.

Proposed paragraph (b) would prompt applicants to ask the BLM for a copy of any applicable communications site management plan for the site of the proposed project. Having a communications site management plan would assist the applicant in developing a project proposal consistent with the communications site management plan and streamline the processing of an application.

Paragraph (c) would specify what an applicant should acquire before submitting an application to the BLM. A complete communications uses application almost always requires proof of an FCC license. If an applicant already has included a license as part of its application, it eliminates the need for the BLM to request that information, and thereby cuts down on processing times.

Section 2864.12 What must I do when submitting my application?

Proposed § 2864.12 would describe the supplemental information needed to accompany the SF–299, which is required for all communications uses applications. Proposed § 2864.12 is based on existing § 2804.12 but proposes additional specific communications uses requirements for applications. Existing § 2804.12(f) states that the BLM may require you to submit additional information during the processing of your application. This proposed section standardizes the requirements specific to communications uses, to streamline the application process for these types of authorizations.

Proposed paragraph (a) of this section would clarify that when an application for a ROW is filed electronically, an actual signature may not be required. Instead of a manual signature, the applicant could meet the BLM's standards for electronic commerce. This proposed revision would allow applicants to file their applications electronically. These changes would streamline application submissions and allow for more flexibility in how applications are submitted.

Proposed paragraph (a)(1) of this section refers to § 2804.12 for a list of attachments that should be included in all applications.

Proposed paragraph (a)(2) would require an applicant to provide proof of their FCC license. This requirement is consistent with current BLM practice, and the BLM proposes to incorporate this requirement into the regulations to notify applicants what to expect. There is no expectation that this new language would create any additional burden for communications uses applicants.

Paragraph (a)(3) of this section would require an applicant to submit the GIS shapefiles for a map of the proposed project. That requirement is consistent with proposed changes to § 2804.12(a)(4), which already requires an applicant to submit a map of the proposed project and would further require the applicant to submit GIS shapefiles, upon request, under the proposed rule. When a BLM office is conducting a NEPA analysis, it is not uncommon for the various resource specialists to request that an applicant provide project data electronically in a GIS format. It is also likely the individual or entity responsible for the application already has the proposed project in a GIS format, and therefore, the BLM would not be adding a significant burden upon the applicant. This new requirement would be expected to reduce application processing times by allowing the BLM to integrate project locations into existing resource datasets and analyze the potential resource impacts more quickly.

Paragraph (a)(4) of this section would require an application to include draft engineering or construction drawings. By including these drawings, applicants could expect faster application processing times. An applicant usually produces draft construction drawings before an applicant intends to submit their application, so the BLM does not expect this requirement to create any additional burden. The BLM expects that the inclusion of this information in the application would streamline application processing times.

Paragraph (a)(5) of this section would require that a communications uses application include technical data related to communication equipment used in and on the proposed facility. The proposed rule would specify the

types of technical data, such as frequencies and power output of the proposed use, that applicants must submit to allow the BLM to determine whether the proposed use would be consistent with the applicable communications site management plan and would be compatible with existing communications uses at the proposed communications site. This provision is consistent with current BLM policy, which requires this information from applicants.

Paragraph (a)(6) would require an applicant to provide a communications uses plan of development (POD) in support of an application. The BLM may require a POD for an application under existing § 2804.25(c). The POD is an essential tool for the BLM to understand the scope and complexity of the proposed project. A complete POD can drastically reduce the time spent on processing an application, primarily during the NEPA process. Current BLM policy requires a POD be submitted with all applications and the proposed rule would not be expected to create any additional burden on the applicant.

Proposed paragraph (b) would state that the BLM may require additional information from an applicant about their application while it is being processed. For example, the BLM may require an applicant to submit information about the applicant's plans to comply with a visual plan included in the RMP for the area (*e.g.,* paint color or stealth design). The proposed changes explain that the BLM would not process an application until the additional information has been submitted. The BLM anticipates this change would help expedite application review and processing. This proposed paragraph is based on existing § 2804.12(f).

Section 2864.24 Do I always have to use Standard Form 299 when submitting my application for a grant?

Proposed § 2864.24 would require that the SF–299 be used for all communications uses applications, consistent with Section 606(b)(2) of the MOBILE NOW Act. This proposed section would be consistent with current BLM practice, as well as that of many other Federal agencies, and would clarify requirements to the applicant.

Section 2864.25 How will the BLM process my Communications Uses application?

Proposed § 2864.25 provides that the BLM would process communications uses applications consistent with existing § 2804.25. In addition, this section would require the BLM to approve or deny a duly filed application for a grant within 270 days. This is in accordance with the MOBILE NOW Act, which requires Federal agencies to approve or deny a communications facility installation application within 270 days of receiving a duly filed application. The BLM anticipates this new regulation would shorten application processing times and establish consistency among BLM offices.

Section 2864.26 Under what circumstances may the BLM deny my application?

Proposed § 2864.26 is based on existing § 2804.26 and describes when an application for communications uses may be denied. Reasons for denial include the provisions of existing § 2804.26, along with reasons specific to communications uses, such as interference with other communications users.

Proposed paragraph (a) of this section is based on § 2804.26(a)(1), which states that an application may be denied if the proposed use is inconsistent with any other previously authorized ROW, including communications uses on the public lands. It is the goal of the BLM to allow multiple communications uses within a communications site area if they are compatible with one another. Existing communications uses ROW authorization holders would be given the opportunity during the application process to provide evidence of potential interference with their use. The BLM would evaluate any such evidence to determine if the subsequently proposed communications uses might potentially interfere with the previously authorized communications uses, and if so, whether a denial is warranted under the circumstances.

Under proposed paragraphs (b) and (c) of this section, an application could be denied if the proposed use presents a public health or safety issue or is not in conformance with the RMP or communications site management plan.

Section 2864.35 How will the BLM prioritize my Communications Uses application?

Proposed § 2864.35 describes how the BLM would prioritize applications for grants. This section is based on existing § 2804.35, which describes how the BLM prioritizes solar and wind applications. Under this proposed section, the BLM would prioritize processing applications for grants that meet the needs of underserved, rural, and Tribal communities, as well as first responders. The BLM would like the public to comment on any further criteria the BLM should consider when prioritizing processing communications uses applications.

This proposed section was added in response to E.O. 13821, discussed earlier in this preamble.

Subpart 2865—Terms and Conditions of Grants

Section 2865.14 What rights does a grant provide?

Proposed § 2865.14 would describe the rights provided by a grant, in addition to the rights described in existing § 2805.14.

Proposed paragraph (a) of this section is based on existing § 2805.14(a) and would be revised to clarify that only facilities explicitly allowed by an authorization are acceptable.

Proposed paragraph (b) of this section is based on existing § 2805.14(b) and would describe when the holder of an authorization may allow subleasing of their facilities to others. The term ''subleasing'' is added to maintain consistency with current BLM policy when administering grants. Currently, many authorizations are managed by another entity that was not approved by the BLM. This paragraph would clarify what an authorization may allow.

Proposed paragraph (c) of this section is based on existing § 2805.14(c) and states that the authorization holder may allow another entity to conduct day-to-day operations of the facility, as authorized by the BLM. The existing section describes access to lands, but the proposed rule would instead refer to ''lands or facilities.'' This change is consistent with other changes to the regulations proposed to be moved to part 2860, which are intended to acknowledge that an authorization may be either a grant to use a facility or a grant for the use of public lands.

Proposed paragraph (d) of this section would set the standard length for a grant at 30 years. The BLM considers a 30-year-term to be consistent with Section 504(b) of FLPMA's ''reasonable term'' limitation, and that interpretation would be carried forward for grants. The BLM could determine in a given case that a shorter term is appropriate for an authorization. For example, a BLM office could determine the resource issues at the proposed site, such as environmental or Tribal concerns, may warrant a shorter term for the authorization.

Subpart 2866—Annual Rents and Payments

Proposed subpart 2866 would contain the rental requirements for grants. Many of the sections would be moved from

existing subpart 2806 with no substantive changes from existing requirements. The proposed changes from existing requirements are intended to streamline the rental process for communications uses and are discussed in detail in the following section-by-section analysis. The following chart shows which sections of existing subpart 2806 would be moved into proposed subpart 2866.

TABLE 4—PROPOSED SUBPART 2866 VS EXISTING SUBPART 2806

Section 2866 based on or moved from 2806			
Current section	Current title	Proposed section	Proposed title
Subpart 2806	Annual Rents and Payments	Subpart 2866	Annual Rents and Payments.
Based on § 2806.14	Under what circumstances am I exempt from paying rent?	§ 2866.14	Under what circumstances am I exempt from paying rent?
Based on § 2806.15	Under what circumstances may BLM waive or reduce my rent?	§ 2866.15	Under what circumstances may the BLM waive or reduce my rent?
Based on § 2806.23	How will the BLM calculate my rent for linear rights-of-way the Per Acre Rent Schedule covers?	§ 2866.23	How will the BLM calculate my rent for linear rights-of-way for Communications Uses?
Moved from § 2806.30	What are the rents for communication site rights-of-way?	§ 2866.30	What are the rents for Communications Uses?
Moved from § 2806.31	How will BLM calculate rent for a right-of-way for communication uses in the schedule?	§ 2866.31	How will the BLM calculate rent for Communications Uses in the schedule?
Moved from § 2806.32	How does BLM determine the population strata served?	§ 2866.32	How does the BLM determine the population strata served for your facility?
Moved from § 2806.33	How will BLM calculate the rent for a grant or lease authorizing a single use communication facility?	§ 2866.33	How will the BLM calculate the rent for a single use communication facility grant?
Moved from § 2806.34	How will BLM calculate the rent for a grant or lease authorizing a multiple-use communication facility?	§ 2866.34	How will the BLM calculate the rent for a multiple-use communication facility grant?
Moved from § 2806.35	How will BLM calculate rent for private mobile radio service (PMRS), internal microwave, and ''other'' category users?	§ 2866.35	How will the BLM calculate rent for private mobile radio service (PMRS), internal microwave, and ''other'' category uses?
Moved from § 2806.36	If I am a tenant or customer in a facility, must I have my own grant or lease and if so, how will this affect my rent?	§ 2866.36	If I am a tenant or customer in a facility, must I have my own grant and if so, how will this affect my rent?
Moved from § 2806.37	How will BLM calculate rent for a grant or lease involving an entity with a single use (holder or tenant) having equipment or occupying space in multiple BLM-authorized facilities to support that single use?	§ 2866.37	How will the BLM calculate rent for a grant involving an entity with a single use (holder or tenant) having equipment or occupying space in multiple BLM-authorized facilities to support that single use?
Based on § 2806.38	Can I combine multiple grants or leases for facilities located on one site into a single grant or lease?	§ 2866.38	Can I combine multiple grants for facilities located at one site into a single grant?
Moved from § 2806.39	How will BLM calculate rent for a lease for a facility manager's use?	§ 2866.39	How will the BLM calculate rent for a grant for a facility manager's use?
Moved from § 2806.40	How will BLM calculate rent for a grant or lease for ancillary communication uses associated with communication uses on the rent schedule?	§ 2866.40	How will the BLM calculate rent for an authorization for ancillary Communications Uses associated with Communications Uses on the rent schedule?
Based on § 2806.41	How will BLM calculate rent for communication facilities ancillary to a linear grant or other use authorization?	§ 2866.41	How will the BLM calculate rent for communications facilities ancillary to a linear grant or other use authorization?
Based on § 2806.42	How will BLM calculate rent for a grant or lease authorizing a communication use within a federally-owned communication facility?	§ 2866.42	How will the BLM calculate rent for Communications Uses within a federally owned communications facility?
Moved from § 2806.43, but the terms would be moved to § 2861.5.	How does BLM calculate rent for passive reflectors and local exchange networks?	§ 2866.43	How does the BLM calculate rent for passive reflectors and local exchange networks?
Moved from § 2806.44	How will BLM calculate rent for a facility owner's or facility manager's grant or lease which authorizes communication uses?	§ 2866.44	How will the BLM calculate rent for a facility owner's or facility manager's grant which authorizes Communications Uses?

For a discussion of the sections in subpart 2806 that would be removed by this proposed rule, see the preamble discussion of subpart 2806.

Section 2866.14 Under what circumstances am I exempt from paying rent?

Proposed § 2866.14 describes when a holder would be exempt from paying rent. Proposed paragraph (a)(1) of this section states that Federal, State, and local governments, along with their instrumentalities, would be exempt from paying rent. Proposed paragraphs (a)(2) and (a)(3) carry over from paragraphs (a)(3) and (a)(4) of § 2806.14. Proposed paragraph (b) describes the proposed exceptions to these exemptions.

Under paragraph (b)(1) of this section, a holder would not be exempt from paying rent if the holder is in trespass. This is not a change from existing requirements but would be added to the regulations to provide clarity to holders.

Proposed paragraphs (b)(2)(i) and (b)(2)(ii) would explain that a State or local government entity would not be exempt from paying rent when the facility is being used for commercial purposes or when the principal source of revenue is generated from customer use charges. These requirements are consistent with existing § 2804.16(a).

Under new paragraph (b)(2)(iii), a State or local government entity would not be exempt from rent if it charges rent to the United States Government for occupancy within an exempt facility (above routine operation and maintenance costs). Currently, the BLM and other Federal agencies are often charged rent to occupy space in another governmental (State or local

government) facility when their authorization to occupy the public lands is exempt from rental. The BLM is proposing this change to reciprocate rent exemptions for the United States. The provisions of this section are intended to ensure that the Federal Government is charged reasonable rates for maintenance and operations only.

Section 2866.15 Under what circumstances may the BLM waive or reduce my rent?

Proposed § 2866.15 would include rental reduction or waiver provisions that would apply specifically to the communications uses program.

Under proposed paragraph (a) of this section, the BLM could waive or reduce rent for holders that are licensed by the FCC as non-commercial and educational broadcasters.

Under proposed paragraph (b) of this section, the BLM could waive or reduce rent for amateur radio clubs that provide a benefit to the general public or to the programs of the Secretary, for verified nonprofit organizations, or for entities that can demonstrate undue hardship and public interest. A holder could request a waiver or reduction in rent under proposed § 2806.15(b)(5).

Paragraph (c) of this section would describe when the BLM could not waive or reduce rent. These exceptions include when an organization operates for the benefit of its members; when any portion of the authorized facility is being used for commercial purposes; when the holder is charging the United States to occupy a facility; and when a holder charges fees beyond reasonable operation and maintenance for the occupants whose use is normally exempt or waived by the BLM. This provision would be consistent with proposed § 2866.14(b)(2).

Paragraph (d) of this section would describe when the BLM would revoke a holder's waiver of rent. Under paragraph (d) of this section, the BLM would revoke a holder's waiver if it determines that the authorization holder no longer meets the criteria for a waiver.

This proposed section would provide several additional ways by which the BLM could waive the rent of users who provide a public benefit and are not operating solely to make a profit. This proposed section would streamline our processes by demonstrating to the public when rent could be waived or reduced and by reducing the need for the BLM to further analyze a request.

Section 2866.23 How will the BLM calculate my rent for linear rights-of-way for Communications Uses?

Proposed § 2866.23 is based on existing § 2806.23 and would provide some additional clarification that linear communications uses, such as for fiber optic and telephone cable, would be charged rent using the linear ROW rent schedule found in § 2806.23. The communications uses rent schedule is specific to small areas, while the linear schedule is used for long and narrow ROWs, such as pipelines or power lines. Since a linear communications use is a long and narrow facility, the linear rent schedule is more appropriate.

Section 2866.30 What are the rents for Communications Uses?

While much of proposed part 2860 is based on sections of part 2800, which would remain as part of the proposed rule, the communications site rent provisions (proposed §§ 2866.30 through 2866.44) contain the provisions that would be moved from subpart 2806 to new subpart 2866. Changes from existing provisions are discussed in the following sections of this preamble.

Proposed § 2866.30 contains the provisions of existing § 2806.30. This proposed section describes how the BLM would assess annual rent for communications uses. Only the address for the BLM would be updated.

Section 2866.31 How will the BLM calculate rent for Communications Uses in the schedule?

Proposed § 2866.31 contains the provisions of existing § 2806.31 and there would be no substantive changes from existing requirements.

Section 2866.32 How does the BLM determine the population strata served for your facility?

Proposed § 2866.32 contains the provisions of existing § 2806.32 and there would be no substantive changes from existing requirements.

Section 2866.33 How will the BLM calculate the rent for a single use communication facility grant?

Proposed § 2866.33 contains the provisions of existing § 2806.33 and there would be no substantive changes from existing requirements.

Section 2866.34 How will the BLM calculate the rent for a multiple-use communication facility grant?

Proposed § 2866.34 contains the provisions of existing § 2806.34, and there would be no substantive changes from existing requirements.

Section 2866.35 How will the BLM calculate rent for private mobile radio service (PMRS), internal microwave, and ''other'' category uses?

Proposed § 2866.35 contains the provisions of existing § 2806.35, and there would be no substantive changes from existing requirements.

Section 2866.36 If I am a tenant or customer in a facility, must I have my own grant and if so, how will this affect my rent?

Proposed § 2866.36 contains the provisions of existing § 2806.36, and there would be no substantive changes from existing requirements.

Section 2866.37 How will the BLM calculate rent for a grant involving an entity with a single use (holder or tenant) having equipment or occupying space in multiple BLM-authorized facilities to support that single use?

Proposed § 2866.37 contains the provisions of existing § 2806.37, and there would be no substantive changes from existing requirements.

Section 2866.38 Can I combine multiple grants for facilities located at one site into a single grant?

Proposed § 2866.38 contains the provisions of existing § 2806.38 and would now require submittal of an SF 299 for BLM authorization to combine facilities into a single grant.

Section 2866.39 How will the BLM calculate rent for a grant for a facility manager's use?

Proposed § 2866.39 contains the provisions of existing § 2806.39, and there would be no substantive changes from existing requirements.

Section 2866.40 How will the BLM calculate rent for an authorization for ancillary Communications Uses associated with Communications Uses on the rent schedule?

Proposed § 2866.40 contains the provisions of existing § 2806.40, and there would be no substantive changes from existing requirements. The BLM considers ''ancillary'' communication facilities to be those used solely for the purpose of internal communications.

Section 2866.41 How will the BLM calculate rent for communications facilities ancillary to a linear grant or other use authorization?

Proposed § 2866.41 contains the provisions of existing § 2806.41, and there would be no substantive changes from existing requirements.

Section 2866.42 How will the BLM calculate rent for Communications Uses within a federally owned communications facility?

Proposed § 2866.42 contains the provisions of existing § 2806.42, and there would be no substantive changes from existing requirements.

Section 2866.43 How does the BLM calculate rent for passive reflectors and local exchange networks?

Proposed § 2866.43 contains the provisions of existing § 2806.43, except that the definitions for ''passive reflector'' and ''local exchange network'' have been added to proposed § 2861.5 instead.

Section 2866.44 How will the BLM calculate rent for a facility owner's or facility manager's grant which authorizes Communications Uses?

Proposed § 2866.44 contains the provisions of existing § 2806.44, and there would be no substantive changes from existing requirements.

Subpart 2868—Communications Uses Trespass

Section 2868.10 What is a Communications Uses trespass?

Proposed § 2868.10 is based on § 2808.10 but would provide for additional communications uses-specific circumstances that the BLM considers trespass. The intent of this section is to define a trespass so that facility owners and users understand how best to avoid unauthorized use.

Paragraph (a) would state that adding to or altering from the communications facilities described in the authorization without approval from the BLM would be a trespass.

Paragraph (b) of this section would state that facility owners who permit communications uses of other users by allowing them to sublease any portion of their facilities without approval would be considered a trespass.

Paragraph (c) would explain that natural structures, such as trees and rocks, may not be used to house or support equipment without the BLM's prior approval, and that doing so constitutes trespass. Using trees and rocks leads to unacceptable resource damage and is not a sustainable practice.

All the provisions in this section have been a part of BLM policy for years, but it became clear that there was some confusion by users as to exactly what the BLM considered trespass. The BLM believes that publishing these provisions as regulations would lead to a reduction in unauthorized use.

43 CFR Part 2880 Rights-of-Way Under the Mineral Leasing Act

The MLA requires that the applicant reimburse the United States for administrative and other costs incurred in processing the application. The BLM refers to such costs as ''actual costs'' and defines that term to include the financial resources the BLM expends in processing and monitoring ROW activities under the MLA, including the direct and indirect costs, exclusive of management overhead costs.

Section 28 of the MLA (30 U.S.C. 185(*l*)) requires applicants for either MLA pipeline ROWs or temporary use permit (TUPs) to reimburse the United States for administrative and other costs incurred in processing applications and monitoring the construction, operation, maintenance, and termination of any pipeline and related facilities.

The MLA does not limit or qualify the actual cost requirement, nor does it list any factors that the BLM may consider when determining reimbursable costs. The BLM bases actual cost information on Federal accounting and reporting systems. The BLM is proposing changes to part 2880 to provide consistency with the general ROW regulations of part 2800.

Subpart 2881—General Information

Section 2881.2 What is the objective of the BLM's right-of-way program?

The proposed rule would add the words ''wherever practical'' to the objective described in § 2881.2(c). This proposed change would be consistent with proposed § 2801.2(c). For a more detailed discussion, please see the preamble discussion for § 2801.2(c).

Section 2881.5 What acronyms and terms are used in the regulations in this part?

The BLM proposes to amend § 2881.5(b) for consistency with proposed § 2801.5. For a detailed discussion of these changes, please see the preamble discussion of proposed § 2801.5.

Section 2881.7 Scope.

The BLM proposes to amend paragraphs (a) and (b)(1) in § 2881.7. These modifications would clarify when an action would be processed under the regulations of part 2880 and when an action would be processed under the application for permit to drill (APD) regulations (43 CFR part 3160). Within the APD lease area, the BLM would process ''related facilities'' under the APD as defined in § 2881.5. Once a pipeline or related facility leaves the APD lease area and is outside the boundary of the APD lease area it would be considered ''off lease'' and, at the lease boundary, would become an activity processed under these regulations to the extent still on Federal land and subject to paragraph (b). Moreover, pipelines and related facilities operated by a party who is not the lessee or lease operator of a Federal oil and gas lease or that are downstream from a custody transfer metering device would be processed under these regulations regardless of whether the pipelines and related facilities are on or off lease.

These proposed changes would not impact oil and gas operators, who would still coordinate with the BLM to manage their pipelines and related facilities. The proposed rule would ensure consistency in BLM operations and how these facilities are managed under these regulations.

Section 2881.8 Severability.

The BLM proposes to redesignate § 2881.9 as 2881.8 to be consistent with the same sections in the 2800 and 2860 regulations.

Subpart 2883—Qualifications for Holding MLA Grants and TUPs

Section 2883.14 What happens to my grant or TUP if I die?

Because an application is not an inheritable interest, the BLM proposes to change the title of this section from ''What happens to my application, grant, or TUP if I die?'' to ''What happens to my grant or TUP if I die?'' Paragraph (a) would also be revised to remove the reference to the applicant and the application.

Subpart 2884—Applying for MLA Grants or TUPs

Section 2884.11 What information must I submit in my application?

The proposed rule would revise §§ 2884.11(a) and 2884.11(c)(6) for consistency with proposed § 2804.12. For a more detailed discussion of these proposed changes, see the preamble discussion of § 2804.12.

Section 2884.12 What are the fee categories for cost recovery?

The proposed rule would revise the title of this section to read, ''What are the fee categories for cost recovery?'' for consistency with proposed § 2804.14. For a detailed discussion of the other changes to this section, please see the preamble discussion of proposed § 2804.14.

Section 2884.13 When will the BLM waive cost recovery fees?

The proposed rule would revise the title of this section to read ''When will the BLM waive cost recovery fees?'' rather than ''Who is exempt from paying processing and monitoring fees?'' The BLM proposes to amend § 2884.13 for consistency with proposed § 2804.16. For a detailed discussion of these changes, please see the preamble discussion of proposed § 2804.16.

Section 2884.14 When does the BLM reevaluate the cost recovery fees?

The proposed rule would revise the title of this section to change ''processing and monitoring'' to ''cost recovery.'' This change is consistent with the proposed changes to § 2804.15.

Section 2884.15 What is a Master Agreement (Cost Recovery Category 5) and what information must I provide to the BLM when I request one?

The proposed rule would amend § 2884.15 to clarify the use of a Master Agreement and to replace the term ''processing and monitoring'' with ''cost recovery'' to be inclusive of administrative actions. These changes are consistent with the proposed changes to § 2804.17. For a more detailed discussion of these changes, please see the preamble discussion of § 2804.17.

Section 2884.16 What provisions do Master Agreements contain and what are their limitations?

The proposed rule would amend provisions in § 2884.16(a) that describe how processing and monitoring activities are included in a Master Agreement. Section 2884.16(c) would be added to clarify that a Master Agreement would waive a holder's rights to request a reduction in cost recovery fees. This is the current practice of the BLM and is not a substantive change. These changes are consistent with the proposed amendments to § 2804.18. For a more detailed discussion of these revisions, please see the preamble discussion of § 2804.18.

Section 2884.17 How will the BLM manage my Category 6 project?

The proposed rule would amend § 2884.17 by revising the heading to read ''How will the BLM manage my Category 6 project?'' The BLM proposes to revise § 2884.17(a) to include processing and monitoring activities. Revised § 2884.17(b) would describe what the BLM would do in monitoring your grant. Proposed paragraph (b)(4) of this section states that the BLM could collect a deposit before beginning work on a Category 6 project. These changes are consistent with the proposed amendments to § 2804.19. For a more detailed discussion of these revisions, please see the preamble discussion of § 2804.19.

Section 2884.21 How will the BLM process my application?

The proposed rule would amend § 2884.21 for consistency with the proposed revisions to § 2804.25. For a more detailed discussion of these revisions, please see the preamble discussion of § 2804.25.

Section 2884.23 Under what circumstances may the BLM deny my application?

The proposed rule would revise paragraph (a)(6) of this section, which states that the BLM could deny your ROW application if you fail to comply with a deficiency notice. This revision would make this paragraph consistent with §§ 2804.26 and 2864.26.

Section 2884.24 What fees must I pay if the BLM denies my application, or if I withdraw my application or relinquish my grant or TUP?

The proposed rule would amend § 2884.24 to provide consistency with proposed § 2804.27. For a more detailed discussion of these amendments, please see the preamble discussion of § 2804.27.

Section 2884.27 What additional requirements are necessary for grants for pipelines 24 or more inches in diameter?

The proposed rule would amend § 2884.27 by revising the title to read, ''What additional requirements are necessary for grants for pipelines 24 or more inches in diameter?'' Also, this section would be revised to remove any reference to a temporary use permit (TUP). Currently, any time a new grant or TUP application is filed with the BLM and the project involves a pipeline 24 or more inches in diameter, the regulations say BLM must notify Congress of the filed application.

The reasons for removing TUPs from this section are as follows:

(1) Section 185(w) of the MLA, which is the statutory source of the notification requirement, does not mention TUPs, only ROWs;

(2) Congressional notification for TUPs creates a significant, unnecessary workload for BLM offices, the Department of the Interior, and Congress; and

(3) The TUPs are temporary in nature, unlike new grants.

Subpart 2885—Terms and Conditions of MLA Grants and TUPs

Section 2885.12 What rights does a grant or TUP provide?

The proposed rule would amend the title of 2885.12 from ''What rights does a grant or TUP convey?'' to ''What rights does a grant or TUP provide?'' in order to be clear that the BLM does not convey any ownership rights to a ROW holder.

Section 2885.17 What happens if I do not pay rents and fees or if I pay the rents or fees late?

The proposed rule would amend § 2885.17 to provide consistency with proposed § 2806.13. For a more detailed discussion of these changes, please see the preamble discussion of § 2806.13.

Section 2885.19 What is the rent for a linear right-of-way grant?

The proposed rule would revise paragraph (b) to update the contact address of the BLM and highlight availability of the Per Acre Rent Schedule on the BLM website.

Section 2885.24 If I hold a grant or TUP, what cost recovery fees must I pay?

The proposed rule would amend the title for § 2885.24 to read, ''If I hold a grant or TUP, what cost recovery fees must I pay?'' to include permitting and monitoring activities. The proposed rule would revise §§ 2885.24(a) and 2885.24(b), and add a new § 2885.24(c). Section 2885.24(a) would refer you to § 2884.12(b) for the descriptions of the proposed minor category fees. Section 2885.24(b) would state that Categories 1 through 4 would be updated on an annual basis. Added § 2885.24(c) would explain how to obtain a copy of the current cost recovery fee schedule.

Subpart 2886—Operations on MLA Grants and TUPs

Section 2886.17 Under what conditions may the BLM suspend or terminate my grant or TUP?

Section 2886.17 would be revised to add a new paragraph (c)(3), which states that the BLM may terminate your grant or TUP if it is terminated by court order. If a court were to terminate a grant or TUP, the BLM must implement the court order. This is not a change to BLM practice but provides clarity to the public.

Subpart 2887—Amending, Assigning, or Renewing MLA Grants and TUPs

Section 2887.10 When must I amend my application, seek an amendment of my grant or TUP, or obtain a new grant or TUP?

Section 2887.10(b) would be revised to change the term ''processing and monitoring'' to ''cost recovery,'' consistent with proposed § 2807.20(b).

Section 2887.11 May I assign or make other changes to my grant or TUP?

Section 2887.11(i) would be added to clarify that an authorization amendment is necessary for a substantial deviation from location or use.

Section 2887.12 How do I renew my grant?

The proposed rule would amend § 2887.12 to provide consistency with proposed § 2807.22. For a more detailed discussion of these changes, please see the preamble discussion of § 2807.22.

PART 2920—LEASES, PERMITS AND EASEMENTS

Subpart 2920—Leases, Permits and Easements: General Provisions

Section 2920.0–5 Definitions.

Section 2920.0–5 would be amended to add the term and a definition of ''cost recovery'' and would be reorganized to be in alphabetical order.

Section 2920.6 Payment of cost recovery fees.

The title of § 2920.6 would be amended from ''Reimbursement of costs'' to ''Payment of cost recovery fees,'' and the content of the section would be updated to reflect this change. The change better explains the process to collect estimated cost recovery fees before the work is performed rather than afterward through reimbursement.

Section 2920.8 Fees.

Section 2920.8 would be amended by revising § 2920.8(b) to say, ''cost recovery fees,'' to provide consistency with the revisions made to part 2800.

IV. Procedural Matters

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order (E.O.) 12866 (58 FR 51725, October 4, 1993) provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. The OIRA has determined that this rule is not significant.

E.O. 13563 (76 FR 3821, January 11, 2011) reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, reduce uncertainty, and use the best, most innovative, and least burdensome tools for achieving regulatory ends. The E.O. directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rule making process must allow for public participation and an open exchange of ideas. The BLM has developed this rule in a manner consistent with these requirements.

The BLM reviewed the proposed requirements and has determined that the proposed rule does not meet any of the E.O. 12866 criteria of significance. OIRA has also concluded that the proposed rule is not a significant regulatory action. Therefore, the proposed rule is not a significant regulatory action, and the BLM is not required to submit a regulatory impact analysis to OMB for review.

The proposed rule would not have a significant effect on the economy. The BLM estimated that the proposed rule would have distributional impacts in the form of transfer payments of about $3.47 million per year from firms and individuals to the BLM. Transfer payments are monetary payments from one group to another that do not affect total resources available to society. While disclosing the estimated transfers are important for describing the distributional effects of the proposed rule, these payments should not be included in the estimated costs and benefits per OMB Circular A4.

For more detailed information, see the Economic and Threshold Analysis prepared for this proposed rule. The economic analysis has been posted in the docket for the proposed rule on the Federal eRulemaking Portal: *https://www.regulations.gov*. In the Searchbox, enter ''RIN 1004–AE60,'' click the ''Search'' button, open the Docket Folder, and look under Supporting Documents.

Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations (E.O. 12898)

E.O. 12898 (59 FR 7629, February 16, 1994) requires that, to the extent practicable and permitted by law, each Federal agency must make achieving environmental justice part of its mission. E.O. 12898 provides that each Federal agency conduct its programs, policies, and activities that substantially affect human health or the environment in a manner that ensures that such programs, policies, and activities do not have the effect of excluding persons (including populations) from participation in, denying persons (including populations) the benefits of, or subjecting persons (including populations) to discrimination under such programs, policies, and activities because of their race, color, or national origin. This rule streamlines the processing of ROWs and their associated fees and requires operations and maintenance plans for powerline ROWs. These proposed rule changes are not expected to have an effect on any particular population. Therefore, this rule is not expected to negatively impact any community and is not expected to cause any disproportionately high and adverse impacts to minority or low-income communities.

Regulatory Flexibility Act

This rule would not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*). The RFA generally requires that Federal agencies prepare a regulatory flexibility analysis for rules subject to the ''notice-and-comment'' rulemaking requirements found in the Administrative Procedure Act (5 U.S.C. 500 *et seq.*) if the rule would have a significant economic impact, whether detrimental or beneficial, on a substantial number of small entities. See 5 U.S.C. 601–612. Congress enacted the RFA to ensure that government regulations do not unnecessarily or disproportionately burden small entities. Small entities include small businesses, small governmental jurisdictions, and small not-for-profit enterprises.

The BLM reviewed the Small Business Size standards for the affected industries. We determined that a large share of the entities in the affected industries are small businesses as defined by the Small Business Act (SBA). However, the BLM believes that the impact on the small entities is not significant.

The proposed rule would benefit small businesses by streamlining the BLM's processes. Cost recovery fees would increase, but the impact of the increases is not expected to be substantial for the small entities, nor would it fall disproportionately on small businesses.

For the purpose of carrying out its review pursuant to the RFA, the BLM believes that the proposed rule would

not have a ''significant economic impact on a substantial number of small entities,'' as that phrase is used in 5 U.S.C. 605. An initial regulatory flexibility analysis is therefore not required.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under the Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. 804(2). This rule:

(a) Does not have an annual effect on the economy of $100 million or more. The proposed rule would result in additional cost recovery payments (or receipts to the United States Government) paid mostly by firms and individuals. These payments are ''transfer payments.'' Transfer payments are monetary payments from one group to another that do not affect total resources available to society.

(b) Would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. The BLM determined that the relatively minor increase in minor category fees would not pose an impact to small businesses, because the proposed increase in fees represents a very minor percentage of the average annual receipts of these entities. Based on our review of these data, we believe that there is only a very small potential for the smallest of the small businesses to be impacted. Further, there are aspects of the rule that would provide operating flexibility for small businesses, likely allowing them to manage their powerline and communications site ROWs more efficiently or at reduced cost.

(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. The proposed rule would not have adverse effects on any of these criteria, it would encourage the development of communications uses in rural areas in accordance with E.O. 13821 and the MOBILE NOW Act.

Unfunded Mandates Reform Act

This rule does 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. Under the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531 *et seq.*), agencies must prepare a written statement about benefits and costs, prior to issuing a proposed or final rule that may result in aggregate expenditure by State, local, and Tribal governments, or by the private sector, of $100 million or more in any one year.

This rule is not subject to the requirements under the UMRA. The rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or to the private sector in any one year. The rule would not significantly or uniquely affect small governments. A statement containing the information required by the UMRA is not required.

Takings (E.O. 12630)

This rule does not affect a taking of private property or otherwise have taking implications under E.O. 12630. Section 2(a) of E.O. 12630 (53 FR 8859, March 15, 1988) identifies policies that do not have takings implications, such as those that abolish regulations, discontinue governmental programs, or modify regulations in a manner that lessens interference with the use of private property. The proposed rule would not interfere with private property. A takings implication assessment is not required.

Federalism (E.O. 13132)

Under the criteria in section 1 of E.O. 13132 (64 FR 43255, August 4, 1999), this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. It 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. A federalism summary impact statement is not required.

Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988 (61 FR 4729, February 5, 1996). Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (E.O. 13175 and Departmental Policy)

The Department of the Interior (DOI) strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty.

In accordance with E.O. 13175 (65 FR 67249, November 9, 2000), the BLM has evaluated this rulemaking and determined that it would not have substantial direct effects on federally recognized Indian tribes. Nevertheless, on a government-to-government basis we initiated consultation with Tribal governments that wish to discuss the rule.

In August 2021, the BLM sent a letter to federally recognized Indian Tribes notifying them about the BLM's intent to pursue this rulemaking. In that letter, the BLM invited the tribes to government-to-government consultation. We look forward to continuing close interaction with Tribal leaders as we proceed through this rulemaking process.

Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*)

This proposed rule contains new information collections. All information collections require approval under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). We may not conduct or sponsor and, notwithstanding any other provision of law, you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

The information collection activities associated with the application process in this proposed rule require the use of SF–299 (Application for Transportation, Utility Systems, Telecommunications and Facilities on Federal Lands and Property) and the Communications Site Tenant/Customer Inventory Certification of Facility Owner or Manager. The OMB has previously approved the information collection requirements associated with BLM's use of Common Form SF–299 as part of the application process (U.S. Department of Agriculture—U.S. Forest Service OMB Control Number 0596–0249, expires 02/28/2023). You may view our approved Request for Common Form at *http://www.reginfo.gov/public/do/PRAMain*. Additionally, § 2884.11 refers to BLM forms Application for Permit to Drill or Reenter (BLM Form 3160–3) and Sundry Notice and Report on Wells (BLM Form 3160–5). These forms are part of the requirements for applying for MLA Grants or TUPs. The information required as part of these applications is contained in the current regulations under this paragraph and is currently approved by OMB under OMB control number 1004–0137 (expires 01/31/2025). The proposed rule would not

change these forms or the associated information collected as part of the application requirements.

This proposed rule includes provisions pertaining to non-hour burdens authorized by the FLPMA and the MLA. The FLPMA is the only authority under which communications uses on BLM-managed lands may be authorized. However, both the FLPMA (43 U.S.C. 1734(b) and 1764(g)) and the MLA (30 U.S.C. 185(*l*)) authorize the BLM and other applicable Federal agencies to collect funds from ROW applicants or holders to reimburse an agency for expenses incurred while processing an application and monitoring a grant. If this proposed rule becomes effective, the BLM would include non-hour burdens for other uses (*e.g.,* electric generation and pipelines) in requests to revise OMB Control Numbers 1004–0137 (Onshore Oil and Gas Operations and Production) and 1004–0206 (Competitive Processes, Terms and Conditions for Leasing of Public Lands for Solar and Wind Energy Development).

The information collection requirements identified below require approval by OMB:

(1) *Appeals/Petitions for a Stay (43 CFR 2801.10 and 43 CFR 2881.10)*—Current regulations at 43 CFR 2801.10 and 43 CFR 2881.10 provide a process for applicants to appeal a BLM decision issued under the regulations in parts 2800 and 2880, respectively, in accordance with part 4 of title 43. All BLM decisions under parts 2800 and 2880 remain in effect pending appeal unless the Secretary of the Interior rules otherwise, or as noted in the respective part. The applicant may petition for a stay of a BLM decision under part 4 with the Office of Hearings and Appeals, Department of the Interior. Unless otherwise noted, the BLM would take no action on the application while the appeal is pending. (43 CFR 2801.10(b), 2881.10(b).)

(2) *Designation of Agent or Third Party (43 CFR 2803.11)*—Proposed amendments to § 2803.11 would require notification of an intent to designate another person or entity to act on behalf of a holder of a FLPMA grant (*i.e.,* any authorization or instrument issued under FLPMA Title V, 43 U.S.C. 1761–1772). This is a new information collection activity, although existing § 2803.11 states that another person may act on the holder's behalf if the holder has ''authorized the person to do so under the laws of the State where the ROW is or will be located.'' The proposed amendments retain the existing language and, in addition, require the following in a designation notification:

(A) Notify the BLM office having jurisdiction over the grant in writing of their intention and provide a copy of the Power of Attorney, if one exists; and

(B) Provide and maintain the current contact information for the intended agent.

If an applicant designates an agent or third party to act on their behalf, they are still responsible for following the terms and conditions of the grant. In addition, the proposed amendments require the holder of the grant to maintain current contact information for the intended agent.

(3) *Request for a Master Agreement (43 CFR 2804.17 & 43 CFR 2884.15)* Sections 2804.17 and 2884.15 describe the information a holder of a FLPMA grant, MLA grant, or Temporary Use Permit (TUP) must provide to the BLM when requesting a ''Master Agreement (Cost Recovery Category 5).'' A Master Agreement, as described in existing §§ 2804.17 and 2884.15, is a written agreement covering processing and monitoring fees negotiated between the BLM and the holder. The term ''Cost Recovery Category 5'' refers to agreements involving multiple BLM grant approvals within defined geographic areas. As amended, §§ 2804.17 and 2884.15 would further define Cost Recovery Category 5 as involving projects within defined geographic areas ''or for a specific common activity for many projects.'' These are the only proposed amendments for §§ 2804.17 and 2884.15.

Sections 2804.17 and 2884.15 require that a request for a Master Agreement include:

(A) A description of the geographic area covered by the Agreement and the scope of the activity the holder plans;

(B) A preliminary work plan that states what work the holder must do and what work the BLM must do to process the application;

(C) A preliminary cost estimate and a timetable for processing the application and completing the projects;

(D) A statement whether the holder wants the Agreement to apply to future applications in the same geographic area that are not part of the same projects; and

(E) Any other relevant information that the BLM needs to process the application (*e.g.,* financial information, maps, environmental or cultural data about the area covered by the grants).

(4) *Written Agreements—Category 6 Projects (43 CFR 2804.19 and 43 CFR 2884.17)*—The term ''Cost Recovery Category 6'' refers to agreements involving a large scale or highly complex FLPMA grant, MLA grant, or TUP approval. As amended, §§ 2804.14 and 2884.12 would define Cost Recovery Category 6 to include activities that will require more than 64 hours or require an environmental impact statement. For Category 6 applications, the applicant and the BLM must enter into a written agreement that describes how the BLM will process the application and monitor the grant. The BLM may require that the final agreement contains a work plan and a financial plan, and a description of any existing agreements they have with other Federal agencies for cost reimbursement associated with the application or grant.

For the BLM to determine reasonable costs associated with a Category 6 project, the written agreement must include a written analysis of those factors applicable to the project, unless the applicant agrees in writing to waive consideration of reasonable costs and elects to pay actual costs. The BLM may require the applicant to submit additional information in support of their position.

(5) *Analysis of Factors—Cost Recovery Fee Determination (43 CFR 2804.21)*—Along with the written application, applicants may submit their analysis of how each of the factors, as applicable, in § 2804.21(a), pertains to their application. The BLM will notify the applicant in writing of the fee determination.

(6) *Withdrawing Applications/ Relinquishing Grants (43 CFR 2804.27 and 43 CFR 2884.24)*—Applicants may withdraw their application in writing before the BLM issues a grant. Applicants may relinquish their grant in writing. If they withdraw their application or relinquish their grant, they are liable for all processing costs the United States has incurred up to the time of the withdrawal or relinquishment and for the reasonable costs of termination proceedings. Any money not paid by the applicant is due within 30 calendar days after receiving a bill for the amount due. Any money paid by the applicant that is not used to cover costs the United States incurred as a result of their application would be refunded to them.

(7*) Request for Alternative Requirement (43 CFR 2804.40)*—If the applicant is unable to meet any of the requirements in subpart 2804, they may request approval for an alternative requirement from the BLM. Any such request is not approved until the BLM provides their approval in writing. The request for alternative must:

(A) Show good cause for the applicant's inability to meet a requirement;

(B) Suggest an alternative requirement and explain why that requirement is appropriate; and

(C) Be received in writing by the BLM in a timely manner, before the deadline to meet a particular requirement has passed.

(8) *Request for Extension (43 CFR 2805.12(c)(5))*—Grant holders must take appropriate remedial action within 30 days after receipt of a written noncompliance notice unless they have been provided an extension of time by the BLM. Alternatively, they must show good cause for any delays in repairs, use, or removal; estimate when corrective action will be completed; provide evidence of diligent operation of the facilities; and submit a written request for an extension of the 30-day deadline. If they do not comply with this provision, the BLM may suspend or terminate the authorization.

(9) *Rights the United States Retains—Financial Documents (43 CFR 2805.15)*—A proposed amendment to § 2805.15 would add to the list of rights retained by the United States the right to require a holder to submit applicable financial documents and supporting documents including, but not limited to, contractual and subleasing agreements. This amendment would be consistent with the requirements of existing § 2805.12(a)(15).

(10) *Operations, Maintenance, and Fire Prevention Plans (43 CFR 2804.25(c)(2) and 43 CFR 2805.21(a))*—Proposed §§ 2804.25(c)(2) and 2805.21(a) would require an operations, maintenance, and fire prevention plan for all new powerline ROWs. Applications to amend and renew powerline ROWs must follow the same procedures as applications for new ROWs and would also be subject to this proposed requirement. Existing holders of powerline ROWs would not be required to submit an operations, maintenance, and fire prevention plan under the proposed rule until they renew or amend their grant but may submit such plans on a voluntary basis. Holders of ROWs may submit an operations, maintenance, and fire prevention plan to the BLM on a voluntary basis even if their ROW is not for a powerline.

Under existing § 2804.25(c), the BLM may require applicants to submit a POD for a ROW, as necessary. Proposed § 2805.21(c) describes requirements of the operations, maintenance, and fire prevention plans that powerline ROW applicants would also be required to submit, as follows:

(A) Plan requirements: An operations, maintenance, and fire prevention plan must:

(i) Identify the applicable facilities to be maintained;

(ii) Take into account the holder's own operating operations and maintenance plans for the applicable right-of-way;

(iii) Describe the vegetation management, inspection, and operation and maintenance methods that may be used to comply with applicable law, including fire safety requirements and reliability standards established by the ERO;

(iv) Include schedules for:

(a) The applicable owner or operator to notify the BLM about non-emergency routine and major maintenance;

(b) The applicable owner or operator to request approval from the BLM about undertaking non-emergency routine and major maintenance; and

(c) The BLM to respond to a request by an owner or operator;

(v) Describe processes for:

(a) Identifying changes in conditions; and

(b) Modifying the approved operations, maintenance, and fire prevention plan, if necessary; and

(vi) Additionally, § 2805.21 includes a requirement for a fire prevention plan (removal and disposal of cut trees and branches, including plans for sale of forest products).

(11) *Modification of Operations, Maintenance, and Fire Prevention Plans (43 CFR 2805.21(e))*—Proposed § 2805.21(e) describes how the BLM would notify the holder that an operations, maintenance, and fire prevention plan requires modifications. The BLM would provide advance reasonable notice to the holder that a modification is necessary, and the holder would submit the proposed modification to the BLM. The BLM would review and approve the proposed operations, maintenance, and fire prevention plan modification in the timeframe identified for submitting new approvals. Under § 2805.21(e)(4), the holder may continue to operate and maintain the ROW or facility in accordance with the approved operations, maintenance, and fire prevention plan, as long as the activity does not conflict with the identified condition that requires a plan modification.

(12) *Agreements in Lieu of Operations, Maintenance, and Fire Prevention Plans (43 CFR 2805.21(f))*—Proposed § 2805.21(f) provides that certain holders may enter into an agreement with the BLM in lieu of an operations, maintenance, and fire prevention plan. Qualifications to enter into agreements, in lieu of operations, maintenance, and fire prevention plans, are described in § 2805.21(g). An agreement must contain the same general requirements of operations, maintenance, and fire prevention plans described in § 2805.21. Agreements would need to include schedules, as described in proposed § 2805.21(c)(4) and are subject to the same modification requirements of proposed § 2805.21(e).

(13) *Notifications—Emergency Conditions (43 CFR 2805.22(a))*—Owners or operators of electric transmission or distribution lines shall notify the authorized officer not later than 1 day after the date of their response to emergency conditions.

(14) *Request for Approval—Non-Emergency Conditions (43CFR 2805.22(b))*—Owners or operators must request approval from the BLM for a proposed activity if their plan:

(A) Requires them to seek specific approval for the proposed activity; or

(B) Does not address the proposed activity. They may also need to amend their operations, maintenance, and fire prevention plan if they anticipate conducting this activity on a recurring basis.

(15) *Phasing Rent—Hardship (43 CFR 2806.22 & 43 CFR 2866.31)*—The BLM uses separate rental schedules for linear ROWs (see § 2806.22) and for communications uses grants (see proposed § 2866.30). When the BLM adjusts its rental schedule under these sections, some holders' rents may increase dramatically. The proposed rule includes provisions in each of these sections (see proposed §§ 2806.22(c) and 2866.30) to provide holders experiencing undue hardship with the option to phase in the cost difference over a 3-year period. If a holder's rent would more than double from the previous year, the holder may request a phase-in of the increased rent in accordance with § 2806.15(b)(5).

(16) *Amendments (43 CFR 2807.20 and 43 CFR 2887.10)*—Applicants must amend their application or seek an amendment of their grant when there is a proposed substantial deviation in location or use. The requirements to amend an application or grant are the same as those for a new application, including paying cost recovery fees and rent according to §§ 2804.14, 2805.16, and 2806.10.

(17) *Renewals (43 CFR 2807.22 and 43 CFR 2887.12)*—Applicants must submit an application to renew their existing grant at least 120 days prior to grant expiration.

(18) *Request for Preliminary Application Review (43 CFR 2864.10)*—

In addition to the provisions listed in § 2804.10, before filing their application, the applicant should:

(A) Schedule a preliminary application review meeting with the appropriate personnel in the BLM field office with jurisdiction over the lands the applicant seeks to use. During the preliminary application review meeting, the BLM can:

(i) Identify potential constraints;

(ii) Determine whether the lands are located inside a communications site management plan area;

(iii) Tentatively schedule the processing of the proposed application; and

(iv) Inform the applicant of financial obligations, such as processing and monitoring costs and rents.

(B) Request a copy of the most recent communications site management plan for that site, if one is available.

(C) Ensure the applicant has all other necessary licenses, authorizations, or permits required for the operation of the facility.

(19) *Request for Exemption (43 CFR 2806.14 and 43 CFR 2866.14)*—Applicants for or holders of an authorization for electric or telephone facilities may request an exemption if they were financed in whole or in part by, or were eligible for financing under, the Rural Electrification Act of 1936, as amended (REA) (7 U.S.C. 901 *et seq.*) or if their facilities are extensions of facilities that are exempt from paying rental. This exemption may be requested during the application process for a new grant, or an existing grant holder may request an exemption if they are now eligible after a change in policy. The BLM issued an Instruction Memorandum in 2016 (IM–2016–122) after a Memorandum of Understanding in 2014 established the new policy. Holders do not need to have sought financing from the Rural Utilities Service to qualify for this exemption. Holders would need to document the facility's eligibility for REA financing.

(20) *Request for Waiver or Reduction in Annual Rent (43 CFR 2806.15, 43 CFR 2866.15, and 43 CFR 2866.30)*—A holder may request a rent waiver or reduction if paying the full rent would cause the holder undue hardship and it is in the public interest to waive or reduce the rent. For example, an undue hardship can be a financial impact on a small business, or it could involve situations where there is a need to relocate the facility to comply with public health and safety or environmental protection laws not in effect at the time the original grant issued. The holder would also need to submit information to support an undue hardship claim. Several other sections of the proposed rule allow a holder to request a waiver or reduction to their rent under the provisions of §§ 2806.15, 2866.15, and 2866.30.

(21) *Annual Statement (43 CFR 2866.31(c))*—By October 15 of each year, communications uses grantees must submit to the BLM a certified statement listing any tenants and customers in their facility or facilities and the category of use for each tenant or customer as of September 30 of the same year. The BLM may require grant holders to submit additional information to calculate their rent. The BLM would determine the rent based on the annual inventory certification statement provided. We require only facility owners or facility managers to hold a grant (unless they are an occupant in a federally owned facility as described in § 2866.42) and would charge rent for grants based on the total number of communications uses within the right-of-way and the type of uses and population strata the facility or site serves. Failure to submit the annual inventory certification (by electronic correspondence or postmarked) by October 15 may result in the grantee not receiving any discounts, reductions, exemptions, or waivers (see §§ 2866.14, 2866.15, and 2866.34), for which they may have been entitled.

(22) *Request to Authorize Facilities Under a Single Grant (43 CFR 2866.38)*—Applicants holding authorizations for two or more facilities on the same communications site may submit a written request to authorize those facilities under a single grant.

(23) *Request for Collocation within Ancillary Facilities (43 CFR 2866.41)*—Proposed § 2866.41 would add a regulation to require holders with ancillary facilities to request collocation. Under this proposed section, holders of a communications facility grant issued as an ancillary facility to a linear authorization could apply to the BLM for the right to allow subleasing within that facility. The BLM considers ''ancillary'' communication facilities to be those used solely for the purpose of internal communications for the grant. Once the BLM grants subleasing authority, the holder would not be charged any additional rent for the occupancy of additional uses in that facility.

If the BLM does not respond to a holder's request for collocation within 60 days from acceptance of a complete application, the request would be considered approved. This conditional approval would be consistent with the streamlining measures proposed in this rule. These new provisions would make it easier for rural broadband providers to utilize existing infrastructure, thereby further facilitating the deployment of broadband in rural areas.

(24) *Environmental Impact Statement (43 CFR 2804.14(e), 43 CFR 2884.12(e))*—In processing your application, the BLM may determine at any time that an Environmental Impact Statement (EIS) is necessary to evaluate the application. The EIS may be prepared by the applicant, the BLM, or by both parties.

Title of Collection: Rights-of-Way Communications Uses, Cost Recovery, and 512 of FLPMA (Vegetation Management) 43 CFR parts 2800, 2860, 2880 AND 2920.

OMB Control Number: 1004-New.

Form Number: SF–299 (Burden approved by OMB in Request for Common Form under OMB Control No. 0596–0249); BLM Forms 3160–3 and 3160–5 (Burden approved by OMB under OMB Control No. 1004–0137).

Type of Review: New Collection (Request for a new OMB control number).

Respondents/Affected Public: Individuals, private sector, and State/local/Tribal governments who seek or hold rights-of-way on public lands.

Respondent's Obligation: Required to Obtain or Retain a Benefit.

Frequency of Collection: On occasion and annually for the Annual Statement required in 43 CFR 2866.31

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on any aspect of this information collection, including:

(1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information would have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond, including by using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Send your comments and suggestions on this information collection by the date indicated in the **DATES** and **ADDRESSES** sections above. Comments on the information collection aspects of

this proposed rule will be summarized, along with the BLM's response to those comments, at the final rule stage of the rulemaking action.

You may view the information collection request(s) at *http://www.reginfo.gov/public/do/PRAMain.*

National Environmental Policy Act

The BLM has determined that the changes that would be made by this proposed rule are administrative or procedural in nature in accordance with 43 CFR 46.210(i). Therefore, the proposed action is categorically excluded from environmental review under the National Environmental Policy Act (NEPA).

We have also determined that the proposed rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

Effects on the Energy Supply (E.O. 13211)

This rule is not a significant energy action under E.O. 13211 (66 FR 28355, May 22, 2001). Section 4(b) of E.O. 13211 defines a ''significant energy action'' as ''any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) that is a significant regulatory action under E.O. 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of OIRA as a ''significant energy action.''

The BLM reviewed the proposed rule and determined that it is not a significant energy action as defined by E.O. 13211. A Statement of Energy Effects is not required.

Clarity of This Regulation

We are required by E.O.s 12866 (section 1(b)(12)), 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use common, everyday words and clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you believe that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Authors

The principal authors of this rule are: Karen Montgomery, BLM Division of Lands, Realty and Cadastral Survey; Erica Pionke, BLM Division of Lands, Realty and Cadastral Survey; Robert Wilson, BLM Division of Lands, Realty and Cadastral Survey; James Tichenor, BLM Division of Lands, Realty and Cadastral Survey, Business Management Office; Jeff Holdren, BLM Division of Lands, Realty and Cadastral Survey; Jennifer Noe, BLM Division of Regulatory Affairs; assisted by the DOI Office of the Solicitor.

Delegation of Authority

The action taken herein is pursuant to an existing delegation of authority.

Laura Daniel-Davis,

Principal Deputy Assistant Secretary, Land and Minerals Management.

List of Subjects

43 CFR Part 2800

Electric power, Highways and roads, Penalties, Public lands and rights-of-way, Reporting and recordkeeping requirements.

43 CFR Part 2860

Communications, Penalties, Public lands and rights-of-way, Reporting and recordkeeping requirements.

43 CFR Part 2880

Administrative practice and procedures, Common carriers, Pipelines, Federal lands and rights-of-way, Reporting and recordkeeping requirements.

43 CFR Part 2920

Penalties, Public lands, Reporting and recordkeeping requirements.

Accordingly, for the reasons stated in the preamble, the BLM proposes to amend 43 CFR parts 2800, 2880, and 2920, and add a new 43 CFR part 2860 as set forth below:

PART 2800—RIGHTS-OF-WAY UNDER THE FEDERAL LAND POLICY AND MANAGEMENT ACT

■ 1. The authority citation for part 2800 continues to read as follows:

Authority: 43 U.S.C. 1733, 1740, 1763, and 1764.

■ 2. Amend § 2801.2 by revising paragraph (c) to read as follows:

§ 2801.2 What is the objective of the BLM's right-of-way program?

* * * * *

(c) Promotes the use of rights-of-way in common wherever practical, considering engineering and technological compatibility, national security, and land use plans; and

* * * * *

■ 3. Amend § 2801.5 by:

■ a. Removing the acronym ''RMA'';

■ b. Removing the terms of ''base rent'' and ''communication use rent schedule'';

■ c. Adding terms for ''complete application'' and ''cost recovery'';

■ d. Removing the term of ''customer'';

■ e. Adding the term of ''exempt from rent'';

■ f. Revising the definition for ''facility'';

■ g. Removing the terms of ''facility manager'' and ''facility owner'';

■ h. Adding the term of ''hazard tree'';

■ i. Removing the term of ''monitoring'';

■ j. Adding the term of ''monitoring activities'';

■ k. Adding the terms for ''operations and maintenance,'' ''operations, maintenance, and prevention plan,'' and ''processing activities'';

■ l. Removing the term of ''site'';

■ m. Revising the definition of ''substantial deviation'';

■ n. Removing the term of ''tenant'';

■ o. Revising the definition of ''transportation and utility corridor'';

■ p. Adding the term of and ''waived from rent''; and

■ q. Revising the definition of ''zone.''

The additions and revisions read as follows:

§ 2801.5 What acronyms and terms are used in the regulations in this part?

* * * * *

Complete application means the BLM has verified that your application contains all of the required information under § 2804.12. The BLM will notify you after it determines that your application is complete.

Cost recovery is a fee charged to an applicant or holder to pay the United States for processing and monitoring costs that concern applications and other documents relating to the public lands, or that are incurred when processing, inspecting, or monitoring any proposed or authorized rights-of-way located on the public lands.

* * * * *

Exempt from rent means that the BLM is precluded by statute or regulation from collecting rent.

Facility means an improvement or structure, whether existing or planned,

that is or would be owned and controlled by the grantee within a right-of-way.

* * * * *

Hazard tree, when used in § 2805.22 of this part, means any tree or part thereof (whether located inside or outside a right-of-way) that has been designated, prior to tree failure, by a certified or licensed arborist or forester under the supervision of the Secretary or the owner or operator of a transmission or distribution facility to be:

(1) Dead, likely to die within the routine vegetation management cycle, or likely to fail within the routine vegetation management cycle; and

(2) If the tree or part of the tree failed, likely to:

(i) Cause substantial damage or disruption to a transmission or distribution facility; or

(ii) Come within 10 feet of an electric power line.

Monitoring activities means those activities the Federal Government performs to ensure compliance with a right-of-way grant, including administrative actions, such as assignments, amendments, or renewals.

(1) For Monitoring Categories 1 through 4, monitoring activities include inspecting construction, operation, maintenance, and termination of permanent or temporary facilities and protection and rehabilitation activities up to the time the holder completes rehabilitation of the right-of-way and the BLM approves it;

(2) For Monitoring Category 5 (Master Agreements), monitoring activities include those actions or activities agreed to in the Master Agreement; and

(3) For Monitoring Category 6, monitoring activities include those actions or activities agreed to between the BLM and the applicant

* * * * *

Operations and maintenance means activities conducted by the right-of-way holder to manage facilities and vegetation within and adjacent to the right-of-way. Activities must comply with right-of-way regulations of this Chapter and the terms and conditions of the right-of-way authorization.

Operations, maintenance, and fire prevention plan means a vegetation management, facility inspection, and operation and maintenance plan that:

(1) Is prepared by the owner or operator of one or more facilities to cover one or more rights-of-way; and

(2) Provides for the long-term, cost-effective, efficient, and timely management of facilities and vegetation on or adjacent to the right-of-way, including hazard trees, to enhance electric reliability, promote public safety, and avoid fire hazards.

* * * * *

Processing activities means those actions or activities the Federal Government undertakes to evaluate an application for a right-of-way grant, including administrative actions, such as assignments, amendments, or renewals. It also includes preparation of an appropriate environmental document and compliance with other legal requirements in evaluating an application.

(1) For Processing Categories 1 through 4, processing activities include preliminary application reviews, application processing and administrative actions to the right-of-way or temporary use permit;

(2) For Processing Category 5 (Master Agreements), processing activities include those actions or activities agreed to in the Master Agreement; and

(3) For Processing Category 6, processing activities include those actions or activities agreed to between the BLM and the applicant.

* * * * *

Substantial deviation means a change in the authorized location or use that requires-construction or use outside the boundaries of the right-of-way, or any change from, or modification of, the authorized use. The BLM may determine that there has been a substantial deviation in some of the following circumstances: When a right-of-way holder adds overhead or underground lines, pipelines, structures, or other facilities within the right-of-way not expressly included in the current grant. Operation and maintenance actions or safety-related improvements within an existing right-of-way are not considered a substantial deviation. Activities undertaken to reasonably prevent and suppress wildfires on or adjacent to the right-of-way do not constitute a substantial deviation.

* * * * *

Transportation and utility corridor means a parcel of land identified through a land use planning process as being a preferred location for existing and future linear rights-of-way and facilities. The corridor may be suitable to accommodate more than one right-of-way use or facility, provided that the uses are compatible with one another and the corridor designation.

Waived from rent means a discretionary decision by the BLM to reduce the rent. Waivers may result in a reduction in rent or no rent at all.

Zone means a geographic grouping necessary for linear right-of-way rent assessment purposes, covering all lands in the contiguous United States.

§ 2801.9 [Amended]

■ 4. Amend § 2801.9 by removing paragraph (a)(5) and re-designating paragraphs (a)(6) and (7) as paragraphs (a)(5) and (6).

■ 5. Amend § 2802.10 by revising paragraph (c) to read as follows:

§ 2802.10 What lands are available for grants?

* * * * *

(c) You should contact the BLM to:

(1) Determine the appropriate BLM office with which to coordinate;

(2) Determine whether or not the land you want to use is available for that use; and

(3) Begin discussions about any application(s) you may need to file.

■ 6. Revise § 2803.11 to read as follows:

§ 2803.11 Can another person act on my behalf?

Another person may act on your behalf if you have authorized that person to do so under the laws of the State where the right-of-way is or will be located.

(a) If you intend to designate another person or entity to act on your behalf or operate as your third-party agent, you must first:

(1) Notify the BLM office having jurisdiction over your grant in writing of your intention and provide a copy of the Power of Attorney, if one exists; and

(2) Provide and then maintain the current contact information for the intended agent.

(b) If you designate an agent or third-party to act on your behalf after you have been issued a grant, you will still be held responsible to follow the terms and conditions of the grant.

■ 6. Amend § 2803.12 by revising the section heading and paragraph (a) to read as follows:

§ 2803.12 What happens to my grant if I die?

(a) If a grant holder dies, any inheritable interest in a grant will be distributed under State law.

* * * * *

■ 7. Amend § 2804.12 by revising paragraphs (a) and (a)(4) to read as follows:

§ 2804.12 What must I do when submitting my application?

(a) File your application on Standard Form 299, available from any BLM office or at *https://www.blm.gov,* and fill in the required information. The application must include the applicant's

original signature or meet the BLM standards for electronic commerce.

Your complete application must include the following:

(1) * * *

(4) A map of the project showing its proposed location and existing facilities adjacent to the proposal, and Geographic Information Systems (GIS) shapefiles, or equivalent format, when requested by the BLM;

* * * * *

■ 8. Revise § 2804.14 to read as follows:

§ 2804.14 What are the fee categories for cost recovery?

(a) Unless your fees are waived under § 2804.16, you must pay cost recovery fees for the reasonable costs associated with your application and grant. Subject to applicable laws and regulations, if your application involves Federal agencies other than the BLM, your fee may also include the reasonable costs estimated to be incurred by those Federal agencies. Instead of paying the BLM a fee for the reasonable costs incurred by other Federal agencies in processing your application, you may pay other Federal agencies directly. The fees for Categories 1 through 4 (see paragraph (b) of this section) are one-time fees and are not refundable. Reasonable costs are those costs defined in Section 304(b) of FLPMA (43 U.S.C. 1734(b)). The fees are categorized based on an estimate of the amount of time that the Federal Government will expend to process your application, issue a decision granting or denying the application, and monitor that land use authorization.

(b) The BLM bases cost recovery fees on categories. The BLM will update the fee schedule for Categories 1 through 4 each calendar year, based on the previous year's change in the IPD–GDP, as measured second quarter to second quarter rounded to the nearest dollar. The BLM will update Category 5 fees, which may include preliminary application review, processing, and monitoring, as specified in the applicable Master Agreement. Category 6 fees are for situations when a right-of-way activity will require more than 64 hours, or when an environmental impact statement (EIS) is required and may include preliminary application review costs. The cost recovery categories and the estimated range of Federal work hours for each category are:

Cost Recovery Categories

FLPMA right-of-way cost recovery category descriptions	Federal work hours involved
Category 1. Processing and monitoring associated with an application or existing grant.	Estimated Federal work hours are ≤8.
Category 2. Processing and monitoring associated with an application or existing grant.	Estimated Federal work hours are > 8 ≤24.
Category 3. Processing and monitoring associated with an application or existing grant.	Estimated Federal work hours are > 24 ≤40.
Category 4. Processing and monitoring associated with an application or existing grant.	Estimated Federal work hours are > 40 ≤64.
Category 5. Master Agreements *	Varies, depending on the agreement.
Category 6. Processing and monitoring associated with an application or existing grant, including preliminary-application reviews *.	Estimated Federal work hours are >64.

* Preliminary application review costs are those expenses related to meetings held between a Federal agency and the applicant to discuss a right-of-way application. These reviews are required only when an application is for a wind or solar right-of-way but are encouraged for other right-of-way application filings. A Master Agreement may include preliminary application review costs.

(c) You may obtain a copy of the current year's cost recovery fee schedule at *https://www.blm.gov,* by contacting your local BLM state, district, or field office, or by writing: Attention to the Division of Lands, Realty and Cadastral Survey, U.S. Department of the Interior, Director (HQ–350), Bureau of Land Management, Room 5625, C Street NW, Washington, DC 20240.

(d) After an initial review of your application, the BLM will notify you of the cost recovery category into which your application fits. You must then submit to the BLM the appropriate payment for that category before the BLM will begin processing your application. Your signature on a cost recovery Master Agreement constitutes your agreement with the cost recovery category decision. If you disagree with the category that the BLM has determined for your application, you may appeal the decision under § 2801.10 of this part. For Category 5 and 6 applications or grants, see §§ 2804.17, 2804.18, and 2804.19 of this subpart. If you paid the cost recovery fee and you appeal a Category 1 through 4 or Category 6 determination, the BLM will work on your application or grant while the appeal is pending. If the Interior Board of Land Appeals (IBLA) finds in your favor, you will receive a refund or adjustment of your cost recovery fee.

(e) In processing your application, the BLM may determine at any time that the application requires preparing an EIS. If this occurs, the BLM will send you a decision changing your cost recovery category to Category 6. You may appeal this decision under § 2801.10 of this part.

(f) To expedite processing of your application, you may notify the BLM in writing that you are waiving application of the factors identified in §§ 2804.20(a) and 2804.21 of this subpart to determine reasonable costs and are electing to pay the actual costs incurred by the BLM in processing your application and monitoring your grant.

■ 9. Amend § 2804.15 by revising the section heading to read as follows:

§ 2804.15 When does the BLM reevaluate the cost recovery fees?

* * * * *

■ 10. Revise § 2804.16 to read as follows:

§ 2804.16 When will the BLM waive cost recovery fees?

(a) The BLM may waive your cost recovery fees if:

(1) You are a State or local government, or an agency of such a government, and the BLM issues the grant for governmental purposes benefitting the general public. However, if you collect revenue from charges you levy on customers for services similar to those of a profit-making corporation or business, or you assess similar fees to the United States for similar purposes, cost recovery fees will not be waived;

(2) Your application under this subpart is associated with a cost-share road or reciprocal right-of-way agreement; or

(3) You are a Federal agency, and your cost recovery category determination is Category 1 to 4.

(b) The BLM will not waive your cost recovery fees if you are in trespass.

■ 11. Amend § 2804.17 by revising the section heading and paragraph (a) to read as follows:

§ 2804.17 What is a Master Agreement (Cost Recovery Category 5) and what information must I provide to the BLM when I request one?

(a) A Master Agreement (Cost Recovery Category 5) is a written agreement covering processing and monitoring fees (see § 2804.14 of this part) negotiated between the BLM and you that involves multiple BLM grant approvals for projects within defined geographic areas or for a specific common activity for many projects.

* * * * *

■ 12. Amend § 2804.18 by revising paragraphs (a)(2), (a)(5), and (c) to read as follows:

§ 2804.18 What provisions do Master Agreements contain and what are their limitations?

(a) * * *

* * * * *

(2) Describes the work you will do and the work the BLM will do to complete right-of-way activities.

* * * * *

(5) Explains how the BLM will monitor a grant and how the BLM will receive payment for this work;

* * * * *

(c) If you sign a Master Agreement, you waive your right to request a reduction of cost recovery fees.

■ 13. Amend § 2804.19 by revising the section heading and paragraphs (a) and (b) to read as follows:

§ 2804.19 How will the BLM manage my Category 6 project?

(a) For Category 6 applications, you and the BLM must enter into a written agreement that describes how the BLM will process your application and monitor your grant. The BLM may require that the final agreement contain a work plan and a financial plan, and a description of any existing agreements you have with other Federal agencies for cost reimbursement associated with your application or grant.

(b) In processing your application, the BLM will:

(1) Determine the issues subject to analysis under NEPA;

(2) Prepare a preliminary work plan, if applicable;

(3) Develop a preliminary financial plan, if applicable, which estimates the reasonable costs of processing your application and monitoring your project;

(4) Collect, in advance and at BLM's discretion, a deposit for your Category 6 project to initiate processing your application while all of the plans and agreements are being completed;

(5) Discuss with you:

(i) The preliminary plans and data;

(ii) The availability of funds and personnel;

(iii) Your options for the timing of processing and monitoring fee payments; and

(iv) Financial information you must submit; and

(6) Complete final scoping and develop final work and financial plans that reflect any work you have agreed to do. The BLM will also present you with the final estimate of the reasonable costs for which you must reimburse the BLM, including the cost for monitoring the project, using the factors in §§ 2804.20 and 2804.21 of this subpart.

* * * * *

■ 14. Amend § 2804.20 by revising the section heading, introductory text, and paragraph (a) to read as follows:

§ 2804.20 How does the BLM determine reasonable costs for Category 6 right-of-way activities?

The BLM will consider the factors in paragraph (a) of this section and § 2804.21 of this subpart to determine reasonable costs. Submit to the BLM field office having jurisdiction over the lands covered by your application a written analysis of those factors applicable to your project unless you agree in writing to waive consideration of those factors and elect to pay actual costs (see § 2804.14(f) of this subpart). Submitting your analysis with the application will expedite its handling. The BLM may require you to submit additional information in support of your position. The BLM will continue to work on your application while you are responding to our request, as long as a deposit has been received by the BLM as provided in § 2804.19(a)(4).

(a) *FLPMA factors.* If the BLM determines that a Category 6 cost recovery fee is appropriate for your project, the BLM will apply the following factors as set forth in Section 304(b) of FLPMA, 43 U.S.C. 1734(b), to determine the amount you owe:

* * * * *

■ 15. Amend § 2804.21 by revising the section heading and paragraphs (a), (a)(2), (a)(7), and (b) to read as follows:

§ 2804.21 What other factors will the BLM consider in determining cost recovery fees?

(a) *Other factors.* If you include this information in your application, in arriving at your cost recovery fee in any category, the BLM will consider whether:

(1) * * *

(2) The costs of performing any or all right-of-way activities grossly exceed the costs of constructing the project;

* * * * *

(7) For whatever other reason, such as public benefits or public services provided, cost recovery fees would be inconsistent with prudent and appropriate management of public lands and with your equitable interests or the equitable interests of the United States.

(b) *Fee determination.* With your written application, submit your analysis of how each of the factors, as applicable, in paragraph (a) of this section, pertains to your application. The BLM will notify you in writing of the fee determination. You may appeal this decision under § 2801.10 of this part.

■ 16. Amend § 2804.25 by:

■ a. Revising the section heading and paragraphs (a)(1);

■ b. Redesignating paragraph (c)(2) as (c)(3);

■ c. Adding a new paragraph (c)(2), and

■ d. Revising paragraph (d).

The revisions and additions read as follows:

§ 2804.25 How will the BLM process my application?

(a) * * *

(1) Identify your cost recovery fee described at § 2804.14, unless your fees are exempt; and

* * * * *

(c) * * *

(2) For all powerline rights-of-way, you must submit an operations, maintenance, and fire prevention plan, unless you have an approved plan that meets the requirements of § 2805.21; or

(3) If you are unable to meet any of the requirements of this section, you must show good cause and submit a request for an alternative under § 2804.40.

(d) *Customer service standard.* The BLM will process your complete application as follows:

Processing category	Processing time	Conditions
1–4	60 calendar days	If processing your application will take longer than 60 calendar days, the BLM will notify you in writing of this fact prior to the 30th calendar day and inform you of when you can expect a final decision on your application.
5	As specified in the Master Agreement	The BLM will process applications as specified in the Master Agreement.
6	Over 60 calendar days	The BLM will notify you in writing within the initial 60-day processing period of the estimated processing time.

* * * * *

■ 17. Amend § 2804.26 by adding a new paragraph (a)(9) to read as follows:

§ 2804.26 Under what circumstances may the BLM deny my application?

(a) * * *

* * * * *

(9) You do not comply with a deficiency notice (see § 2804.25(c) of this subpart) or with a BLM request for additional information needed to process your application.

* * * * *

■ 18. Revise § 2804.27 to read as follows:

§ 2804.27 What fees must I pay if the BLM denies my application or if I withdraw my application or I relinquish my grant?

If the BLM denies your application, you withdraw it, or you relinquish your grant, you owe the current fees for the applicable cost recovery category as set forth at § 2804.14, unless you have a Category 5 or 6 application, in which case, the following conditions apply:

(a) If the BLM denies your Category 5 or 6 right-of-way application, you are liable for all reasonable costs that the United States incurred in processing it. The money you have not paid is due within 30 calendar days after receiving a bill for the amount due;

(b) You may withdraw your Category 5 or 6 application in writing before the BLM issues a grant. If you do so, you are liable for all reasonable processing costs the United States has incurred up to the time you withdraw the application and for the reasonable costs of terminating your application. Any money you have not paid is due within 30 calendar days after receiving a bill for the amount due. Any money you paid that is not used to cover costs the United States incurred as a result of your application will be refunded to you; and

(c) You may relinquish your grant in writing. If you do so, you are liable for all reasonable costs the United States has incurred up to the time you relinquish the grant and for the reasonable costs of closing your grant. Any cost recovery fees you have not previously paid are due within 30 calendar days after receiving a bill for the amount due. The BLM will refund any cost recovery fees you paid in Categories 5 or 6 that were not used to cover costs the United States incurred as a result of your grant.

■ 19. Amend § 2805.11 by redesignating existing paragraphs (b) and (c) as paragraphs (c) and (d) and adding a new paragraph (b) to read as follows:

§ 2805.11 What does a grant contain?

* * * * *

(b) *Right of ingress and egress to a right-of-way.* To facilitate the use of a right-of-way, the authorized officer must include in the grant rights of ingress and egress, as may be necessary for access to the right-of-way. Access routes must be identified in the grant and may include existing roads or other infrastructure.

* * * * *

■ 20. Amend § 2805.12 by rrevising the section heading, paragraphs (a)(4), (a)(8)(vi), (c)(5) and (d)(3) to read as follows:

§ 2805.12 With what terms and conditions must I comply?

* * * * *

(a) * * *

(4) Do everything reasonable to prevent and suppress wildfires on or adjacent to the right-of-way;

* * * * *

(8) * * *

(vi) Ensure that you construct, operate, maintain, and terminate the facilities on the lands in the right-of-way in a manner consistent with the grant, including the approved POD, if one was required, or any approved operations, maintenance, and fire prevention plan;

* * * * *

(c) * * *

(5) Repair and place into service, or remove from the site, damaged or abandoned facilities that (i) have been inoperative for any continuous period of 3 months and present a hazard to the public lands; or (ii) present a hazard to human health or safety. You must take appropriate remedial action within 30 days after receipt of a written noncompliance notice unless you have been provided an extension of time by the BLM. Alternatively, you must show good cause for any delays in repairs, use, or removal; estimate when corrective action will be completed; provide evidence of diligent operation of the facilities; and submit a written request for an extension of the 30-day deadline. If you do not comply with this provision, the BLM may suspend or terminate the authorization under §§ 2807.17 through 2807.19; and

* * * * *

(d) * * *

(3) You must repair and place into service, or remove from the site, damaged or abandoned facilities that

(i) have been inoperative for any continuous period of 3 months and present a hazard to the public lands; or

(ii) present a hazard to human health or safety; and

* * * * *

■ 21. Amend § 2805.14 by revising the section heading and paragraphs (d) and (e) to read as follows:

§ 2805.14 What rights does a grant provide?

* * * * *

(d) Do trimming, pruning, and removal of vegetation to maintain the right-of-way or facility and protect public health and safety;

(e) Use common varieties of stone and soil which are necessarily removed during construction of the project in constructing the project within the authorized right-of-way, or use vegetation removed during maintenance of the right-of-way, so long as any necessary authorization to remove or use such materials has been obtained from the BLM pursuant to applicable laws;

* * * * *

■ 22. Amend § 2805.15 by revising paragraphs (a) and (e) and adding new paragraphs (f) and (g) to read as follows:

§ 2805.15 What rights does the United States retain?

* * * * *

(a) Access the lands and enter the facilities described in the authorization. The BLM will give you reasonable notice before it enters any facility on the right-of-way;

* * * * *

(e) Change the terms and conditions of your grant as a result of changes in legislation, regulation, or as otherwise necessary to protect public health or safety or the environment. After a grant is signed by the BLM, any modification of the terms and conditions generally requires the BLM to issue a new or amended grant;

(f) Terminate your authorization for non-compliance; and

(g) Require you to provide applicable financial documents and supporting documents including, but not limited to, contractual and subleasing agreements.

■ 23. Amend § 2805.16 by revising it to read as follows:

§ 2805.16 If I hold a grant, what cost recovery fees must I pay?

(a) You must pay a fee to the BLM for the reasonable costs the Federal Government incurs in processing, inspecting, and monitoring the construction, operation, maintenance, and termination of the project and protection and rehabilitation of the public lands that your grant covers. Instead of paying the BLM a fee for the reasonable costs incurred by other Federal agencies in processing or monitoring your grant, you may pay the other Federal agencies directly for such costs. The BLM will annually adjust the Category 1 through 4-cost recovery fees in the manner described at § 2804.14(b). The BLM will update Category 5 cost recovery fees as specified in the applicable Master Agreement. Category 6 cost recovery fees are addressed at § 2805.17(c). The BLM categorizes the cost recovery fees based on the estimated number of work hours necessary to process and monitor your grant. Category 1 through 4 cost recovery fees are not refundable. The Federal work hours for each category and their descriptions are found at § 2804.14(b).

(b) The BLM will update the cost recovery fee schedule for Categories 1 through 4 each calendar year, based on the previous year's change in the IPD–GDP, as measured second quarter to second quarter and rounded to the nearest dollar. The BLM will update Category 5 cost recovery fees as specified in the applicable Master Agreement.

(c) You may obtain a copy of the current year's cost recovery fee schedule from any BLM state, district, or field office, or by writing: U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW, Room 5625, Attention: Division of Lands, Realty and Cadastral Survey, Washington, DC 20240. The BLM also posts the current cost recovery fee schedule at *https://www.blm.gov.*

■ 24. Add new §§ 2805.21 and 2805.22 to read as follows:

§ 2805.21 What is an operations, maintenance, and fire prevention plan for electric transmission and distribution and other rights-of-way?

(a) *Operations, maintenance, and fire prevention plans.*

(1) Are required for all new, renewed, and amended powerline rights-of-way (see § 2804.25(c)(2)); and

(2) May be submitted on a voluntary basis by:

(i) Holders of powerline rights-of-way not subject to paragraph (a)(1); and

(ii) Holders of ROWs other than powerline rights-of-way.

(b) *Electric Reliability Organization (ERO) standards:* Holders subject to mandatory reliability standards established by the ERO (or superseding standards) may use those standards as part of the operations, maintenance, and fire prevention plan.

(c) *Plan requirements:* An operations, maintenance, and fire prevention plan must:

(1) Identify the applicable transmission or distribution facilities to be maintained;

(2) Take into account the holder's own operations and maintenance plans for the applicable right-of-way;

(3) Describe the vegetation management, inspection, and operation and maintenance methods that may be used, including methods to comply with applicable law, such as fire safety requirements and reliability standards established by the ERO;

(4) Include schedules for:

(i) The holder to notify the BLM about routine and major maintenance;

(ii) The holder to request approval from the BLM about undertaking routine and major maintenance; and

(iii) The BLM to respond to a request by a holder under paragraph (c)(4)(ii) of this section; and

(5) Describe processes for:

(i) Identifying changes in conditions; and

(ii) Modifying the approved operations, maintenance, and fire prevention plan, if necessary.

(6) Provide for removal and disposal of cut trees and branches, including plans for sale of forest products.

(d) *Review and approval process.* The BLM will, to the extent practicable, review and decide whether to approve operations, maintenance, and fire prevention plans within 120 days.

(e) *Operations, maintenance, and fire prevention plan modifications:* The BLM may notify a holder that changed conditions warrant a modification to the operations, maintenance, and fire prevention plan.

(1) The BLM will provide advance reasonable notice that the holder must submit an operations, maintenance, and fire prevention plan modification.

(2) The holder must submit a proposed operations, maintenance, and fire prevention plan modification to the BLM to address the changed condition identified by the BLM.

(3) The BLM will, to the extent practicable, review and approve modifications in the same 120-day timeframe that applies to new operations, maintenance, and fire prevention plans.

(4) The holder may continue to implement any element of an approved operations, maintenance, and fire prevention plan that does not directly and adversely affect the condition precipitating the need for modification.

(f) *Agreements, in lieu of operations, maintenance, and fire prevention plans:* Certain holders meeting the requirements described in paragraph (g) of this section may enter into an agreement with the BLM in lieu of an operations, maintenance, and fire prevention plan.

(g) *Eligibility to enter into an agreement:* Holders of a right-of-way for an electric transmission or distribution facility are eligible to enter into an agreement with the BLM if they:

(1) Are not subject to the mandatory reliability standards established by the ERO; or

(2) Sold less than or equal to 1,000,000 megawatt hours of electric energy for purposes other than resale during each of the 3 calendar years prior to submitting a request to the BLM.

§ 2805.22 Special provisions for vegetation management for electric transmission and distribution rights-of-way.

(a) Emergency Conditions.—If vegetation or hazard trees have contacted or present an imminent danger of contacting an electric transmission or distribution line from within or adjacent to an electric transmission or distribution right-of-way, the electric transmission or distribution line holder:

(1) May prune or remove the vegetation or hazard tree to avoid the disruption of electric service or to eliminate immediate fire and safety hazards; and

(2) Shall notify the authorized officer not later than 1 day after the date of the response to emergency conditions.

(b) *Non-Emergency Conditions.*—For non-emergency conditions, the holder of a right-of-way for an electric

transmission or distribution facility must conduct vegetation management activities in accordance with the terms and conditions of the grant, §§ 2805.12(a)(4) and 2805.14(d), and any approved operations, maintenance, and fire prevention plan.

(1) You must request approval from the BLM for a proposed activity if your plan:

(i) Requires you to seek specific approval for the proposed activity; or

(ii) Does not address the proposed activity. You may also need to amend your operations, maintenance, and fire prevention plan if you anticipate conducting this activity on a recurring basis.

(2) If the BLM does not timely respond to your request according to the schedule set forth in the approved operations, maintenance, and fire prevention plan, if your request pertains to vegetation management activities, including the removal of hazard trees or other wildfire risk reduction activities, and if the proposed action does not conflict with your approved operations, maintenance, and fire prevention plan, you may proceed with the proposed activity.

(c) *Reasonable measures for prevention and suppression.* You must do everything reasonable to prevent and suppress wildfires on or adjacent to the right-of-way. Reasonable actions include:

(1) Pruning or removal of vegetation or hazard trees to prevent fire ignition from electric transmission and distribution facilities during emergency conditions or cyclic maintenance; and

(2) Cooperating with the BLM in its efforts to investigate, suppress, and respond to fires within and near the right-of-way.

■ 25. Amend § 2806.13 by revising paragraph (e) and adding paragraph (h) to read as follows:

§ 2806.13 What happens if I do not pay rents and fees or if I pay the rents or fees late?

* * * * *

(e) Subject to applicable laws and regulations, we will retroactively bill for uncollected or under-collected rent, fees, and late payments.

* * * * *

(h) You must pay rent even if you have not been sent or received a courtesy bill.

■ 26. Amend § 2806.14 by removing the fourth sentence of paragraph (a)(4) to read as follows.

§ 2806.14 Under what circumstances am I exempt from paying rent?

(a) * * *

(4) Electric or telephone facilities constructed on the right-of-way were financed in whole or in part, or eligible for financing, under the Rural Electrification Act of 1936, as amended (REA) (7 U.S.C. 901 *et seq.*), or are extensions of such facilities. You do not need to have sought financing from the Rural Utilities Service to qualify for this exemption. BLM may require you to document the facility's eligibility for REA financing.

* * * * *

■ 27. Amend § 2806.15 by revising paragraphs (b), (b)(3), and (4), redesignating paragraph (c) as paragraph (b)(5), and revising new paragraph (b)(5) to read as follows:

§ 2806.15 Under what circumstances may BLM waive or reduce my rent?

* * * * *

(b) A BLM State Director may, on a case-by-case basis, evaluate and approve any requests for waiver or reduction in the annual rent for grants if you show the BLM that:

* * * * *

(3) Your grant describes your intended use of new and existing routes to access your right-of-way (see § 2805.11(b)). This paragraph does not apply to oil and gas leases issued under part 3100 of this chapter;

(4) Your grant involves a cost share road or a reciprocal right-of-way agreement not subject to subpart 2812 of this chapter. In these cases, the BLM will determine the rent based on the proportion of use; or

(5) Paying the full rent will cause you undue hardship and it is in the public interest to waive or reduce your rent. In your request for a waiver or rental reduction you must include a suggested alternative rental payment plan or timeframe within which you anticipate resuming full rental payments. The BLM may also require you to submit specific financial and technical data or other information that corrects or modifies the statement of financial capability required by § 2804.12(a)(5) of this part.

■ 28. Amend § 2806.20 by revising paragraph (c) to read as follows:

§ 2806.20 What is the rent for a linear right-of-way grant?

* * * * *

(c) You may obtain a copy of the current Per Acre Rent Schedule at *https://www.blm.gov,* from any BLM state, district, or field office, or by writing: Attention to the Division of Lands, Realty and Cadastral Survey, U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW, Room 5625, Washington, DC 20240.

§ § 2806.30 through 2806.44 [Removed]

■ 29. Remove the undesignated heading ''Communication Site Rights-of-Way'' and

§ § 2806.30 through 2806.44.

■ 30. Amend § 2806.52 by revising paragraphs (a)(6) and (b)(2) as follows:

§ 2806.52 Rents and fees for solar energy development grants.

* * * * *

(a) * * *

(6) *Contact address.* You may obtain a copy of the current per acre zone rates for solar energy development (solar energy acreage rent schedule) at *https://www.blm.gov,* from your local BLM state, district, or field office, or by writing: Attention to the National Renewable Energy Coordination Office, U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW, Room 5625, Washington, DC 20240.

(b) * * *

(2) *MW rate schedule.* You may obtain a copy of the current MW rate schedule for solar energy development at *https://www.blm.gov,* from your local BLM state, district, or field office, or by writing: Attention to the National Renewable Energy Coordination Office, U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW, Mail Stop 2134LM, Washington, DC 20240.

* * * * *

■ 31. Amend § 2806.62 by revising paragraphs (a)(7) and (b)(2) as follows:

§ 2806.62 Rents and fees for wind energy development grants.

* * * * *

(a) * * *

(7) *Wind energy acreage rent schedule.* You may obtain a copy of the current per acre zone rates for wind energy development at *https://www.blm.gov,* by contacting your local BLM state, district, or field office, or by writing: Attention to the National Renewable Energy Coordination Office, U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW, Room 5625, Washington, DC 20240.

(b) * * *

(2) *MW rate schedule.* You may obtain a copy of the current MW rate schedule for wind energy development at *https://www.blm.gov,* by contacting your local BLM state, district, or field office, or by writing: Attention to the National Renewable Energy Coordination Office, U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW, Room 5625, Washington, DC 20240.

* * * * *

■ 32. Amend § 2807.12 by redesignating paragraph (g) as paragraph (h) and

adding a new paragraph (g) to read as follows:

§ 2807.12 If I hold a grant, for what am I liable?

* * * * *

(g) The BLM will not impose strict liability for damages or injuries resulting from:

(1) The BLM unreasonably withholding or delaying approval of an operations, maintenance, and fire prevention plan submitted under § 2805.21 of this part; or

(2) The BLM failing to adhere to an applicable schedule in an approved plan (see § 2805.21(d)).

* * * * *

■ 33. Amend § 2807.17 by revising paragraph (b)(2), redesignating paragraph (b)(3) as paragraph (b)(4) and adding a new paragraph (b)(3) to read as follows:

§ 2807.17 Under what conditions may the BLM suspend or terminate my grant?

* * * * *

(b)* * *

* * * * *

(2) BLM consents in writing to your request to relinquish the grant;

(3) A court terminates it or requires the BLM to terminate it; or

* * * * *

■ 34. Amend § 2807.20 by revising paragraphs (b) and (d) to read as follows:

§ 2807.20 When must I amend my application, seek an amendment of my grant, or obtain a new grant?

* * * * *

(b) The requirements to amend an application or grant are the same as those for a new application, including paying cost recovery fees and rent according to §§ 2804.14, 2805.16, and 2806.10 of this part.

* * * * *

(d) Grants issued prior to October 21, 1976:

(1) If there is a proposed substantial deviation in the location or use, or terms and conditions of your right-of-way grant, you must apply for a new grant consistent with the remainder of this section. The BLM may keep the old grant in effect for the portion of the right-of-way not amended and issue a new grant for the new use or location, or terms and conditions.

(2) If you wish to renew your grant, you must apply for a new grant.

(3) If the BLM has terminated your grant due to non-compliance with the terms and conditions of your grant, you must apply for a new grant.

(4) If the BLM approves your application for an amendment, the BLM will terminate your old grant and you will receive a new grant under 43 U.S.C. 1761 *et seq.* and the regulations in this part. The BLM may include the same terms and conditions in the new grant as were in the original grant as to annual rent, duration, and nature of interest if the BLM determines, based on current land use plans and other management decisions, that it is in the public interest to do so.

* * * * *

■ 35. Amend § 2807.22 by revising paragraph (f) and adding a new paragraph (h) to read as follows:

§ 2807.22 How do I renew my grant or lease?

* * * * *

(f) If you make a timely and sufficient application for a renewal of your existing grant, in accordance with this section, and you are in conformance with applicable laws, regulations, and terms and conditions in your grant, the existing grant does not expire until we have issued a decision to approve or deny the renewal application. Within 60 days of receiving an application for a renewal, the BLM will notify you in writing of its determination regarding the timeliness and sufficiency of your application. If the BLM determines that your application is timely and sufficient, the BLM's written notice will confirm that until the BLM issues a decision on your renewal application, your existing grant will remain valid, provided that you remain in compliance with applicable laws, regulations, and terms and conditions.

* * * * *

(h) If you do not submit your application under paragraph (a) or (b) of this section at least 120 days prior to grant expiration, it is considered delinquent; the BLM will not be subject to the customer service standards in this section; and it will be processed only as the BLM has time and resources available.

■ 36. Amend § 2809.19 by revising paragraph (d) to read as follows:

§ 2809.19 Applications in designated leasing areas or on lands that later become designated leasing areas.

* * * * *

(d) You may file a new application under part 2804 for testing and monitoring purposes inside designated leasing areas. If the BLM approves your application, you will receive a short term grant in accordance with §§ 2805.11(c)(2)(i) or (ii), which may qualify you for an offset under § 2809.16.

■ 37. Add a new part 2860 to read as follows:

PART 2860—COMMUNICATIONS USES

Authority: 43 U.S.C. 1733, 1740, 1763, and 1764.

Subpart 2861—General Information

§ 2861.1 What requirements of part 2800 apply to my grant?

Grants issued under this part must comply with the requirements of part 2800, except as otherwise described in this part.

§ 2861.2 What is the objective of the BLM's Communications Uses program?

It is the BLM's objective to authorize and administer communications uses under Title V of the Federal Land Policy and Management Act of 1976 and the regulations in this part to qualified individual, business, or governmental entities and to direct and control communications uses on public lands in a manner that:

(a) Protects the natural resources associated with public lands and adjacent lands, whether private or administered by a government entity;

(b) Facilitates the orderly development of communications uses on BLM-administered lands and provides for a safe and high-quality communications environment for the public;

(c) Prevents unnecessary or undue degradation to public lands;

(d) Collects fair market value for communications uses that occupy BLM-administered lands through the collection of annual rental fees;

(e) Promotes the expansion of communications uses in rural America and use of rights-of-way in common wherever practical, considering engineering and technological compatibility, national security, and land use plans; and

(f) Coordinates, to the fullest extent possible, all BLM actions under the regulations in this part with State and local governments, interested individuals, and appropriate quasi-public entities.

§ 2861.5 What acronyms and terms are used in the regulations in this part?

In addition to the acronyms and terms listed in this section, the acronyms and terms listed in part 2800 of this chapter apply to this part. As used in this part:

RMA means the Ranally Metro Area Population Ranking as published in the most recent edition of the Rand McNally Commercial Atlas and Marketing Guide.

Annual inventory certification means a report that the holder of a grant submits to the BLM each year to report the uses within or on their facilities (see § 2866.31(c)).

Base rent means the dollar amount required from an authorization holder on BLM managed lands based on the communications uses with the highest value in the associated facility or facilities, as calculated according to the communications uses rent schedule. If a facility manager's or facility owner's scheduled rent is equal to the highest rent charged a tenant in the facility or facilities, then the facility manager's or facility owner's use determines the dollar amount of the base rent. Otherwise, the facility owner's, facility manager's, customer's, or tenant's use with the highest value, and which is not otherwise excluded from rent, determines the base rent.

Collocation means another use, other than the holder's use, added to a communications use facility. Collocation may occur inside the building or on a tower.

Communications site means an area of public land designated for wireless communications uses that may be limited to a single communications facility, but most often encompasses more than one, and is identified by name, usually featuring a local prominent landmark.

Communications site management plans means implementation-level plans that provide direction to the users for the day-to-day operations of the communications site.

Communications uses means any uses associated with the transmission of data, voice, or video, or any other transmission or reception uses authorized by 43 U.S.C. 1761(a)(5). Communications uses may occur in or on a communications facility or a linear facility, such as a telephone line or fiber optic cable line.

Communications uses rent schedule is a schedule of rents for the following types of communications uses, including related technologies, located in a facility associated with a particular grant. All use categories include ancillary communications equipment, such as internal microwave or internal one-or two-way radio, that are directly related to operating, maintaining, and monitoring the primary uses listed below. The Federal Communications Commission (FCC) may or may not license the primary uses. The type of use and community served, identified on an FCC license, if one has been issued, do not supersede either the definitions in this subpart or the procedures in § 2866.30 of this part for calculating rent for communication facilities and uses located on public land:

(1) *Television broadcast* means a use that broadcasts UHF and VHF audio and video signals for general public reception. This category does not include low-power television (LPTV) or rebroadcast devices, such as translators, or transmitting devices, such as microwave relays serving broadcast translators;

(2) *AM and FM radio broadcast* means a use that broadcasts amplitude modulation (AM) or frequency modulation (FM) audio signals for general public reception. This category does not include low-power FM radio; rebroadcast devices, such as translators; or boosters or microwave relays serving broadcast translators;

(3) *Cable television* means a use that transmits video programming to multiple subscribers in a community over a wired or wireless network. This category does not include rebroadcast devices that retransmit television signals of one or more television broadcast stations, or personal or internal antenna systems, such as private systems serving hotels and residences;

(4) *Broadcast translator, low-power television, and low-power FM radio* means a use of translators, LPTV, or low-power FM radio (LPFM). Translators receive a television or FM radio broadcast signal and rebroadcast it on a different channel or frequency for local reception. In some cases, the translator relays the true signal to an amplifier or another translator. LPTV and LPFM are broadcast translators that originate programming. This category also includes translators associated with public telecommunication services;

(5) *Commercial mobile radio service (CMRS)* means commercial mobile radio uses that provide mobile communication service to individual customers. Examples of CMRS include: Community repeaters, trunked radio

(specialized mobile radio), two-way radio voice dispatch, public switched network (telephone/data) interconnect service, microwave communications link equipment, and other two-way voice and paging services;

(6) *Facility Managers* are grant holders that lease building, tower, and related facility space to a variety of tenants and customers as part of the holder's business enterprise, but do not own or operate communication equipment in the facility for their own uses;

(7) *Cellular telephone* means a system of mobile or fixed communication devices that use a combination of radio and telephone switching technology and provide public switched network services to fixed or mobile users, or both, within a defined geographic area. The system consists of one or more cell sites containing transmitting and receiving antennas, cellular base station radio, telephone equipment, or microwave communications link equipment. Examples of cellular telephone include: Personal Communication Service, Enhanced Specialized Mobile Radio, Improved Mobile Telephone Service, Air-to-Ground, Offshore Radio Telephone Service, Cell Site Extenders, and Local Multipoint Distribution Service;

(8) *Private mobile radio service (PMRS)* means uses supporting private mobile radio systems primarily for a single entity for mobile internal communications. PMRS service is not sold and is exclusively limited to the user in support of business, community activities, or other organizational communication needs. *Examples of PMRS include:* Private local radio dispatch, private paging services, and ancillary microwave communications equipment for controlling mobile facilities;

(9) *Microwave* means communications uses that:

(i) Provide long-line intrastate and interstate public telephone, television, and data transmissions; or

(ii) Support the primary business of pipeline and power companies, railroads, land resource management companies, or wireless internet service provider (ISP) companies;

(10) *Internet service provider (ISP)* refers to a holder who utilizes wireless technology to connect subscribers to the internet;

(11) *Passive reflector* means various types of non-powered reflector devices used to bend or ricochet electronic signals between active relay stations or between an active relay station and a terminal. A passive reflector commonly serves a microwave communication system. The reflector requires point-to-point line-of-sight with the connecting relay stations, but does not require electric power;

(12) *Local exchange network* means radio service that provides basic telephone service, primarily to rural communities; and

(13) *Other communications uses* means private communications uses, such as amateur radio, personal/private receive-only antennas, natural resource and environmental monitoring equipment, and other small, low-power devices used to monitor or control remote activities.

Customer means an occupant who is paying a facility manager, facility owner, or tenant for using all or any part of the space in the facility, or for communication services, and is not selling communication services or broadcasting to others. We consider persons or entities benefitting from private or internal communications uses located in a holder's facility as customers for purposes of calculating rent. Customer uses are not included in calculating the amount of rent owed by a facility owner, facility manager, or tenant, except as noted in §§ 2806.34(b)(4) and 2866.42 of this subchapter. Examples of customers include: Users of PMRS, users in the microwave category when the microwave use is limited to internal communications, and all users in the category of ''Other communications uses'' (see paragraph (13) of the definition of *communications uses rent schedule* in this section).

Duly filed application means an application which includes all the elements required by § 2804.25.

Facility means an improvement or structure, whether existing or planned, that is or would be owned and controlled by the authorization holder. For purposes of communications site rights-of-way, facility means the building, tower, cabinet, and related incidental structures or improvements authorized under the terms of the authorization.

Facility manager means a person or entity that leases space in a facility to communications users and:

(1) Holds a communication use grant;

(2) Owns a communications facility on lands covered by that grant; and

(3) Does not own or operate communications equipment in the facility for personal or commercial purposes.

Facility owner means a person or entity that may or may not lease space in a facility to communications users and:

(1) Holds a communications uses grant;

(2) Owns a communications facility on lands covered by that grant; and

(3) Owns and operates his or her own communications equipment in the facility for personal or commercial purposes.

Grant means an authorization or instrument (*e.g.,* lease) BLM issues under Title V of the Federal Land Policy and Management Act, 43 U.S.C. 1761 *et seq.,* and those authorizations and instruments BLM and its predecessors issued for like purposes before October 21, 1976, under then existing statutory authority.

Occupant means an entity who uses any portion of a facility owned by a grant holder.

Site means an area, such as a mountaintop, where a holder locates one or more communication or other right-of-way facilities.

Tenant means an occupant who is paying a facility manager, facility owner, or other entity for occupying and using all or any part of a facility. A tenant operates communication equipment in the facility for profit by broadcasting to others or selling communication services. For purposes of calculating the amount of rent that BLM charges, a tenant's use does not include:

(1) Private mobile radio or internal microwave use that is not being sold; or

(2) A use in the category of ''Other Communications Uses'' (*see* paragraph (13) of the definition of *Communications uses rent schedule* in this section).

§ 2861.8 Severability.

If a court holds any provisions of the rules in this part or their applicability to any person or circumstances invalid, the remainder of these rules and their applicability to other people or circumstances will not be affected.

§ 2861.9 When do I need a grant?

You must have an authorization under this part to use public lands for communications uses systems or facilities over, under, on, or through public lands. These include, but are not limited to systems for transmitting or receiving electronic signals and other means of communication by:

(a) Installing a facility that is not under a current valid authorization; or

(b) Installing a linear communications facility, such as fiber optic cable.

Subpart 2862—Lands Available for Grants

§ 2862.11 How does the BLM designate communications sites and establish communications site management plans?

(a) The BLM may determine the location and boundaries of communications sites. When establishing a communications site, the BLM coordinates with other Federal agencies, State, local, and Tribal governments, and the public to identify resource-related issues, concerns, and needs.

(b) When determining which lands may be suitable for communications sites, the BLM will consider all factors described in § 2802.11(b). Additional factors the BLM considers include but are not limited to access to the site, existing infrastructure, signal coverage, available space, and industry demand.

(c) The BLM may establish a communications site management plan to guide the development of communications uses at the site. The plans describe the types of communications uses that are permitted to operate at a communications site.

Subpart 2864—Applying for Grants

§ 2864.10 What should I do before I file my application?

In addition to the suggested actions listed in § 2804.10, before you file your application you should:

(a) Schedule a preliminary application review meeting with the appropriate personnel in the BLM field office having jurisdiction over the lands you seek to use. Preliminary application review meetings help you to plan your project, coordinate with the BLM, and ensure a smooth permitting process. During the preliminary application review meeting, the BLM can:

(1) Identify potential constraints;

(2) Determine whether the lands are located inside a communications site management plan area;

(3) Tentatively schedule the processing of your proposed application; and

(4) Inform you of your financial obligations, such as processing and monitoring costs and rents.

(b) Request a copy of the most recent communications site management plan for that site if one is available.

(c) Ensure you have all other necessary licenses, authorizations, or permits required for the operation of your facility.

§ 2864.12 What must I do when submitting my application?

(a) You must file your application on Standard Form 299, available from any BLM office or at *https://www.blm.gov,* and fill in the required information as completely as possible. The application must include the applicant's original signature or meet the BLM standards for electronic commerce. Your complete application must include the following:

(1) All necessary information under § 2804.12 of this chapter;

(2) Federal Communications Commission (FCC) call sign, or license, for all licensed uses;

(3) Geographic Information Systems (GIS) shapefiles, or equivalent format;

(4) Draft engineering/construction drawings of your proposed facility;

(5) Technical data related to your project; and

(6) Draft communications use plan of development.

(b) The BLM may at any time during the application process request additional information relevant to the permitting of your proposal. You must submit this information before the BLM will continue processing your application.

§ 2864.24 Do I always have to use Standard Form 299 when submitting my application for grant?

You must file an application for communications uses using Standard Form 299.

§ 2864.25 How will the BLM process my Communications Uses application?

The BLM will process your communications uses application in accordance with the provisions in § 2804.25. The BLM will notify you in writing with an offer of an authorization or a denial of your application within 270 days of receiving a duly filed application.

§ 2864.26 Under what circumstances may the BLM deny my application?

In addition to the considerations listed in § 2804.26, the BLM may deny your application under this part if:

(a) The proposed use would interfere with previously authorized rights-of-way, including communications uses on public lands;

(b) The proposed use presents a public health or safety issue; or

(c) The proposed use is not in conformance with the applicable resource management plan or communications site management plan.

§ 2864.35 How will the BLM prioritize my Communications Uses application?

The BLM will prioritize your application in a manner that assists in meeting the needs of underserved, rural, and Tribal communities and first responders to strengthen telecommunications infrastructure throughout the United States.

Subpart 2865—Terms and Conditions of Grants

§ 2865.14 What rights does a grant provide?

In addition to the rights listed in § 2805.14, the authorization provides to you the right to:

(a) Use the described lands to construct, operate, maintain, and terminate authorized facilities within the right-of-way for authorized purposes under the terms and conditions of your authorization;

(b) If your authorization specifically allows for subleasing, charge reasonable fees for such use. If your authorization does not specifically authorize subleasing, you may not let anyone else collocate within or on your facilities;

(c) Allow others to utilize the lands or facilities if the authorization specifies; and

(d) Hold the grant for a term of 30 years, unless the BLM determines a shorter term is appropriate.

Subpart 2866—Annual Rents and Payments

General Provisions

§ 2866.14 Under what circumstances am I exempt from paying rent?

(a) You are exempt from rent under this part if:

(1) You are a Federal, State, or local governmental entity (except as provided by paragraph (b) of this section);

(2) You have been granted an exemption under a statute providing for such; or

(3) Your facilities were financed in whole or in part, or are eligible for financing, under the Rural Electrification Act of 1936, as amended (REA) (7 U.S.C. 901 *et seq.*), or are extensions of such facilities. When a holder who is exempt from rent under REA adds non-eligible tenant uses on the authorization, the holder will become subject to rent in accordance with §§ 2866.30 through 2866.44 of this subpart.

(b) Exceptions:

(1) The exemptions in this section do not apply if you are in trespass.

(2) If you are a governmental entity, you are not exempt from rent, when:

(i) The facility, system, space, or any part of the authorization is being used for commercial purposes;

(ii) You are a municipal utility or cooperative whose principal source of revenue is customer charges; or

(iii) You charge the United States rent for occupancy within or on your facility beyond standard operation and maintenance fees.

§ 2866.15 Under what circumstances may the BLM waive or reduce my rent?

(a) The BLM may waive or reduce your rent if you are licensed by the FCC as noncommercial and educational.

(b) The BLM may evaluate and approve, in writing, any requests for waiver or reduction in the annual rent for authorizations granted to:

(1) An amateur radio club (such as Civil Air Patrol) which provides a benefit to the general public or to the programs of the Secretary of the Interior;

(2) A nonprofit organization; or

(3) Holders that demonstrate that their rates will cause undue hardship and that it is in the public interest to waive or reduce the rent (see § 2806.15(b)(5)).

(c) The BLM may not waive or reduce your rent when:

(1) Your organization exists and operates for the principal benefit of its members;

(2) The facility, system, space, or any part of the right-of-way area is being used for commercial purposes;

(3) You charge the United States to occupy your facility; or

(4) You charge rent to your occupant or occupants, beyond standard operation and maintenance fees, when those occupants' use or uses are exempted or waived from rent by the BLM.

(d) The BLM may revoke your existing waiver of rent if the BLM determines that you no longer meet the criteria above for a waiver.

Communications Uses Rental

§ 2866.23 How will the BLM calculate my rent for linear rights-of-way for Communications Uses?

The BLM will calculate your rent for linear rights-of-way for communications uses, such as telephone lines and fiber optic cable, as provided in § 2806.23.

§ 2866.30 What are the rents for Communications Uses?

(a) Rent schedule. You may obtain a copy of the current schedule from any BLM state, district, or field office, or by writing: Attention to the Division of Lands, Realty and Cadastral Survey, U.S. Department of the Interior, Bureau of Land Management, 1849 C St. NW, Room 5647, Washington, DC 20240. We also post the current communications use rent schedule at *https://www.blm.gov.*

(1) The BLM uses a rent schedule to calculate the rent for communications uses. The schedule is based on population strata (the population served), as depicted in the most recent version of the Ranally Metro Area (RMA) Population Ranking, and the type of communications use or uses for which we normally grant communication site rights-of-way. These uses are listed as part of the definition of ''communications uses rent schedule,'' set out at § 2861.5.

(2) The BLM will update the schedule annually based on the U.S. Department of Labor Consumer Price Index for All Urban Consumers, U.S. City Average (CPI–U), as of July of each year (difference in CPI–U from July of one year to July of the following year), and the RMA population rankings.

(3) The BLM will limit the annual adjustment based on the Consumer Price Index to no more than 5 percent. The BLM will review the rent schedule to ensure that the schedule reflects fair market value.

(b) Uses not covered by the schedule. The communications uses rent schedule does not apply to:

(1) Communications uses located entirely within the boundaries of an oil and gas lease, and solely supporting the operations of the oil and gas lease (see parts 3160 through 3190 of this Chapter);

(2) Communications facilities and uses ancillary to a linear authorization that are entirely within the scope of an authorized linear right-of-way, such as a railroad authorization or an oil and gas pipeline authorization that solely support the operations authorized by that right-of-way and that are owned and operated by the authorization holder for that right-of-way;

(3) Linear communications uses not listed on the schedule, such as telephone lines, fiber optic cables, and new technologies;

(4) Grants for which the BLM determines the rent by competitive bidding; or

(5) Communication facilities and uses for which a BLM State Director concurs that:

(i) The expected annual rent, that the BLM estimates from market data, exceeds the rent from the rent schedule by five times; or

(ii) The communication site serves a population of one million or more and the expected annual rent for the communications use or uses is more than $10,000 above the rent from the rent schedule.

§ 2866.31 How will the BLM calculate rent for Communications Uses in the schedule?

(a) Basic rule. The BLM calculates rents for:

(1) Single-use facilities by applying the rent from the communications uses rent schedule (see § 2866.30 of this subpart) for the type of use and the population strata served; and

(2) Multiple-use facilities, whose authorizations provide for subleasing, by setting the rent of the highest value use in the facility or facilities as the base rent (taken from the rent schedule) and adding to it 25 percent of the rent from the rent schedule for all tenant uses in the facility or facilities, if a tenant use is not used as the base rent (rent = base rent + 25 percent of all rent due to additional tenant uses in the facility or facilities) (see also §§ 2866.32 and 2866.34 of this subpart).

(b) Exclusions. When calculating rent, the BLM will exclude customer uses, except as provided for at §§ 2866.34(b)(4) and 2866.42 of this subpart. The BLM will also exclude those uses exempted from rent by § 2866.14 of this subpart, and any uses whose rent has been waived or reduced to zero as described in § 2866.15 of this subpart.

(c) Annual statement. By October 15 of each year, you, as a grant holder, must submit to the BLM a certified statement listing any tenants and customers in your facility or facilities and the category of use for each tenant or customer as of September 30 of the same year. The BLM may require you to submit additional information to calculate your rent. The BLM will determine the rent based on the annual inventory certification statement provided. We require only facility owners or facility managers to hold a grant (unless you are an occupant in a federally owned facility as described in § 2866.42 of this subpart) and will charge you rent for your grant based on the total number of communications uses within the right-of-way and the type of uses and population strata the facility or site serves. If you fail to submit your annual inventory certification by October 15 (by electronic correspondence or postmarked), you may not receive any discounts, reductions, exemptions, or waivers (see §§ 2866.14, 2866.15, and 2866.34), to which you may have been entitled.

§ 2866.32 How does the BLM determine the population strata served for your facility?

(a) The BLM determines the population strata served as follows:

(1) If the site or facility is within a designated RMA, the BLM will use the population strata of the RMA;

(2) If the site or facility is within a designated RMA, and it serves two or more RMAs, the BLM will use the population strata of the RMA having the greatest population;

(3) If the site or facility is outside an RMA, and it serves one or more RMAs, the BLM will use the population strata

of the RMA served having the greatest population;

(4) If the site or facility is outside an RMA and the site does not serve an RMA, the BLM will use the population strata of the community it serves having the greatest population, as identified in the current edition of the Rand McNally Road Atlas; or

(5) If the site or facility is outside an RMA, and it serves a community of less than 25,000, the BLM will use the lowest population strata shown on the rent schedule.

(b)(1) The BLM considers all facilities (and all uses within the same facility) located at one site to serve the same RMA or community. However, the BLM may make case-by-case exceptions in determining the population served at a particular site by uses not located within the same facility and not authorized under the same grant. The BLM has the sole responsibility to make this determination. For example, when a site has a mix of high-power and low-power uses that are authorized by separate grants, and only the high-power uses are capable of serving an RMA or community with the greatest population, the BLM may separately determine the population strata served by the low-power uses (if not collocated in the same facility with the high-power uses), and calculate their rent as described in § 2866.30 of this subpart.

(2) For purposes of rent calculation, all uses within the same facility and/or authorized under the same grant must serve the same population strata.

(3) For purposes of rent calculation, the BLM will not modify the population rankings published in the Rand McNally Commercial Atlas and Marketing Guide or the population of the community served.

§ 2866.33 How will the BLM calculate the rent for a single use communication facility grant?

The BLM calculates the rent for a grant authorizing a single-use communication facility from the communications uses rent schedule (see § 2866.30 of this subpart), based on your authorized single use and the population strata it serves (see § 2866.32 of this subpart).

§ 2866.34 How will the BLM calculate the rent for a multiple-use communication facility grant?

(a) *Basic rule.* The BLM first determines the population strata the communication facility serves according to § 2866.32 of this subpart and then calculates the rent assessed to facility owners and facility managers for a grant for a communication facility that authorizes subleasing with tenants, customers, or both, as follows:

(1) The BLM will determine the rent of the highest value use in the facility or facilities as the base rent, and add to it 25 percent of the rent from the rent schedule (see § 2866.30 of this subpart) for each tenant use in the facility or facilities;

(2) If the highest value use is not the use of the facility owner or facility manager, the BLM will consider the owner's or manager's use like any tenant or customer use in calculating the rent (see § 2866.35(b) for facility owners and § 2866.39(a) for facility managers);

(3) If a tenant use is the highest value use, the BLM will exclude the rent for that tenant's use when calculating the additional 25 percent amount under paragraph (a)(1) of this section for tenant uses;

(4) If a holder has multiple uses authorized under the same grant, such as a TV and a FM radio station, the BLM will calculate the rent as in paragraph (a)(1) of this section. In this case, the TV rent would be the highest value use and the BLM would charge the FM portion according to the rent schedule as if it were a tenant use.

(b) *Special applications.* The following provisions apply when calculating rents for communications uses exempted from rent under § 2866.14 of this subpart or communications uses whose rent has been waived or reduced to zero under § 2866.15 of this subpart:

(1) The BLM will exclude exempted uses or uses whose rent has been waived or reduced to zero (see §§ 2866.14 and 2866.15 of this subpart) of either a facility owner or a facility manager in calculating rents. The BLM will exclude similar uses (see §§ 2866.14 and 2866.15 of this subpart) of a customer or tenant if they choose to hold their own grant (see § 2866.36 of this subpart) or are occupants in a Federal facility (see § 2866.42(a) of this subpart);

(2) The BLM will charge rent to a facility owner whose own use is either exempted from rent or whose rent has been waived or reduced to zero (see §§ 2866.14 and 2866.15 of this subpart), but who has tenants in the facility, in an amount equal to the rent of the highest value tenant use plus 25 percent of the rent from the rent schedule for each of the remaining tenant uses subject to rent;

(3) The BLM will not charge rent to a facility owner, facility manager, or tenant (when holding a grant) when all of the following occur:

(i) The BLM exempts from rent, waives, or reduces to zero the rent for the holder's use (see §§ 2866.14 and 2866.15 of this subpart);

(ii) Rent from all other uses in the facility is exempted, waived, or reduced to zero, or the BLM considers such uses as customer uses; and

(iii) The holder is not operating the facility for commercial purposes (see § 2866.15(c)(2) of this part) with respect to such other uses in the facility; and

(4) If a holder, whose own use is exempted from rent or whose rent has been waived or reduced to zero, is conducting a commercial activity with customers or tenants whose uses are also exempted from rent or whose rent has been waived or reduced to zero (see §§ 2866.14 and 2866.15 of this subpart), the BLM will charge rent, notwithstanding § 2866.31(b), based on the highest value use within the facility. This paragraph (b)(4) does not apply to facilities exempt from rent under § 2866.14(a)(3) except when the facility also includes ineligible facilities.

§ 2866.35 How will the BLM calculate rent for private mobile radio service (PMRS), internal microwave, and ''other'' category uses?

If an entity engaged in a PMRS, internal microwave, or ''other'' use is:

(a) Using space in a facility owned by either a facility owner or facility manager, the BLM will consider the entity to be a customer and not include these uses in the rent calculation for the facility; or

(b) The facility owner, the BLM will follow the provisions in § 2866.31 of this subpart to calculate rent for a grant involving these uses. However, we include the rent from the rent schedule for a PMRS, internal microwave, or other use in the rental calculation only if the value of that use is equal to or greater than the value of any other use in the facility. The BLM excludes these uses in the 25 percent calculation (see § 2866.31(a) of this subpart) when their value does not exceed the highest value in the facility.

§ 2866.36 If I am a tenant or customer in a facility, must I have my own grant and if so, how will this affect my rent?

(a) You may have your own authorization, but the BLM does not require a separate grant for tenants and customers using a facility authorized by a BLM grant that contains a subleasing provision. The BLM charges the facility owner or facility manager rent based on the highest value use within the facility (including any tenant or customer use authorized by a separate grant) and 25 percent of the rent from the rent schedule for each of the other uses subject to rent (including any tenant or customer use a separate grant authorizes

and the facility owner's use if it is not the highest value use).

(b) If you own a building, equipment shelter, or tower on public lands for communication purposes, you must have an authorization under this part, even if you are also a tenant or customer in someone else's facility.

(c) The BLM will charge tenants and customers who hold their own grant in a facility, as grant holders, the full annual rent for their use based on the BLM communications use rent schedule. The BLM will also include such tenant or customer use in calculating the rent the facility owner or facility manager must pay.

§ 2866.37 How will the BLM calculate rent for a grant involving an entity with a single use (holder or tenant) having equipment or occupying space in multiple BLM-authorized facilities to support that single use?

The BLM will include the single use in calculating rent for each grant authorizing that use. For example, a television station locates its antenna on a tower authorized by grant ''A'' and locates its related broadcast equipment in a building authorized by grant ''B.'' The statement listing tenants and customers for each facility (see § 2866.31(c) of this subpart) must include the television use because each facility is benefitting economically from having the television broadcast equipment located there, even though the combined equipment is supporting only one single end use.

§ 2866.38 Can I combine multiple grants for facilities located at one site into a single grant?

If you hold grants for two or more facilities on the same communications site, you may submit an SF–299 application and be subject to cost recovery for the BLM to authorize those facilities under a single grant. The highest value use in all the combined facilities determines the base rent. The BLM then charges for each remaining use in the combined facilities at 25 percent of the rent from the rent schedule. These uses include those uses we previously calculated as base rents when the BLM authorized each of the facilities on an individual basis.

§ 2866.39 How will the BLM calculate rent for a grant for a facility manager's use?

(a) The BLM will follow the provisions in § 2866.31 of this subpart to calculate rent for a grant involving a facility manager's use. However, we include the rent from the rent schedule for a facility manager's use in the rental calculation only if the value of that use is equal to or greater than the value of any other use in the facility. The BLM excludes the facility manager's use in the 25 percent calculation (see § 2866.31(a) of this subpart) when its value does not exceed the highest value in the facility.

(b) If you are a facility owner and you terminate your use within the facility, but want to retain the grant for other purposes, the BLM will continue to charge you for your authorized use until the BLM amends the grant to change your use to facility manager or to some other communications use.

§ 2866.40 How will the BLM calculate rent for an authorization for ancillary Communications Uses associated with Communications Uses on the rent schedule?

If the ancillary communication equipment is used solely in direct support of the primary use (see the definition of communications uses rent schedule in § 2861.5 of this part), the BLM will calculate and charge rent only for the primary use.

§ 2866.41 How will the BLM calculate rent for communications facilities ancillary to a linear grant or other use authorization?

When a communications facility is authorized as ancillary to (*i.e.,* used for the sole purpose of internal communications) a grant or some other type of use authorization (*e.g.,* a mineral lease or sundry notice), the BLM will determine the rent using the linear rent schedule (see § 2866.20) or rent scheme associated with the other authorization, and not the communications uses rent schedule

§ 2866.42 How will the BLM calculate rent for Communications Uses within a federally owned communications facility?

(a) If you are an occupant of a federally owned communication facility, you must have your own grant and pay rent in accordance with these regulations; and

(b) If a Federal agency holds a grant and agrees to operate the facility as a facility owner under § 2866.31 of this subpart, occupants do not need a separate BLM grant, and the BLM will calculate and charge rent to the Federal facility owner under § 2866.30 through § 2866.43 of this subpart.

§ 2866.43 How does the BLM calculate rent for passive reflectors and local exchange networks?

The BLM calculates rent for passive reflectors and local exchange networks by using the same rent schedules for passive reflectors and local exchange networks as the Forest Service uses for the region in which the facilities are located. You may obtain the pertinent schedules from the Forest Service or from any BLM state or field office in the region in question. For passive reflectors and local exchange networks not covered by a Forest Service regional schedule, we use the provisions in § 2806.70 to determine rent. See the Forest Service regulations at 36 CFR chapter II.

§ 2866.44 How will the BLM calculate rent for a facility owner's or facility manager's grant which authorizes Communications Uses?

This section applies to a grant that authorizes a mixture of communications uses, some of which are subject to the communications uses rent schedule and some of which are not. We will determine rent for these grants under the provisions of this section.

(a) The BLM establishes the rent for each of the uses in the facility that are not covered by the communications uses rent schedule using § 2806.70.

(b) BLM establishes the rent for each of the uses in the facility that are covered by the rent schedule using §§ 2866.30 and 2866.31 of this subpart.

(c) BLM determines the facility owner or facility manager's rent by identifying the highest rent in the facility of those established under paragraphs (a) and (b) of this section and adding to it 25 percent of the rent of all other uses subject to rent.

Subpart 2868—Communications Uses Trespass

§ 2868.10 What is a Communications Uses trespass?

In addition to the provisions of § 2808.10, holders of a grant must comply with this section. The following are prohibited:

(a) Placement of any type of facilities such as generators, fuel tanks, equipment cabinets, additional towers or wind or solar power generation equipment on the public lands without formal BLM authorization to do so;

(b) Subleasing communications facilities by allowing another entity to place equipment or utilize your tower without having BLM subleasing authority to do so; or

(c) Affixing communications equipment, such as antennas, to vegetation or rocks on public lands without express authorization to do so.

PART 2880—RIGHTS-OF-WAY UNDER THE MINERAL LEASING ACT

■ 38. The authority citation for part 2880 continues to read as follows:

Authority: 30 U.S.C. 185 and 189, and 43 U.S.C. 1732(b), 1733, and 1740.

Subpart 2881—General Information

■ 39. Amend § 2881.2 by revising paragraph (c) to read as follows:

§ 2881.2 What is the objective of the BLM's right-of-way program?

* * * * *

(c) Promotes the use of rights-of-way in common wherever practical, considering engineering and technological compatibility, national security, and land use plans; and

* * * * *

■ 40. Amend § 2881.5 by:
■ a. Adding the terms ''complete application,'' ''cost recovery,'' and ''exempt from rent'';
■ b. Removing the term ''monitoring'';
■ c. Adding the terms ''monitoring activities'' and ''processing activities''; and
■ d. Revising the term ''substantial deviation''.

The additions and revisions read as follows:

§ 2881.5 What acronyms and terms are used in the regulations in this part?

* * * * *

Complete application means your application contains all the required information under § 2884.11 and you received notification from the BLM that your application is complete.

Cost recovery is a fee charged to an applicant or holder to cover the costs incurred by the BLM in the processing and monitoring associated with a right-of-way grant or TUP on public lands.

Exempt from rent means that the BLM is precluded by statute or policy from collecting rent.

* * * * *

Monitoring activities means those activities, subject to § 2886.11 of this part, the Federal Government performs to ensure compliance with a right-of-way grant or TUP, such as assignments, amendments, or renewals.

(1) For Monitoring Categories 1 through 4, monitoring activities include inspecting construction, operation, maintenance, and termination of permanent or temporary facilities and protection and rehabilitation activities up to the time the holder completes rehabilitation of the right-of-way or TUP and the BLM approves it;

(2) For Monitoring Category 5 (Master Agreements), monitoring activities include those actions or activities agreed to in the Master Agreement; and

(3) For Monitoring Category 6, monitoring activities include those actions or activities agreed to between the BLM and the applicant.

* * * * *

Processing activities means those activities the Federal Government undertakes to evaluate an application for a right-of-way grant or TUP, including activities such as assignments, amendments, or renewals. It also includes preparation of an appropriate environmental document and compliance with other legal requirements in evaluating an application.

(1) For Processing Categories 1 through 4, processing activities include preliminary application reviews, application processing and administrative actions such as assignments and amendments to the right-of-way or TUP;

(2) For Processing Category 5 (Master Agreements), processing activities include those actions or activities agreed to in the Master Agreement; and

(3) For Processing Category 6, processing activities include those actions or activities agreed to between the BLM and the applicant.

* * * * *

Substantial deviation means a change in the authorized location or use that requires-construction or use outside the boundaries of the right-of-way or TUP area or any change from, or modification of, the authorized use. The BLM may determine that there has been a substantial deviation in some of the following circumstances: When a right-of-way holder adds overhead or underground lines, pipelines, structures, or other facilities not expressly included in the current grant or TUP. Operation and maintenance actions or safety related improvements within an existing right-of-way are not considered a substantial deviation. Activities undertaken to reasonably prevent and suppress wildfires on or adjacent to the right-of-way do not constitute a substantial deviation.

* * * * *

■ 41. Amend § 2881.7 by revising paragraphs (a)(1) and (2) and (b)(1) to read as follows:

§ 2881.7 Scope.

(a) * * *

(1) Issuing, amending, assigning, renewing, and terminating grants and TUPs for pipelines, or parts thereof, that are:

(i) On Federal land and outside the boundary of any Federal oil and gas lease;

(ii) Within the boundary of a Federal oil and gas lease but owned by a party who is not a lessee or lease operator with respect to that lease; or

(iii) Within the boundary of a Federal oil and gas lease but downstream from a custody transfer metering device; and

(2) All grants and permits the BLM and its predecessors previously issued under section 28 of the Act.

(b) * * *

(1) Production facilities on an oil and gas lease that operate for the benefit of the lease;

* * * * *

§ 2881.9 [Redesignated as § 2881.8]

■ 42. Redesignate § 2881.9 as § 2881.8.
■ 43. Amend § 2883.14 by revising the title and paragraph (a) to read as follows:

§ 2883.14 What happens to my grant or TUP if I die?

(a) If a grant or TUP holder dies, any inheritable interest in the grant or TUP will be distributed under State law.

* * * * *

■ 44. Amend § 2884.11 by revising paragraph (a) and paragraph (c)(6) to read as follows:

§ 2884.11 What information must I submit in my application?

(a) File your application on Form SF–299 or as part of an Application for Permit to Drill or Reenter (BLM Form 3160–3) or Sundry Notice and Report on Wells (BLM Form 3160–5), available from any BLM office. The application must include the applicant's original signature or meet the BLM standards for electronic commerce. Your complete application must include:

* * * * *

(c) * * *

(6) A map of the project, showing its proposed location and showing existing facilities adjacent to the proposal and Geographic Information Systems (GIS) shapefiles, or equivalent format, when requested by the BLM;

* * * * *

■ 45. Revise § 2884.12 to read as follows:

§ 2884.12 What are the fee categories for cost recovery?

(a) You must pay a cost recovery fee with the application to cover the costs to the Federal Government of processing your application before the Federal Government incurs them. These cost recovery fees are for the processing and monitoring activities associated with your grant. Subject to applicable laws and regulations, if your application will involve Federal agencies other than the BLM, your fee may also include the reasonable costs estimated to be incurred by those Federal agencies. Instead of paying the BLM a fee for the estimated work of other Federal agencies in processing your application, you may pay other Federal agencies directly for the costs estimated to be

incurred by them. The cost recovery fees for Categories 1 through 4 (see paragraph (b) of this section) are not refundable. The fees are categorized based on an estimate of the amount of time that the Federal Government will spend to process your application and monitor your grant.

(b) The BLM bases cost recovery fees on categories. The BLM will update the fee schedule for Categories 1 through 4 each calendar year, based on the previous year's change in the IPD–GDP, as measured second quarter to second quarter, rounded to the nearest dollar. The BLM will update Category 5 fees, which may include preliminary application review, processing, and monitoring, as specified in the applicable Master Agreement. Category 6 fees are for situations when a right-of-way activity will require more than 64 hours, or when an environmental impact statement (EIS) is required and may include preliminary application review costs. The cost recovery categories and the estimated range of Federal work hours for each category are:

MLA RIGHT-OF-WAY COST RECOVERY FEE CATEGORIES

MLA right-of-way cost recovery category descriptions	Federal work hours involved
Category 1. Processing and monitoring associated with an application or existing grant or TUP.	Estimated Federal work hours are ≤8.
Category 2. Processing and monitoring associated with an application or existing grant or TUP.	Estimated Federal work hours are <8 ≤24.
Category 3. Processing and monitoring associated with an application or existing grant or TUP.	Estimated Federal work hours are <24 ≤40.
Category 4. Processing and monitoring associated with an application or existing grant or TUP.	Estimated Federal work hours are >40 ≤64
Category 5. Master Agreements	Varies, depending on the agreement
Category 6. Processing and monitoring associated with an application or existing grant or TUP, including preliminary-application reviews. *.	Estimated Federal work hours are >64

* Preliminary application review costs are those expenses related to meetings held between a Federal agency and the applicant to discuss a right-of-way application. These reviews are not required but are encouraged.

(c) You may obtain a copy of the current cost recovery fee schedule at *https://www.blm.gov,* by contacting your local BLM state, district, or field office, or by writing: Attention to the Division of Lands, Realty and Cadastral Survey, U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW, Room 5625, Washington, DC 20240.

(d) After an initial review of your application, the BLM will notify you of the processing category into which your application fits. You must then submit the appropriate payment for that category before the BLM will begin processing your application. Your signature on a cost recovery Master Agreement constitutes your agreement with the cost recovery category decision. For reimbursement of the BLM's costs for Category 5 and 6 right-of-way applications or grants, see §§ 2804.17, 2804.18, and 2804.19 of subpart 2804. If you disagree with the category that the BLM has determined for your application, you may appeal the decision under § 2881.10 of this part. If you paid the cost recovery fee and you appeal a Category 1 through 4 determination, the BLM will work on your application, grant, or TUP while the appeal is pending. If IBLA finds in your favor, you will receive a refund or adjustment of your cost recovery fee.

(e) In processing your application, the BLM may determine at any time that the application requires preparing an EIS. If this occurs, the BLM will send you a decision changing your cost recovery category to Category 6. You may appeal the decision under § 2881.10 of this part.

(f) If you hold an authorization relating to TAPS, the BLM will send you a written statement seeking reimbursement of actual costs within 60 calendar days after the close of each quarter. Quarters end on the last day of March, June, September, and December. In processing applications and administering authorizations relating to TAPS, the Department of the Interior will avoid unnecessary employment of personnel and needless expenditure of funds.

■ 46. Revise § 2884.13 to read as follows:

§ 2884.13 When will the BLM waive cost recovery fees?

(a) The BLM may waive your cost recovery fees if you are a:

(1) State or local government, or an agency of such a government and the BLM issues the grant for governmental purposes benefitting the general public. However, if you collect revenue from charges you levy on customers for services similar to those of a profit-making corporation or business, or you assess similar fees to the United States for similar purposes, cost recovery fees will not be waived; or

(2) Federal agency, and your cost recovery category determination is Category 1 to 4.

(b) The BLM will not waive your cost recovery fees if you are in trespass.

■ 47. Revise the section heading of § 2884.14 to read as follows:

§ 2884.14 When does the BLM reevaluate the cost recovery fees?

* * * * *

■ 48. Amend § 2884.15 by revising the section heading and paragraph (a) to read as follows:

§ 2884.15 What is a Master Agreement (Cost Recovery Category 5) and what information must I provide to the BLM when I request one?

(a) A Master Agreement (Cost Recovery Category 5) is a written agreement covering processing and monitoring fees (see § 2884.16 of this part) negotiated between the BLM and you that involves multiple BLM grant or TUP approvals for projects within a defined geographic area or for a specific common activity for many projects.

* * * * *

■ 49. Amend § 2884.16 by revising paragraphs (a)(2) and (5) and adding a new paragraph (c) to read as follows:

§ 2884.16 What provisions do Master Agreements contain and what are their limitations?

(a) * * *

(2) Describes the work you will do and the work the BLM will do to complete right-of-way activities.

* * * * *

(5) Explains how the BLM will monitor actions on a grant or TUP and how the BLM will receive payment for this work;

* * * * *

(c) If you sign a Master Agreement, you waive your right to request a reduction of cost recovery fees.

■ 50. Amend § 2884.17 by:

■ a. Revising the section heading, paragraph (a), and paragraph (b)(3);

■ b. Redesignating paragraphs (b)(4) and (5) as paragraphs (b)(5) and (6); and

■ c. Adding a new paragraph (b)(4) to read as follows:

§ 2884.17 How will the BLM manage my Category 6 project?

(a) For Category 6 applications, you and the BLM must enter into a written agreement that describes how the BLM will process your application or monitor your grant. The BLM may require that the final agreement contains a work plan and a financial plan, and a description of any existing agreements you have with other Federal agencies for cost reimbursement associated with such application or grant.

* * * * *

(b) * * *

(3) Develop a preliminary financial plan, if applicable, which estimates the actual costs of processing your application and monitoring your project;

(4) Collect, in advance and at BLM's discretion, a deposit for your Category 6 project to initiate processing your application while all of the plans and agreements are being completed;

* * * * *

■ 51. Amend § 2884.21 by revising paragraph (c) to read as follows:

§ 2884.21 How will the BLM process my application?

* * * * *

(c) *Customer service standard.* The BLM will process your complete application as follows:

Processing category	Processing time	Conditions
1–4	60 calendar days	If processing your application(s) for a right-of-way or TUP will take longer than 60 calendar days, the BLM will notify you in writing of this fact prior to the 30th calendar day and inform you of when you can expect a final decision on your application.
5	As specified in the Master Agreement	The BLM will process your right-of-way or TUP application(s) as specified in the Master Agreement.
6	Over 60 calendar days	The BLM will notify you in writing within the initial 60-day processing period of the estimated processing time.

* * * * *

■ 52. Amend § 2884.23 by revising paragraph (a)(6) to read as follows:

§ 2884.23 Under what circumstances may the BLM deny my application?

(a) * * *

(6) You do not comply with a deficiency notice (see § 2804.25(c)) or with any requests from the BLM for additional information needed to process the application.

* * * * *

■ 53. Revise § 2884.24 to read as follows:

§ 2884.24 What fees must I pay if the BLM denies my application, or if I withdraw my application or relinquish my grant or TUP?

If the BLM denies your application, you withdraw it, or you relinquish your grant or TUP, you owe the current fees for the applicable cost recovery category as set forth at § 2884.12(b) of this subpart, unless you have a Category 5 or 6 application. Then, the following conditions apply:

(a) If the BLM denies your Category 5 or 6 application, you are liable for actual costs that the United States incurred in processing it. The money you have not paid is due within 30 calendar days after receiving a bill for the amount due;

(b) You may withdraw your application in writing before the BLM issues a grant or TUP. If you do so, you are liable for all actual processing costs the United States has incurred up to the time you withdraw the application and for the actual costs of terminating your application. Any money you have not paid is due within 30 calendar days after receiving a bill for the amount due; and

(c) You may relinquish your grant or TUP in writing. If you do so, you are liable for all actual costs the United States has incurred up to the time you relinquish the grant and for the actual costs of closing your grant. Any cost recovery money you have not previously paid is due within 30 calendar days after receiving a bill for the amount due. The BLM will refund any cost recovery money you paid in Categories 5 or 6 that was not used to cover costs the United States incurred as a result of your grant.

■ 54. Revise § 2884.27 to read as follows:

§ 2884.27 What additional requirements are necessary for grants for pipelines 24 or more inches in diameter?

If an application is for a grant for a pipeline 24 inches or more in diameter, the BLM will not issue or renew the grant until after we notify the appropriate committees of Congress in accordance with 30 U.S.C. 185(w).

■ 55. Amend § 2885.12 by revising the section heading to read as follows:

§ 2885.12 What rights does a grant or TUP provide?

■ 56. Amend § 2885.17 by revising paragraph (e) and adding a new paragraph (g) to read as follows:

§ 2885.17 What happens if I do not pay rents and fees or if I pay the rents or fees late?

* * * * *

(e) We will retroactively bill for uncollected or under-collected rent, including late payment and administrative fees.

* * *

(g) We will not approve any further activities associated with your right-of-way until we receive any outstanding payments that are due.

■ 57. Amend § 2885.19 by revising paragraph (b) as follows:

§ 2885.19 What is the rent for a linear right-of-way grant?

* * * * *

(b) You may obtain a copy of the current Per Acre Rent Schedule at *https://www.blm.gov,* by contacting your local BLM state, district, or field office, or by writing: Attention to the Division of Lands, Realty and Cadastral Survey, U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW, Room 5625, Washington, DC 20240.

■ 58. Revise § 2885.24 to read as follows:

§ 2885.24 If I hold a grant or TUP, what cost recovery fees must I pay?

(a) Subject to § 2886.11, you must pay a fee to the BLM for any costs the Federal Government incurs in processing, inspecting, and monitoring the construction, operation, maintenance, and termination of the pipeline and protection and rehabilitation of the Federal lands your grant or TUP covers. The BLM categorizes the cost recovery fees based on the estimated number of work hours necessary to manage your grant or TUP. Categories 1 through 4 fees are not refundable. The description of each Category and the associated work hours is found at § 2884.12(b).

(b) The BLM will update the cost recovery fee schedule for Categories 1 through 4 each calendar year, based on the previous year's change in the IPD–

GDP, as measured second quarter to second quarter rounded to the nearest dollar. The BLM will update Category 5 cost recovery fees as specified in the applicable Master Agreement.

(c) You may obtain a copy of the current cost recovery fee schedule at *https://www.blm*.gov, by contacting your local BLM state, district, or field office, or by writing: Attention to the Division of Lands, Realty and Cadastral Survey, U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW, Room 5625, Washington, DC 20240.

■ 59. Amend § 2886.17 by revising paragraph (c)(2), redesignating paragraph (c)(3) as paragraph (c)(4) and adding a new paragraph (c)(3) to read as follows:

§ 2886.17 Under what conditions may BLM suspend or terminate my grant or TUP?

* * * * *

(c) * * *

(2) The BLM consents in writing to your request to relinquish the grant or TUP;

(3) A court terminates it or requires the BLM to terminate it; or

* * * * *

■ 60. Amend § 2887.10 by revising paragraph (b) to read as follows:

§ 2887.10 When must I amend my application, seek an amendment of my grant or TUP, or obtain a new grant or TUP?

* * * * *

(b) The requirements to amend an application or a grant or TUP are the same as those for a new application, including paying cost recovery fees and rent according to §§ 2884.12, 2885.23, 2885.19, and 2886.11 of this part.

* * * * *

■ 61. Amend § 2887.11 by adding new paragraph (i) to read as follows:

§ 2887.11 May I assign or make other changes to my grant or TUP?

* * * * *

(i) You must seek an amendment of your authorization if you propose a substantial deviation in location or use.

* * * * *

■ 62. Amend § 2887.12 by revising paragraph (b) and adding new paragraphs (f) and (g) to read as follows:

§ 2887.12 How do I renew my grant?

* * * * *

(b) The BLM may modify the terms and conditions of the grant at the time of renewal, and you must pay the cost recovery fees.

* * * * *

(f) If you do not submit your application under paragraph (a) of this section at least 120 days prior to authorization expiration, it is considered delinquent; the BLM will not be subject to the customer service standards in this chapter, and it will be processed only as time and resources are available.

(g) The BLM will review your application and determine if you have complied with all of the provisions in this part and whether or not your authorized use will be renewed. The BLM will notify you within 30 days from acceptance of a complete application if it will take longer than 60 days to review your application.

PART 2920—LEASES, PERMITS AND EASEMENTS

■ 63. The authority citation for part 2920 continues to read as follows:

Authority: 43 U.S.C. 1740.

Subpart 2920—Leases, Permits and Easements: General Provisions

■ 64. Revise § 2920.0–5 to read as follows:

§ 2920.0–5 Definitions.

As used in this part, the term:

(a) *Applicant* means any person who submits an application for a land use authorization under this part.

(b) *Authorized officer* means any employee of the Bureau of Land Management to whom has been delegated the authority to perform the duties described in this part.

(c) *Casual use* means any short term non-commercial activity which does not cause appreciable damage or disturbance to the public lands, their resources or improvements, and which is not prohibited by closure of the lands to such activities.

(d) *Cost recovery* is a fee charged to an applicant or holder to reimburse the United States for processing and monitoring costs that concern applications and other documents relating to the public lands, or that are incurred when processing, inspecting, or monitoring any proposed or authorized leases, permits, and easements located on the public lands.

(e) *Easement* means an authorization for a non-possessory, non-exclusive interest in lands which specifies the rights of the holder and the obligation of the Bureau of Land Management to use and manage the lands in a manner consistent with the terms of the easement.

(f) *Knowing and willful* means that a violation is *knowingly and willfully* committed if it constitutes the voluntary or conscious performance of an act which is prohibited or the voluntary or conscious failure to perform an act or duty that is required. The term does not include performances or failures to perform which are honest mistakes or which are merely inadvertent. The term includes, but does not require, performances or failures to perform which result from a criminal or evil intent or from a specific intent to violate the law. The knowing or willful nature of conduct may be established by plain indifference to or reckless disregard of the requirements of law, regulations, orders, or terms of a lease, permit, and easement. A consistent pattern of performance or failure to perform also may be sufficient to establish the knowing or willful nature of the conduct, where such consistent pattern is neither the result of honest mistake or mere inadvertency. Conduct which is otherwise regarded as being knowing or willful is rendered neither accidental nor mitigated in character by the belief that the conduct is reasonable or legal.

(g) *Land use authorization* means any authorization to use the public lands issued under this part.

(h) *Land use proposal* means an informal statement, in writing, from any person to the authorized officer requesting consideration of a specified use of the public lands.

(i) *Land use plan* means resource management plans or management framework plans prepared by the Bureau of Land Management pursuant to its land use planning system.

(j) *Lease* means an authorization to possess and use public lands for a fixed period of time.

(k) *Permit* means a short-term revocable authorization to use public lands for specified purposes.

(l) *Person* means any person or entity legally capable of conveying and holding lands or interests therein, under the laws of the State within which the lands or interests therein are located, who is a citizen of the United States, or in the case of a corporation, is subject to the laws of any State or of the United States.

(m) *Proponent* means any person who submits a land use proposal, either on his/her own initiative or in response to a notice for submission of such proposals.

(n) *Public lands* means lands or interests in lands administered by the Bureau of Land Management, except lands located on the Outer Continental Shelf and lands held for the benefit of Indians, Aleuts, and Eskimos.

■ 65. Amend § 2920.6 by revising the section heading and paragraphs (b), (d), and (h) to read as follows:

§ 2920.6 Payment of cost recovery fees.

* * * * *

(b) The selected land use applicant shall pay cost recovery fees to the United States for reasonable administrative and other costs incurred by the United States in processing a land use authorization application and in monitoring construction, operation, maintenance, and rehabilitation of facilities authorized under this part, including preparation of reports and statements required by the National Environmental Policy Act of 1969 (43 U.S.C. 4321 *et seq.*). The payment of cost recovery fees shall be in accordance with the provisions of §§ 2804.14 and 2805.16 of this chapter.

* * * * *

(d) A selected applicant who withdraws, in writing, a land use application before a final decision is reached on the authorization is responsible for all reasonable costs incurred by the United States in processing the application up to the day that the authorized officer receives notice of the withdrawal and for costs subsequently incurred by the United States in terminating the proposed land use authorization process. Payment of cost recovery fees shall be paid within 30 days of receipt of notice from the authorized officer of the amount due.

* * * * *

(h) The authorized officer shall, on request, give a selected applicant an estimate, based on the best available cost information, of the reasonable costs that may be incurred by the United States in processing the proposed land use authorization. However, payment of cost recovery fees shall not be limited to the estimate of the authorized officer if actual costs exceed the projected estimate.

* * * * *

■ 66. Amend § 2920.8 by revising paragraph (b) to read as follows:

§ 2920.8 Fees.

* * * * *

(b) *Cost Recovery fees.* Each request for renewal, transfer, or assignment of a lease or easement must be accompanied by non-refundable cost recovery fees determined in accordance with the provisions of §§ 2804.14 and 2805.16 of this chapter.

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FEDERAL REGISTER PAGES AND DATE, NOVEMBER

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
10482 65649
10483 66515
10484 66517
10485 66519
10486 66521
10487 66525
10488 66527
10489 66529
10490 66531
10491 66533

Administrative Orders:
Notices:
Notice of November 1, 2022 66225

7 CFR

1230 66535
3550 66075
3555 66075

Proposed Rules:
993 66958
1206 65683
1222 66960

10 CFR

Ch. I 66228
50 66227
52 66227
72 66539
429 ..... 65651, 65856, 66935
430 66935
431 ..... 65651, 65856

Proposed Rules:
72 66613
430 65687

12 CFR

Ch. X 66935, 66940
1006 65668

13 CFR

Proposed Rules:
120 66963

14 CFR

13 66544
39 ..... 65670, 66077, 66080, 66084, 66942
71 ..... 65673, 65674, 65675, 65677, 65679, 65680, 66229, 66544, 66946, 66947
73 66978

Proposed Rules:
39 ..... 65694, 66615, 66619, 66623, 66625, 66971
71 ..... 66627, 66629, 66630, 66632, 66633, 66634, 66636, 66974, 66975

16 CFR

Proposed Rules:
453 66096

17 CFR

240 66412

21 CFR

866 66545
1271 65861
1301 66954

Proposed Rules:
80 66116

28 CFR

2 66549
50 66239

29 CFR

Proposed Rules:
103 66890

33 CFR

100 66244
165 ..... 66086, 66550, 66552, 66955

34 CFR

600 65904
668 65904
674 65904
682 65904
685 65904

37 CFR

Proposed Rules:
385 66976

38 CFR

Proposed Rules:
36 65700

40 CFR

180 66554

Proposed Rules:
52 ..... 65714, 65719, 66086, 66091, 66985
81 65719
84 66372

42 CFR

400 66454
406 66454
407 66454
408 66454
410 66454
412 66558
413 ..... 66558, 67136
423 66454
431 66454
435 66454
482 66558

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List October 20, 2022

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